Three new treatments and a strengthened pipeline highlight DNDi’s efforts into 2009
From the Chair of the Board and the Executive Director

In March 2009, the World Bank estimated that if the current global economic crisis persists, there could be between 200,000 and 400,000 additional child deaths every year – between 1.4 and 2.8 million before 2015—and 100 million of the world’s poorest forced back into poverty. The conclusion of the world leaders was eloquent: “Any reduction in investment in healthcare will have devastating consequences for the sick and untreated, and has the potential to plunge new groups and nations into poverty.”

Now, as we are preparing our annual report, we have no option but to consider this economic breakdown which constitutes a dramatic challenge not only for DNDi and our stakeholders, but also for all those committed to bringing innovation and new tools to those most in need.

Most neglected tropical diseases primarily affect the poor and marginalised who have few resources or possibilities to make a living. The high burden of disease and loss of productivity aggravate poverty which is further compounded by the high cost of long-term care.

For tropical diseases such as sleeping sickness, leishmaniasis, and Chagas disease, for which no adequate treatments or diagnostics exist, research is needed now more than ever, for new, practical, and effective tools, and efficient ways to implement them. With the strongest and most comprehensive drug portfolio for these neglected tropical diseases in history, DNDi continues to engage partners who share our vision and commitment, and to ensure that a well-balanced pipeline is maintained.

For all these R&D disease strategies, DNDi has made major progress in delivering quality, affordable and adapted treatments.

Specifically, advances in combatting one of the most neglected diseases - sleeping sickness - are significant, as this is the role, mission, and the “raison d’être” of DNDi. To deliver an improved therapeutic option for this disease, strong partnerships have been set up with national programmes of most endemic countries, NGOs, public and private research institutions, and the World Health Organization (WHO). Oral nifurtimox and intravenous eflornithine combination therapy (NECT) has been included on the WHO Essential Medicines List. NECT, the first improved treatment for sleeping sickness in 25 years, is now available for...
use in treating the advanced stage of the disease and could save four to five lives of every 100 patients treated, as it is far less toxic than the arsenic drug that is still being used in some areas. It is a major improvement and source of satisfaction for all the partners who have been engaged in our organisation since its creation in 2003. However, delivering a truly simplified treatment which can be orally administered, implemented at the primary healthcare level, and effective against both stages of the disease, is still our ultimate goal.

One promising drug entering into clinical development this year is fexinidazole—the only new clinical candidate currently in the drug pipeline for sleeping sickness. This project holds great promise for patients and practitioners in the field. Both short- and long-term strategies are considered as the core of our scientific approach, which requires the best scientific resources at all stages of R&D to access compounds, technologies, expertise, and knowledge.

Sleeping sickness is one illustration of DNDi’s continuous progress to boost innovation for the most neglected patients. Another example is our successful track record of collaboration with sanofi-aventis in delivering ASAQ for the treatment of malaria. In 2008, more than 5 million treatment courses were procured and 20 to 30 million more will be delivered in 2009.

Six years on from its founding, DNDi is managing more than 300 partnerships with a wide range of public and private partners and NGOs, and ten clinical trials are ongoing in 2009, with more than 400 people engaged in our programmes.

With focused collaboration, innovative thinking, and political leadership, we will meet the noble goals set by our organisation. We remain firmly engaged in making a major and significant contribution to the Millennium Development Goals and bringing those forgotten patients out of the shadows.

The changes seen in the past decade offer a new landscape for collaboration to improve essential healthcare. At a time when the financial crisis could have significant consequences for the poorest, greater investment from governments and the private sector, complemented with new and adapted funding mechanisms, are needed to ensure that these efforts will be sustained and strengthened.

We would like to thank again all our donors for their support, and particularly those who have reinforced their commitment to most neglected diseases with significant multi-year contributions.

We would also like to pay special tribute to our dedicated team working at DNDi for their outstanding commitment and contribution to our successes. In particular, we would like to thank Els Torreele, one of the main sources of inspiration for our organisation, even prior to its creation, and who has played a major role in the successful implementation of our sleeping sickness projects. Els is moving on to new horizons but, no doubt, will remain committed to neglected diseases in her future job.

Investing in R&D for the most neglected patients goes hand in hand with better health and economic growth for affected marginalised communities. Help us meet our goal.

