Summary

DNDi has been developing and delivering new treatments for patients suffering from the most neglected diseases for the past six years. In 2009, DNDi’s third new treatment to reach patients in the field was launched: a new combination against human African trypanosomiasis, Nifurtimox-Eflornithine Co-Administration Therapy (NECT), now included on the World Health Organization (WHO)’s Essential Medicines List.

Since 2003, 68.8 million euros have been spent (21.1 million in 2009 as compared with 17.6 million in 2008) to build a strong and robust portfolio including in 2009:

- A very interesting new chemical entity coming from the lead optimisation programme against human African trypanosomiasis: Oxaborole, which will enter into preclinical studies early in 2010;
- The transition of fexinidazole from preclinical to phase I first-in-human clinical studies, which shows promising signs of efficacy against sleeping sickness;
- An increase in the number of clinical studies (10 in 2009 compared to 7 in 2008) showing DNDi’s intense activity in combination therapy in the fields of visceral leishmaniasis and;
- The NECT success, the third new treatment to come out of the DNDi pipeline after ASAQ (a co-formulation of Artesunate and Amodiaquine, launched in 2007 with over 20 million treatments distributed in 24 countries in Sub-Saharan Africa) and ASMQ (a co-formulation of Artesunate and Mefloquine, launched in 2008, and which has been registered and is distributed in Brazil and is on its way to being pre-qualified by WHO and registered in several countries in South-East Asia), both new treatments against malaria.

In six years, DNDi has quadrupled its budget reaching 21.1 million euros in 2009, an increase of 20% compared with 2008. To achieve these tasks, DNDi partnered with a diverse range of 82 partners and sub-contractors, from the pharmaceutical industry, the academic world, and organisations involved in the fight against neglected diseases.

In 2009, contributions from donors and royalties from one of DNDi’s partners (see explanation in note number: 6), page 21, brought the level of income to 21.6 million euros, leaving a small excess of income over expenditure of 0.5 million euros, mainly due to positive exchange rates linked to the Euro/US dollar rate. DNDi decided to commit the royalties to projects and activities relating to the use of its first new treatment, ASAQ.

Therefore a Restricted Operating Fund was created to support pharmacovigilance projects such as a collaborative observational study of the real life use of ASAQ in Ivory Coast that will start in 2010.

DNDi’s reserve of unrestricted funds reached 9.5 million euros compared with 9.1 million euros as per December 31, 2008. This reserve will be crucial for DNDi in the years to come as the financial and economic crisis is making access to donors more difficult in a more competitive environment.

### STATEMENT OF ACTIVITIES 2004-2009 (SUMMARY)

<table>
<thead>
<tr>
<th>(Euro ‘000s)</th>
<th>2009</th>
<th>2008</th>
<th>2007</th>
<th>2006</th>
<th>2005</th>
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<tr>
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<td>9 563</td>
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<tr>
<td>Private Resources</td>
<td>9 499</td>
<td>10 175</td>
<td>6 290</td>
<td>5 398</td>
<td>5 364</td>
<td>4 225</td>
</tr>
<tr>
<td><strong>Total Income</strong></td>
<td>21 267</td>
<td>20 071</td>
<td>15 852</td>
<td>10 300</td>
<td>5 741</td>
<td>4 226</td>
</tr>
<tr>
<td><strong>EXPENDITURE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research &amp; Development</td>
<td>16 394</td>
<td>13 649</td>
<td>8 577</td>
<td>5 855</td>
<td>3 687</td>
<td>2 292</td>
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<tr>
<td>Strengthening Capacities</td>
<td>1 322</td>
<td>1 111</td>
<td>974</td>
<td>558</td>
<td>448</td>
<td>157</td>
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<tr>
<td>Advocacy</td>
<td>1 194</td>
<td>864</td>
<td>658</td>
<td>650</td>
<td>537</td>
<td>492</td>
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<td>694</td>
<td>363</td>
<td>250</td>
<td>213</td>
<td>81</td>
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<tr>
<td>General &amp; Administration</td>
<td>1 309</td>
<td>1 247</td>
<td>1 251</td>
<td>961</td>
<td>853</td>
<td>1 274</td>
</tr>
<tr>
<td><strong>Total Expenditure</strong></td>
<td>21 109</td>
<td>17 564</td>
<td>11 823</td>
<td>8 274</td>
<td>5 738</td>
<td>4 296</td>
</tr>
<tr>
<td>Operating Surplus</td>
<td>159</td>
<td>2 506</td>
<td>4 029</td>
<td>2 026</td>
<td>3</td>
<td>-70</td>
</tr>
<tr>
<td>Other Income (net)</td>
<td>332</td>
<td>231</td>
<td>83</td>
<td>185</td>
<td>49</td>
<td>70</td>
</tr>
<tr>
<td><strong>Net Surplus for the year</strong></td>
<td>491</td>
<td>2 737</td>
<td>4 113</td>
<td>2 211</td>
<td>52</td>
<td>0</td>
</tr>
</tbody>
</table>
DNDi's work is led by a team of talented staff located throughout the world. This team increased from 46 full time equivalents (FTEs), 33 core staff and 13 associate staff in 2008 to 69 FTEs (41 core staff and 28 associate staff) in 2009. Among them, 43% are working in DNDi Regional Offices in Nairobi, Rio de Janeiro, New Delhi, Penang, Kinshasa, Tokyo and New York, continuing a trend that was 37% in 2008, up from 25% in 2004.

The Finance, Human Resources and Administration Department has been composed of five staff members since 2007: a Director, Financial Controller, Accountant (part-time), HR & Administration Manager and a Travel Assistant/Receptionist. In September 2009, a part-time Finance Officer joined to help manage the increasing workload, raising the total of FTEs from 4.7 to 5.2. They are in charge of accounting and finance, budget, internal control, cash management, human resources, administration, logistics, and IT services for the entire organisation. They have been supported in the Regional Offices by four staff members since 2008 who are an indispensable link with local authorities and local partners.

DNDi’s auditors, Deloitte SA, conducted the organisation’s 2009 financial audit in accordance with Swiss Auditing Standards.

Research & Development Expenditure

DNDi has strengthened a large R&D portfolio for kinetoplastid diseases (visceral leishmaniasis, human African trypanosomiasis and Chagas disease) with seven clinical/post-registration projects, four preclinical projects, and three lead optimisation projects underway, as well as discovery activities.
With the inclusion of NECT on the Essential Medicines List (EML) of the WHO in May 2009, three new treatments have now become available to patients since DNDi successfully delivered two antimalarial products in 2007 (ASAQ) and 2008 (ASMQ).

As of December 2009, 22 R&D projects and several exploratory activities were being managed by eight DNDi Project Managers and six Project Coordinators with total project expenditures of 16.4 million euros. In 2009 DNDi’s growth continues with an increase of 20% in R&D expenditure. Compared to the 59% growth increase in 2008, one can observe a decreasing growth in 2009 as planned in the 2007-2012 Business Plan.

In order to support the clinical/post-registration projects, the R&D coordination team, driven by a Research & Development Director and his Assistant, has been reinforced with a new Clinical Development Director.

In addition, the R&D coordination team conducted research on Intellectual Property and regulatory issues, mainly in collaboration with the George Institute in Australia, and launched a report during the first quarter of 2010 assessing the challenges of registering new drugs for neglected diseases in the African context. The reinforcement of the R&D coordination team explains why expenses reached 1.6 million euros compared to 1.3 million euros in 2008 (+29%).

**DNDi Key Accomplishments**

In May 2009, the WHO included NECT on the Essential Medicines List. NECT is the first new treatment for sleeping sickness in 25 years. NECT, a simplified co-administration of oral nifurtimox with intravenous eflornithine, showed excellent efficacy and safety profiles in patients with stage 2 of the disease. NECT is more convenient for patients, puts fewer burdens on health staff and cuts the cost for medicine, transport, and hospitalisation.

- In July 2009, the Democratic Republic of the Congo (DRC) placed an order with WHO for the first NECT kits to treat 6000 patients.
- In March 2010, five additional countries had signed the supply request: Central African Republic, Chad, Sudan, Uganda, and Equatorial Guinea.