Simply because their wellbeing matters.
Prospects set to improve dramatically for children threatened by sleeping sickness in Mwana-Mputu (Democratic Republic of the Congo), thanks to new treatments developed by DNDi and its partners.
A landmark year for sleeping sickness with two major project milestones achieved: NECT a new and improved treatment approved by WHO and fexinidazole, a new possible drug brought into clinical development.

With the strongest and most comprehensive R&D portfolio in history for the most neglected diseases, DNDi continues to identify and engage partners who share our vision and commitment, to ensure that a well-balanced pipeline is established for the three diseases of primary focus: sleeping sickness (human African trypanosomiasis, HAT), kala-azar (visceral leishmaniasis, VL), and Chagas disease.

Since the launching of two new antimalarials in 2007 and 2008 - ASAQ and ASMQ – DNDi has taken key steps towards ensuring their effective implementation in endemic countries, while advancing other projects from its portfolio, and expanding its worldwide partnerships. For example as a result of working with our partner sanofi-aventis, ASAQ is now registered in 24 countries, over 20 million treatments will be delivered in 2009.

Major progress has particularly been achieved in R&D with regard to sleeping sickness. NECT, a combination of nifurtimox and eflornithine for the treatment of the disease received approval by the WHO Expert Committee on the Selection and Use of Essential Medicines in April 2009. The approval came after positive efficacy and safety results from the clinical study that was run jointly by DNDi, Médecins Sans Frontières, Epicentre, and national programmes. NECT does not only reduce the risk of resistance emerging but also reduces the duration of drug treatment (with infusions twice a day for ten days); and makes it easier to administer through oral doses.

The major breakthrough, however, is the prospect of a simple oral treatment or a pill to treat the disease. Fexinidazole, a compound ‘rediscovered’ by DNDi, is entering into phase I clinical trial this year, in close collaboration with sanofi-aventis. It is the only new clinical candidate currently in the drug pipeline for sleeping sickness.

In the field of Chagas disease, DNDi is also moving forward with its R&D strategies: we are currently developing a paediatric formulation with LAFEPE (a Brazilian public laboratory) and researching the therapeutic utility of azoles, which already have available drugs. However, more must be done, as the burden of Chagas is significantly underestimated in official statistics: few patients receive any treatment at all; and new diagnostics and treatments are still urgently needed. All these factors have prompted DNDi to launch a Chagas campaign in 2009. (see Chapter 4)

**VISION**

To improve the quality of life and the health of people suffering from neglected diseases by using an alternative model to develop drugs for these diseases and ensuring equitable access to new and field-relevant health tools. In this not-for-profit model, driven by the public sector, a variety of partners collaborate to raise awareness of the need to research and develop drugs for those neglected diseases that fall outside the scope of market-driven R&D. They also build public responsibility and leadership in addressing the needs of these patients.

**MISSION**

To develop new drugs or new formulations of existing drugs for patients suffering from the most neglected communicable diseases. Acting in the public interest, DNDi will bridge existing R&D gaps to find essential drugs for these diseases by initiating and coordinating drug R&D projects in collaboration with the international research community, the public sector, the pharmaceutical industry, and other relevant partners.

DNDi’s primary focus is the development of drugs for the most neglected diseases, such as sleeping sickness (Human African Trypanosomiasis, HAT), kala-azar (visceral leishmaniasis, VL), and Chagas disease, and it will also consider engaging in R&D projects for other neglected diseases. In pursuing these goals, DNDi manages R&D networks built on South-South and North-South collaborations. While using and supporting existing capacity in countries where the diseases are endemic, DNDI helps to strengthen additional capacity in a sustainable manner through technology transfer in the field of drug research and development for neglected diseases.

**OBJECTIVES**

The primary objectives are to:

- Deliver 6-8 new treatments by 2014 for leishmaniasis, sleeping sickness, Chagas disease, and malaria
- Establish a robust portfolio for new generation of treatments

Secondary:

- Use and strengthen existing capacity in disease-endemic countries
- Raise awareness and advocate for increased public responsibility

**Total of new drugs developed**

Of the 1,556 new drugs registered between 1975 and 2004, only 21 drugs have indications for tropical diseases and tuberculosis even though these diseases constitute over 12% of the global disease burden. A mere 10% of the world’s health research expenditure is spent on diseases that account for 90% of the global burden of disease.