**ASAQ & ASMQ: Antimalarial products**

ASAQ, the fixed-dose combination (FDC) of artesunate (AS) and amodiaquine (AQ), was the first drug to be made available in 2007 by DNDi through public and private collaborations and an innovative partnership with sanofi-aventis. ASAQ is now registered in 24 African countries, and also in India based on a study managed by DNDi with the Indian Council for Medical Research (ICMR). In 2009, the first full year after prequalification by the WHO, over 20 million malaria treatments were distributed.

- Expenditures decreased from 2008 (1.1 million euros) to 2009 (0.9 million euros). As in 2008, the main efforts were focused on post-registration activities. Most of these activities were terminated or decreased in 2009, including the pharmacovigilance study in Liberia (0.5 million euros), a complementary study in India, and educational activities through national programmes about Artemisinin-based Combination Therapies (ACTs) and ASAQ. The Liberia study is one of the contributions to the risk management plan developed by sanofi-aventis and to which the Medicines for Malaria Venture (MMV), national programmes and DNDi participate.

- In 2009, a new partnership with Komfo Anokye Teaching Hospital Kumasi (KATH) in Ghana was signed to conduct public and private market surveys and policy analyses in Sierra Leone and Burundi. In 2010 a larger survey (up to 1500 outlet interviews) will be conducted by KATH and DNDi with the Global Fund - Affordable Medicines Facility - malaria (AMFm) support in Ghana.

**R&D expenditure by disease**

The percentage breakdown of R&D expenditure by disease highlights the efforts made on the Chagas portfolio in 2009 resulting in an increase of 242% compared to 2008 (800K euros). Clinical trials for VL Combination in Africa started in the beginning of 2009 increasing the expenditure for VL projects by 27% (+900 K€). With this increase, despite the end of the VL paromomycin clinical trial project, the breakdown of expenditure between HAT and VL projects is more balanced in 2009. The proportion of malaria projects in terms of the total expenditure remains stable as the finalization of the ASMQ dossier has required more investment in order to obtain the registration in various countries of Latin America and Asia and to obtain the WHO pre-qualification in 2010.
• In 2009 OTECI, a group of volunteer retired pharmaceutical experts, was working to identify a partner for the transfer of technology (0.15 million euros). The partner was identified in 2009 and the real transfer will start in 2010.

Approximately 1.5 million euros was spent in 2009 for ASMQ (fixed-dose combination of artesunate - AS and Mefloquine - MQ), compared to 0.9 million euros in 2008 and 0.7 million euros in 2007. This major increase (+62%) is due to the finalization of the dossier and conclusion of the transfer of technology.

• April 2009 marked an important milestone for ASMQ as the first public order of treatments was completed by the Brazilian government.

• In 2009 DNDi mainly focused on collecting data in Brazil and India, finalizing all information and making available the International Quality Registration Dossier supported by internal reports and published data (expenditure reached 0.9 million euros). This dossier is needed for registration in various countries other than Brazil and mainly to support the WHO pre-qualification which was submitted in March 2010 and has been accepted for review. It is expected that many questions will need to be answered and will thus require some additional work and expenditure in 2010.

• Following the technology transfer agreement signed in 2008 between Far Manguinhos (Brazil) and CIPLA (India) with the support and facilitation of DNDi, CIPLA was able during the last semester of 2009 to manufacture the regulatory registration batches in India. The transfer of technology will be successfully achieved during the first quarter of 2010.

These investments have been made as ASMQ showed very promising preliminary results from the Brazilian intervention study (more than 25,000 patients were treated) as well as another study performed in Myanmar with the ASMQ fixed-dose combination (FDC) compared to other Artemisinin Combination Therapies (ACT).

Therefore in 2010 further clinical research with partners will examine the potential therapeutic utility of ASMQ in pregnancy and in the African region. The process of registration will have a cost impact for the project.

■ Human African Trypanosomiasis (HAT): Success & progress at each stage

HAT expenditure remained quite stable between 2008 (6.3 million euros) and 2009 (6.5 million euros).

• Fexinidazole, currently in phase I clinical study for stage 2 HAT, is DNDi’s first success from its proactive compound mining strategy. It entered into phase I first-in-human clinical studies in September 2009 which will be completed by mid-2010. The main partners are: sanofi-aventis, France; Swiss Tropical and Public Health Institute, Switzerland; HAT Platform partners, and SGS, France and Belgium. In May 2009, DNDi and sanofi-aventis signed an agreement for the development, manufacturing, and distribution of fexinidazole (see in-kind contribution table). The total budget forecast for phase I is approximately 2 million euros.

In 2009 0.6 million euros were spent for phase I. Preclinical work was still ongoing in 2009, (expenditures of 0.7 million euros in 2009 compared to 1.3 million euros in 2008) and should terminate in 2010. Thus the total expenditure for the fexinidazole project reached 1.3 million euros in 2009.

• With the lead optimisation consortium in place (partnerships with Scynexis and Pace University, USA), one molecule has already been identified and optimised as a drug candidate and has been undergoing preclinical development since the last quarter of 2009. The team is also in the process of identifying a back-up compound in the same chemical series. Expenditure in 2009: 3.7 million euros compared to 3.3 million euros in 2008 and 1.3 million euros in 2007 when the project started. The increase (0.4 million euros) in the budget is due to the preclinical expenditure for the Oxaborole project. Oxaboroles, provided by Anacor and optimized by the team, is a new chemical class.

■ Visceral Leishmaniasis (VL): Promising discovery & ambitious plan for drug combinations

The budget increased by 1 million euros in 2009 and reached 4.1 million euros for the visceral leishmaniasis (VL) projects compared to 3.1 million euros in 2008 and 2.1 million euros in 2007. The major effort has been clinical trials to test combinations of existing medicines for better adapted, less toxic, more affordable shorter-course treatments and to retard the onset of drug resistance.

• VL combination therapy program in Asia, Latin America and Africa:

– In Africa, since 2004, DNDi and the Leishmaniasis East Africa Platform (LEAP) have embarked on a clinical research programme with two specific objectives: to geographically extend all currently available VL drugs in the region and to develop one to two new combination therapies. Currently DNDi is conducting three clinical trials in the VL programme: paromomycin (PM), AmBisome® and miltefosine. The actual costs for these clinical trials in 2009 reached 1.6 million euros compared to 1.4 million euros in 2008. In 2009, 146 patients were enrolled in the AmBisome® study and 1,313 were treated, outside the trials, in the seven clinical trial sites (Ethiopia, Kenya, Sudan, and Uganda). In 2010,
DNDi expects to finalize the PM study and register PM with a recommendation for use in combination with SSG.

- In Asia a phase III clinical trial was designed to study the combination of drugs already registered in India: AmBisome®, miltefosine, and paromomycin. Three arms with a combination of two drugs for treatment of a maximum of 11 days were compared with the standard 30-day therapy. In June 2008, the first patient was enrolled in the study. Enrolment of 634 patients was completed in June 2009, and the results are being analysed. The expenditure was 0.5 million euros in 2008 and 0.7 million euros in 2009. A two-step phase III trial using the same combinations was in preparation in 2009 and is due to start in Bangladesh in the first quarter of 2010 to facilitate registration of combination treatments in this country.

- A VL combination study is in preparation in Brazil to address the needs of patients in that region. This created no significant cost in 2009.

- The VL Lead optimisation consortium with Indian partners (Advinus Therapeutics, a research-based pharmaceutical company and the Central Drug Research Institute, CDRI) has been identifying and optimising molecules since January 2008. Recently the consortium worked on the oxaborole series from Anacor Pharmaceuticals, USA that shows in vivo efficacy. The nitroimidazoles series accessed through the collaboration with TB Alliance produced a number of highly potent compounds, several of which also proved to be efficacious in a VL animal model. Additional pharmacokinetics or safety studies are under way in order to identify preclinical candidates from these promising series. The expenditure reached 0.9 million euros in 2008 and 1.1 million euros in 2009.