Source: Chirac P, Torreele E. Lancet, 2006 May 12, 1560-1561
Over the past five years, the R&D landscape has changed significantly, with greater resources being given to global health and the development of new drugs for poverty-related neglected diseases. However, much attention has been focused on combating the ‘big three’ neglected diseases (HIV/AIDS, malaria, and tuberculosis), many others have failed to attract sufficient resources, and adequate drugs are not available for many diseases affecting poor, neglected populations in the developing world. In 2007, less than 5 per cent of US$ 2.5 billion - the total funding allocated to R&D for neglected diseases - went to kinetoplastid diseases1 although those tropical diseases (NTDs) kill more than 100,000 of people each year and aggravate poverty in the developing world.

Almost everyone in the bottom billion has at least one of these diseases, which reinforces the poverty trap. These diseases prevent the achievement of the first six Millennium Development Goals even though for some of them their control with low cost and cost-effective interventions could start long-term economic growth and development. For some kinetoplastid diseases, the few treatments available date back to colonial times and are simply inadequate by today’s standards.

THREE CHALLENGES AHEAD...

Despite substantial progress proving that PDPs such as DNDi can successfully manage R&D and translate knowledge into tangible results, we are still facing major challenges on three levels:

EXPANDING INNOVATIVE PARTNERSHIPS

DNDi operates through a virtual model, whereby all of its R&D activities are outsourced, contributing to keeping development costs under control, while providing a high level of flexibility. A consequence of this strategic option is that fostering an efficient drug-development programme requires the establishment of strong agreements within the entire biomedical landscape, so as to leverage and mobilise private and public sector resources. The first DNDi successes show how crucial it is to build new collaborative business models through efficient partnerships, alliances and consortia amongst a broad range of public and private players who share an objective driven by needs, not profit.

To put it in perspective: of the 350 agreements signed since the establishment of DNDi, more than 100 have come about since 2008. These include research, technical, and funding agreements with public and private partners such as sanofi-aventis for the development of ASAAQ and Fexinidazole, GlaxoSmithKline, Merck, Farmanguinhos, Adivin, Cipla, BDSI, Griffith University (Aus), University of Antwerp, University of Dundee, Anacor, Scynexcis, among many others.

FACILITATING ACCESS TO TREATMENTS

To immediately address the access barriers during the implementation phase, DNDi’s role is upstream, early, and jointly with the implementers such as the national control programmes, NGOs and WHO. DNDi aims to gather relevant information during the development of treatments so as to facilitate their transition to implementers, for rollout into the field, after registration. The DNDi access strategy and activities adopted by the board of directors in December 2008 are guided by the following principles:

- the need to facilitate equitable access to the new treatments developed by DNDi;
- the desire to transition these treatments, in the long run, to their natural implementers, i.e. national ministries of health (MOH) and control programmes (NCIP, WHO, and NGOs such as MSF, in order for DNDi to focus on its core activity of research and development, and
- a commitment to contribute to the development of approaches for improved access and dissemination of knowledge.

ENSURING A MORE FAVOURABLE ENVIRONMENT FOR R&D

Moreover, public leadership is needed to implement policy changes and to create a more favourable environment that will support the development of new, essential health tools. This leadership must strive to ensure that affected populations have equitable access to treatments and they must also contribute to the development of innovative needs-based measures. Such measures include intellectual property (IP) management policies to encourage a needs-driven R&D agenda, technology transfer, an enabling regulatory environment and the strengthening of research capacities in developing countries.

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Main Progress to 2009

**Malaria**
- **ASAQ** – fixed-dose combination (FDC) of artemunate and amodiaquine for use in sub-Saharan Africa; launched in March 2007; registered in 24 disease-endemic countries; in landmark partnership with sanofi-aventis; obtained WHO prequalification in October 2008; 5 million treatment courses delivered in 2008 and more than 20 million forecast for 2009.
- **ASMO** – FDC of artemunate and mefloquine for treatment in Latin America and Asia; registered in Brazil in March 2008 in partnership with Farman-guinhos/Fiocruz; South-South technology transfer underway to Cipla for availability in Asia and Africa; in use by Brazilian national authorities.