### Discovery stage: Building the pipeline

Two breakthroughs in 2009:
- Access to libraries of compounds for chemical diversity, agreements with pharmaceutical companies:
  - Merck
  - Genomics Institute of the Novartis Research Foundation (GNF)
  - Pfizer
  - Others in negotiation
- Access to high throughput screening (HTS) capacity.

In 2009 assay development for VL and Chagas diseases took place at Institut Pasteur Korea (IPK).

In April 2009 DNDi signed a partnership with the University of Dundee. They are using assay development, medium throughput screening (MTS), for VL and screening for diverse libraries and target sets of compounds.

### Chagas disease: Consolidating our portfolio

The budget reached 1.4 million euros in 2009 compared to 0.6 million euros in 2008 for the Chagas disease projects. This increase, the most significant in 2009, shows that the preparation work done for Chagas is starting to bear fruit.

- The current clinical project, which evaluates E-1224, a new generation triazole compound, was in preparation during 2009. A phase II clinical study is to be initiated in 2010. The 2009 expenditure reached 0.1 million euros.

- Benznidazole, one of only two products registered for Chagas disease, can be highly efficacious in children. Yet no paediatric formulation exists. With the goal of developing an adapted, dispersible tablet of benznidazole, DNDi and LAFEPE (Brazil) signed a development deal in July 2008. Since then, the project team has been engaged in pre-formulation and analytical development activities. In 2009 the team determined the most appropriate paediatric tablet formulation, strength, and associated dosing regimen. Work is progressing, with batch production and stability testing planned for early 2010. 2009 expenditure equalled 0.2 million euros, which is the same level as expenditure in 2008.

- In mid-2008, a lead optimisation consortium devoted to Chagas disease drug discovery was set up by DNDi. This consortium includes institutions in Australia (Monash and Murdoch Universities, Epichem Ltd) and Brazil (Universidade Federal de Ouro Preto). In 2009, five classes of compounds identified in DNDi screening programmes were further assessed in hit-to-lead studies. One of these series has been selected and is currently in the lead optimisation process. The 2009 expenses reached 0.8 million euros, double the 2008 expenditure.

#### Disease High Throughput Screening (HTS)

<table>
<thead>
<tr>
<th>Disease</th>
<th>HTS availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAT</td>
<td>HTS available since 2008</td>
</tr>
<tr>
<td>VL</td>
<td>HTS developed at IPK in 2009</td>
</tr>
<tr>
<td>Chagas</td>
<td>HTS developed at IPK in 2009</td>
</tr>
</tbody>
</table>

The availability of HTS for all diseases has increased the early discovery expenditure between 2008 and 2009 by 0.4 million euros, reaching 0.9 million euros in 2009.

The other discovery projects are phasing out and three projects were closed by the end of 2009 (the Microtubule Inhibitor project, the Kitasato screening tryps project and the Eskitis natural product screening for HAT project). The expenditure for specific discovery projects decreased by 0.4 million euros in 2009. In conclusion, the expenditure for discovery projects (without lead optimisation) remains stable compared to 2008, reaching a total of 1.3 million euros in 2009.
### Project Portfolio 2009 – R&D expenditure by development stage

The total R&D expenditures increased by 20%, which is comparable to the increase for the other DNDi activities (strengthening capacity, advocacy, and general management). The largest expenditure (49%) remains in discovery projects as the lead optimisation activities continued their natural growth, for VL and HAT, and the Chagas lead optimisation program was in operation for the full year in 2009. The 3 lead optimisation projects (for HAT, for VL and for Chagas) represent 39% of the R&D expenditure in 2009 as compared to 37% in 2008. The percentage of the expenditure dedicated to clinical development increased by 5% (+1.2 M €) as the fexinidazole project moved from the preclinical phase to the clinical phase. The fexinidazole preclinical activity is close to being terminated and in consequence the preclinical costs decreased by 5%.