**Human African Trypanosomiasis**
- **NECT** - Clinical Trial of Nifurtimox-Eflornithine Coadministration Therapy – promising study presented at ASTMH in 2008; full dossier submitted to WHO Essential Medicines List (EML) in 2008; in April 2009, NECT is included in the EML list.

**Fexinidazole** – first compound mining success from DNDi’s nitroimidazoles project; pre-clinical studies finalised; entering into clinical development in 2009 and the only new clinical candidate in the drug pipeline for HAT; in May 2009, sanofi-aventis and DNDi sign agreement to develop and make it available.

**Lead Optimisation Partnership** – two compound series have been advanced as attractive leads progressing from early-stage screening research through innovative partnership with U.S. partners: Scynexis & Pace University.

**Visceral Leishmaniasis**
- **VL Combination Trials in Africa, Asia and Latin America** – implemented for evaluating safe and short-course combination therapy, using existing drugs in three regions to stave off parasitic resistance and provide a shorter, more effective treatment course.

**Chagas disease**
- Paediatric Benznidazole – agreement with LAFEPE to develop first benznidazole formulation for children, to be affordable and publicly available in 2010.

**Strengthening Research Capacities**
- Three regional networks for research capacity strengthening:
  - **Africa**: the HAT Platform and the Leishmaniasis East Africa Platform (LEAP); GCP, ethics, and trial-monitoring training; establishment and training of data safety monitoring board (DSMB); workshops on clinical trial methodology and information sharing on recent clinical research developments.
  - **Asia**: Pan Asian Network for neglected diseases (PAN-ND); screening capacity strengthening in the Asian region for purification and identification of chemicals from plant, soil, and marine organisms.

**Fexinidazole entering into Phase I in 2009.**

- Phase III trial (AmBisome, Miltefosine, Paromomycin) designed for India, Bangladesh and Nepal; patient recruitment began in June 2008 in two sites in Bihar (India).
- Paromomycin trial in Africa – more than 1,000 patients included in multi-centre trial in East Africa, aimed to register paromomycin and evaluate the shorter course combination of PM-SSG.
- AmBisome in Africa. Recruitment started in 2009, aimed to achieve geographical extension and potential therapies combination.

**Discovery Projects**
- Consolidation with strategic focus on compound collection, target identification, target validation, assay development, high-throughput screening (HTS), hit identification, and hit to lead selection. For HAT: HTS is available (Eskehrs, Scynexis).
- For VL: HTS with Institut Pasteur Korea, and in development stage for Chagas. DNDi is working closely with Dundee University, London School of Hygiene & Tropical Medicine (LSHTM), University of Antwerp as well as developing synergies with Medicines for Malaria Venture (MMV), Global Alliance for TB drug development (GATB), and the Consortium for Parasitic Drug Development (CPDD). DNDi has established working relations with GSK, sanofi-aventis, Merck, and Novartis, and is currently building relations with Pfizer, Eisai, and many others.

**Agreement signed in May 2009 between DNDi and Institut Pasteur Korea (IPK).**
DNDi Founding Partners and Worldwide Presence

THE KEY ROLE OF THE FOUNDING PARTNERS

Since DNDi’s founding in 2003, seven key stakeholders have helped to propel the initiative. Each Founding Partner is a centre of excellence in neglected disease research and/or patient care.

7 Founding Partners

4 Regional Support Offices

1 Affiliate

2 Project Support Offices

DNDi Founding Partners and Worldwide Presence

OSWALDO CRUZ FOUNDATION (FIOCRUCZ)

Founded in 1900, Fiocruz is the largest biomedical research institution in Latin America. Part of the Brazilian Ministry of Health, Fiocruz has facilitated health tool R&D for neglected diseases via the establishment of dedicated centres for vaccine and drug development: Biomanguinhos and Farmanguinhos.

DND/ NORTH AMERICA

Established in 2007, the affiliate of DNDi in North America supports the advocacy, fundraising, and R&D efforts of DNDi in the region. Based in New York City, USA, this affiliate operates under the direction of the DNDi North America Board of Directors and collaborates with key partners engaged in a variety of R&D activities.

DND/ LATIN AMERICA

Opened in 2004, the DNDi Latin America regional support office is based in Rio de Janeiro. With the primary aim to support regional R&D activities for Chagas disease, malaria, and VL, the Latin American office also undertakes advocacy and communications activities to increase awareness of neglected diseases in the region.

DND/ AFRICA

Established in 2003, the DNDi Africa regional support office is based at the Kenya Medical Research Institute (KEMRI) in Nairobi, Kenya. DNDi Africa provides support to R&D projects in the region, including the paromomycin study, the LEAP and HAT Platforms, and the FACT Project.

INSTITUT PASTEUR

Established in France in 1887, the Pasteur Institut is a non-profit private foundation dedicated to the prevention and treatment of diseases. It focuses on diseases like yellow fever, tuberculosis, poliomyelitis, hepatitis, and HIV/AIDS. With 8 Nobel Prizes awarded to its researchers, the Pasteur Institut is on the forefront of medical research with discoveries of antitoxins, BCG, sulfamides, and anti-histamines, as well as key research in molecular biology and genetic engineering.

DNDi coordination team in Geneva

DND/ coordination team in Geneva
MSF is an independent, private, medical aid organisation that has been operational in emergency medical aid missions around the world since 1971. With offices in 19 countries and ongoing activities in over 80, MSF has also run the Campaign for Access to Essential Medicines since 1999. MSF has received numerous international awards for its activities, including the Nobel Peace Prize in 1999. MSF dedicated this prize to finding long-term, sustainable solutions to the lack of essential medicines crisis (which ultimately led to the founding of DNDi in 2003).

www.msf.org

The Special Programme for Research and Training in Tropical Diseases

As an independent global programme of scientific collaboration, established in 1975 and co-sponsored by the United Nations Children’s Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank and the World Health Organization (WHO), TDR aims to help coordinate, support, and influence global efforts to combat a portfolio of major diseases of the poor and disadvantaged. TDR is a permanent observer of DNDi’s Board of Directors.

www.who.int/tdr

Indian Council of Medical Research (ICMR)

Established in 1911, it was re-designated in 1949 as the Indian Council of Medical Research (ICMR). Funded by the Government of India, ICMR’s activities are focused on the formulation, coordination, and promotion of biomedical research. The Council has a network of 21 Permanent Research Institutes located in different parts of India that conduct research on tuberculosis, leprosy, and visceral leishmaniasis.

www.icmr.nic.in

DND/India

Opened in 2004, the DNDi office in India is based at the Indian Council for Medical Research (ICMR) in New Delhi. The office functions as a relay for DNDi’s operational activities in India, which are primarily focused on two diseases, malaria and visceral leishmaniasis.

www.dndiindia.org

MINISTRY OF HEALTH, MALAYSIA (IMR)

The Institut for Medical Research (IMR), within the Ministry, was established in 1900 to carry out scientific and sustained research into the causes, treatment and prevention of infectious tropical diseases. Initially, it principally focuses on malaria, beriberi, cholera, and dysentery. The IMR is now comprised of eight centres which perform research, diagnostic services, training, and consultative services across diverse health fields.


DND/ Malaysia

Since 2004, the DNDi office in Malaysia has supported a variety of R&D activities across the Asian region, including key preclinical and early clinical studies for the FACT Project, as well as the fostering of the PAN4ND, a regional research platform that is focused on the discovery and development of natural substances as therapeutics to neglected diseases. Based at the Universiti Sains Malaysia, the office also works to facilitate the implementation of ASMQ in the region.

www.dndiasia.org

Kenya Medical Research Institute (KEMRI)

Established in 1979, KEMRI conducts health sciences research and shares its research findings with the international community. One of the leading health research institutions in Africa, KEMRI has been making a significant contribution to regional research capacity for many years. With a focus on infectious and parasitic diseases, and on public health and biotechnology research.

www.kemri.org
The Board of Directors is composed of between ten and thirteen members, including one patient representative. Each of the six funding members nominates one Board member. Board members serve for a term of four years.