#### Discovery
- Compound mining: E.g. nitroimidazoles, macrolides...
- Chemical classes: E.g.: 5SK, Merck...
- Target-based: E.g.: Dundee’s Drug Discovery Unit (DDU),...
- Screening: E.g.: natural products (Kitasato, Eskits), new technology (Institut Pasteur Korea), DDU at Dundee, ...

#### Preclinical
- Nitroimidazole backup (HAT)
- Oxaborole (HAT)
- Alternative formulations Amphotericin B (VL)
- Combination therapy (Chagas)

#### Clinical
- Fexinidazole (HAT)
- Combination Therapy (VL in Asia)
- Combination Therapy (VL in Africa)
- Combination Therapy (VL in Latin America) - in preparation
- Paediatric Benznidazole (Chagas)

#### Available to Patients
- NECT (Stage 2 HAT) Nifurtimox - Eflornithine Co-Administration
- ASMQ (Malaria) Fixed-Dose Artesunate/Mefloquine
- ASAQ (Malaria) Fixed-Dose Artesunate/Amodiaquine

#### Strengthening capacities expenditure

- **In 2009 a new platform was formed for Chagas disease**
  - DNDi works with partners* in disease-endemic countries and ensures their involvement in the R&D process through technology transfer and through a global network of collaborations. Strengthening capacities expenditures increased to 1.3 million euros in 2009 compared to 1.1 million euros in 2008. This included:
    - Supporting platforms, such as the Leishmaniasis East Africa Platform (LEAP, created in 2006), HAT Platform in Africa (created in 2007) and the Chagas Platform (created in 2009). LEAP opened 3 new clinical centres in Sudan, Kenya, and Uganda, reaching a total of 7 sites in 2009. In addition, the HAT Platform welcomed 2 new partners, the Central African Republic and Chad.
    - Total expenditures in 2009 amounted to 0.7 million euros. The main increase (+0.1 million euros) compared to 2008 is related to the new Chagas Platform.
    - The management of the Natural Substance Network has been transferred to a partner in Asia for the future sustainability of the project.
    - Networking was carried out through local representatives and DNDi regional offices based in Nairobi, Rio, Penang, and New Delhi with national control programmes, founding partners, and other existing networks in disease endemic countries. Total expenditure in 2009 was 0.6 million euros.

*In addition, physical upgrading of facilities directly related to clinical trials is taking place within disease-endemic regions. For instance the construction/rehabilitation expenditure of Dooka hospital (clinical trial site in Sudan for LEAP Platform) reached 0.15 million euros.

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*VL and HAT platforms’ partners:
- VL: Kenya Medical Research Institute (KEMRI); Addis Ababa University, Gondar University and Drug Administration & Control Authority (DACA) in Ethiopia; Institute for Endemic Diseases (IEND) and the University of Khartoum in Sudan; Makerere University in Uganda; MSF; WHO-TDR.
- HAT: Institute for the fight and control of trypanosomiasis (ICCT) Angola; National HAT control programs (PNLTHA); Democratic Republic of the Congo and Republic of Congo; Tropical Medicine Research Institute (TMR) Sudan; Ministry of Health and Government of South Sudan (GoSS); Coordination Office for the Control of Trypanosomiasis in Uganda (COCTU); Swiss Tropical Institute (STI); MSF; WHO; KARI-Trypanosomiasis Research Centre, Kenya; Epicentre, France.
Communications & advocacy expenditure

Communications and Advocacy expenditures increased by 38% in 2009 (1.19 million euros compared with 0.86 million euros in 2008).

In 2009, DNDi Advocacy efforts were mainly focused on two events:
1) The launch of a Chagas campaign in partnerships with other organisations to support prioritisation of Chagas disease on the agenda of policy makers and donors; to raise awareness of the disease in order to break the silence which surrounds it; and to boost Research & Development of new tools (diagnostics and treatments) for the disease, which are urgently needed.
2) The organisation of the second stakeholder meeting and third African DNDi meeting in Nairobi where over 250 participants, mainly scientists, researchers, policymakers, and global leaders from 28 countries in Africa, Asia, Europe, Latin America, and North America met to stimulate greater regional research partnerships. These leading experts used this opportunity to examine ongoing DNDi projects in drug research and development, access, and capacity strengthening. It proved to be an excellent forum to share knowledge on the realities of conducting research, managing drug development, ensuring access to treatment, and securing funding for neglected diseases.

The DNDi Communication and Advocacy team also worked to raise awareness of the lack of tools to treat neglected patients; facilitated meetings at regional and national levels; participated in international congresses and conferences; produced educational material (newsletters, video and websites) regarding the three target diseases and malaria, and published the results of its ongoing clinical studies in peer-reviewed medical journals.

The Communications and Advocacy team in 2009 was composed of 4 staff members (3.5 FTEs, same figure as 2008) with the support of temporary staff and consultants in the head office and staff members for regional communications in North America and Latin America.

Fundraising & general management expenditure

Fundraising expenditure increased by 28% in 2009 (0.89 million euros in 2009 and 0.69 million euros in 2008). This increase is due to the reinforcement of human resources to reach the 2009 objectives: to maintain and secure funding renewals from current large contributors (public and private); to engage new major donors; to develop new fundraising strategies for private contributions; to explore fundraising in emerging countries and to monitor new funding mechanisms. Fundraising expenses represent the costs to raise funds: personnel, travel and document production. The Fundraising team was composed in 2009 of 5 staff members (4 FTEs), was compared with 3 FTEs in 2008, and with the support of 2 staff members in DNDi North America, dedicated to fundraising in North America, and some consultants.

General Management & Administration total expenditure remained stable at 4% (1.31 million euros in 2009 and 1.25 million euros in 2008). General Management and Administration expenses represent the costs of managing the organisation: expenses incurred by the Board of Directors, the Executive Director Office, and the Financial and Administration Department. In 2009 with the addition of a new Finance Officer, the team was composed of 8 staff members (6.5 FTEs) compared with 7 staff members (6.5 FTEs) in 2008.

The future

DNDi’s business plan developed in 2003 and updated in 2007 for the 2004–2014 period has served as a framework and guide for DNDi activities until today. However, by the end of 2009, DNDi had accumulated significant information and data providing a deeper insight into the real costs associated with its business model.

DNDi’s accomplishments from 2004 to 2009 and a forecast for the three years to come (2010–2012) have shown that the objectives of delivering six to eight new treatments for neglected diseases and creating a healthy portfolio of projects, do not require a total budget of 274 million Euros as previously envisaged. Careful management of DNDi’s resources, the involvement of DNDi’s partners in building the portfolio and in the development phases, and the fall of the US Dollar against the Euro, has led DNDi to reconsider this total sum and to re-estimate it at 230 million Euros, down from 274.

DNDi will continue to dedicate the majority of funding towards the development of treatments for visceral leishmaniasis (34%), human African trypanosomiasis (35%), and Chagas disease (17%).

On average, the vast majority of funds are devoted to R&D (84%), with a secondary programmatic focus on strengthening capacities (4%) and advocacy (3%). This focus shows a clear emphasis on the social mission with 91% of the funds allocated to this area. From a disease perspective, two thirds of overall expenses are devoted to visceral leishmaniasis and human African trypanosomiasis R&D, which shows DNDi’s commitment to these two diseases.
A new business plan will be developed by the end of 2010 for the period 2011 - 2018. It is an opportunity for DNDi to review its objectives and to re-estimate the expenditure required.

Forecast Social Mission Breakdown DNDi 2004–2014 (in EUR million)

<table>
<thead>
<tr>
<th>Expenditure</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>193</td>
</tr>
<tr>
<td>Strengthening Capacities</td>
<td>9</td>
</tr>
<tr>
<td>Advocacy</td>
<td>8</td>
</tr>
<tr>
<td>Fundraising</td>
<td>9</td>
</tr>
<tr>
<td>General Management</td>
<td>11</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>230</strong></td>
</tr>
</tbody>
</table>

(Previous total = 274)

**Diversification of donors**

To develop its activities and achieve its objectives, DNDi seeks diverse funding, including: cash donations, in-kind contributions, grants, sponsorships, and legacies – from individuals, governments, public institutions, companies, foundations, NGOs, and other mechanisms. Since its creation, DNDi has been working to diversify its funding to include a mix of public and private donors and project, portfolio and initiative funding.