**THE BOARD OF DIRECTORS**

- 01 Marcel Tanner, Chair; Swiss Tropical Institute (STI)
- 02 Reto Brun, Secretary; Swiss Tropical Institute (STI)
- 03 Bruce Mahin, Treasurer
- 04 Alice Dautry, Institut Pasteur, France
- 05 Christophe Fournier, Médecins Sans Frontières (MSF)
- 06 Lalit Kant, Indian Council of Medical Research (ICMR)
- 07 Datuk Mohd Ismail Merican, Ministry of Health, Malaysia
- 08 Carlos Morel, Oswaldo Cruz Foundation (FIOCRUZ), Brazil
- 09 Robert G Ridley, TDR (Permanent Observer of Board)
- 10 Gill Samuels, Global Forum for Health and Research, Geneva
- 11 Bennett Shapiro, Pure Tech Ventures, formerly with Merck & Co, USA
- 12 Paulina Tindana, Patient Representative, Navrongo Health Research Centre, Ghana
- 1 Representative of KEMRI: vacant post

**THE SCIENTIFIC ADVISORY COMMITTEE (SAC)**

The SAC is composed of sixteen prominent scientists with expertise in various scientific disciplines related to drug discovery and development, and/or the specific reality of neglected diseases and neglected patients. They operate independently of the Board of Directors and the Executive team. The SAC has the mandate to advise the Board of Directors on matters related to research and development and choice of projects, as well as the quality of the scientific output.

**DND/ SCIENTIFIC ADVISORY COMMITTEE MEMBERS**

- 01 Julio Urbina, Chair; Venezuelan Institute for Scientific Research (IVIC), Venezuela
- 02 Kirana Bhatt, University of Nairobi, Kenya
- 03 Marleen Boelaert, Institute of Tropical Medicine, Antwerp, Belgium
- 04 Pierre-Etienne Bost, Institut Pasteur, France
- 05 J Carl Craft, Formerly with Medecines for Malaria Ventures, Switzerland
- 06 Alan Hutchinson Fairlamb, University of Dundee, UK
- 07 Chitar Mal Gupta, Central Drug Research Institute, India
- 08 Maria das Graças Henriquez, Oswaldo Cruz Foundation, Fiocruz, Brazil
- 09 Paul Herrling, Novartis International AG, Switzerland
- 10 Marcel Hommel, Institut Pasteur, France
- 11 Nor Shahidah Khairullah, Infectious Diseases Research Center, Malaysia
- 12 Shiv Dayal Seth, Indian Council of Medical Research (ICMR), India
- 13 Mervyn Turne, Merck Research Laboratories, USA
- 14 Muriel Vray, Institut Pasteur, France
- 15 Krisantha Weerasuriya, World Health Organization, (WHO), Geneva
- 16 Haruki Yamada, Kitasato Institute for Life Sciences, Japan
THE EXECUTIVE TEAM (as of June 2009)

DND/ HEADQUARTERS, GENEVA (AS OF DECEMBER 2008)

Bernard Pécoul, Executive Director
Shing Chang, R&D Director
Hyo Jueng Ahn-Degras, Site and Travel Assistant
Jean-François Alesandrini, Fundraising and Advocacy Director
Manica Balasegaram, Clinical Project Manager
Severine Blesson, Project Coordinator [as of July 2009]
Bethania Blum de Oliveira, Project Support Officer, [based in Brazil]
Gwenaëlle Carn, Clinical Project Coordinator
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Robert Don, Senior Project Manager
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Jean-Robert Isset, Screening Coordinator
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Jean-René Kiechel, Senior Product Manager, FACT Project, and Expert, [based in Paris, France]
Delphine Launay, Lead Optimisation Coordinator [as of March 2009]
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Janine Millier, Accountant
Béatrice Mouton, Human Resources & Legal Affairs Manager
Jean-Pierre Paccaud, Business Development Director
Sylvie Renaudin, Research & Development Assistant
Isabela Ribeiro, Senior Project Manager, [based in Rio de Janeiro, Brazil]
Jerôme Saint-Denis, Fundraising Coordinator [as of March 2009]
Ivan Scandale, Lead Optimisation Coordinator
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Nathalie Strub-Wourgaft, Clinical Development Director (as of March 2009)
Els Torreele, Senior Project Manager
Laurence Vielfaure, Financial Controller

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Joy Malongo, Administrative Assistant, Kenya

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Vikash Kumar, Accountant

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