DNDi strives to obtain half of its funding from public sources. DNDi works to achieve a balance of public and private funding, with total public institutional contributions amounting to 11,768,260 euros (55% of total income in 2009, 9,895,423 euros and 49% in 2008) as compared to total private contributions amounting to 9,498,997 euros (45% of total income in 2009, 10,175,249 euros and 51% in 2008).

As of April 2010, 130 million euros have been committed to DNDi to fund its activities from 2003 - 2014.
DNDi received continuing grants from the American, British, Dutch, French, and Spanish governments, the Canton of Geneva, Switzerland, EU, the Medicor Foundation, and the Bill & Melinda Gates Foundation. 2009 was a year of continuity in the efforts to raise funds. DNDi was successful in signing new grants for 2009 and beyond, with current public and private donors demonstrating their confidence in DNDi’s objectives. New grants were secured from the French Ministry of Foreign Affairs and the Agence Française du Développement (MAEE 1.3 million euros and AFD 0.5 million euros); the Spanish government (AECID 5 million euros); the Bill & Melinda Gates Foundation (USD 15 million) and the Medicor Foundation (USD 0.6 million).

Despite a couple of new private donors such as the Starr Foundation, the decrease in private funding in 2009 as compared with 2008 is representative of the difficulties to bring new contributors due to the economic crisis which followed the 2008 financial crisis. In spite of these uncertainties, total grants of 21,116,173 euros plus 151,084 euros of royalties (see financial section) were raised in 2009 as compared with 20,070,672 euros in 2008 (+6%).

At the end of 2009, the cumulative funding mix of 130 million euros was 36% restricted funds (31% by the end of 2008) and 64% unrestricted funds (69% by the end of 2008). This bias toward unrestricted funding is both by design and a result of unrestricted initiative funding from the UK Department for International Development of GBP 24.5 million (2006-2013) from the Spanish Agency for International Development and Cooperation of 10 million euros (2006-2010) and from Médecins Sans Frontières of 42.6 million euros (2003-2014). These significant and multi-year commitments are critical to the success of DNDi for the next years.

In-kind donations grew from 495,315 euros to 1,125,320 euros in 2009, showing the involvement of the founding members of DNDi, international organisations and pharmaceutical partners in new chemical entities development.

As of March 2010, a total of 130 million euros has been committed to DNDi which enabled all of its activities to be funded since 2003. However, DNDi still needs a total of 100 million euros by 2014 to achieve its business plan objectives.

Thanks to all its donors DNDi has been able to deliver three new treatments for the most neglected patients and build a robust pipeline for the future.
DNDi would like to thank the following donors for their support of DNDi activities since July 2003:

**Public Institutional Donors**
- Republic and Canton of Geneva, Switzerland
- Department for International Development (DFID), United Kingdom
- German Agency for Technical Cooperation (GTZ) on behalf of the Government of the Federal Republic of Germany
- European Union – Framework Partnership 5, 6 and 7
- French Development Agency (AFD), France
- Ministry of Foreign Affairs (DGIS), Netherlands
- Ministry of Foreign and European Affairs (MAEE), France
- National Institutes of Health – National Institute of Allergy and Infectious Diseases (NIAID), USA
- Region of Tuscany, Italy
- Spanish Agency for International Cooperation and Development (AECID), Spain
- Swiss Agency for Development and Cooperation (DDC), Switzerland

**Private Donors**
- Bill & Melinda Gates Foundation, USA
- Fondation André & Cyprien, Switzerland
- Guy’s, King's and St Thomas’ Giving Week, UK
- Leopold Bachmann Foundation, Switzerland
- Médecins Sans Frontières, International
- Medecor Foundation, Liechtenstein
- Fondation Pro Victimis, Switzerland
- Sasakawa Peace Foundation, Japan
- Starr International Foundation, Switzerland
- UBS Optimus Foundation, Switzerland
- Other private foundations and private individual donors who wish to remain anonymous