2004

2004 IPM Annual Report—Developing HIV-Prevention Options for Women Worldwide

International Partnership for Microbicides

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Developing HIV-Prevention Options for Women Worldwide
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IPM AT A GLANCE

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Photo credit: Karl Grobl and Richard Lord
Since the first AIDS case was diagnosed in 1981, 20 million people have died from AIDS and 37.8 million people worldwide are living with HIV. If the current epidemiological trends continue, by 2020, AIDS will have claimed up to 100 million lives, making it the worst pandemic in human history. Women bear a disproportionate burden both as caregivers and as people living with HIV.
In 2004, we saw the world turn its attention to the unique challenges faced by women in the developing world in their fight against HIV/AIDS. At both Microbicides 2004 in London and the XV International AIDS Conference in Bangkok, microbicides were featured as never before as a potential woman-initiated prevention method.

It is clear that the HIV pandemic affects all cultures, genders and ages, but World AIDS Day 2004—Women and Girls, HIV and AIDS—was a reminder to us all that women face many unique obstacles in HIV prevention. The day was one of sobering reality as we read the statistics on HIV infection in women. HIV/AIDS is affecting women most severely in places where heterosexual sex is a dominant mode of HIV transmission, as in sub-Saharan Africa where women and girls make up almost 57 percent of adults (15-49) living with HIV.

The microbicide field has made great strides recently. Five candidate microbicides entered, or are about to enter, large-scale efficacy trials. The International Partnership for Microbicides (IPM) and others are now focusing on second-generation microbicides that are specifically active against HIV and products that will combine two or more drugs in the same formula, as well as extended release delivery devices such as vaginal rings. Several such products entered early safety trials in 2004.

Yet, the microbicide field still faces significant challenges over the next several years. In addition to the need for additional clinical trial capacity and increased global awareness of microbicides, a richer pipeline of products is necessary so strong candidates can be identified and marshalled through the development process. This will require a substantial increase in government investment into national research programmes, developers, and public-private partnerships to develop and test products. In addition, incentives need to be established to encourage greater participation and investment from the pharmaceutical industry in the development of new microbicides that meet the HIV prevention needs of developing countries.

While there are many challenges ahead, I am confident that IPM is poised to make a significant contribution. We look forward to many years of progress.

Els Borst-Eilers, M.D., Ph.D.
Chair of the Board

Chair of the Board
I am pleased to present the first Annual Report from IPM. Since our creation in 2002, we have worked tirelessly to establish IPM as a resource for microbicide development so that new prevention options can be accelerated.

This past year proved to be a significant turning point for microbicides as female-initiated methods of prevention gained increased attention from global leaders and policy makers and microbicides garnered headlines around the world as an important prevention option for women.

In 2004, IPM continued its growth and expanded its capacity to provide resources to help fill gaps in microbicide development. By screening compounds, designing optimal formulations, establishing manufacturing capacity, developing trial sites, and conducting access studies, IPM has collaborated with others to provide a wealth of resources and expertise to those working to develop microbicides. An especially noteworthy accomplishment this year was the first clinical trial of a microbicide-containing vaginal ring.

The partnerships and collaborative efforts initiated among public and private sector and non-profit entities incorporate the best practices of each to advance microbicide development. We have built relationships and brokered innovative agreements with a variety of outstanding groups including academic institutions, pharmaceutical and biotechnology companies, non-governmental organizations and international organizations to reach a shared objective to make microbicides for women a reality. IPM was also fortunate to build relationships with several influential champions who helped to spread the message of microbicides.

In 2004, IPM expanded considerably, acquiring greater international expertise by adding new staff and consultants, securing larger headquarters in Silver Spring, Maryland, USA and establishing IPM Belgium. We have been fortunate to work under the guidance and direction of a farsighted and committed Board of Directors. In 2004, our founding Chairman, Dr. Mahmoud Fathalla, handed the Board Chair to Dr. Els Borst-Eilers, who will help lead IPM into the next phase of organizational development and field support. I want to take this opportunity to thank Dr. Fathalla for his stewardship during this critical period of growth for the organization and welcome Dr. Borst-Eilers in her role as Board Chair and Dr. Alex Coutinho in his new role as Vice-Chair.

I also want to extend my appreciation to our donors who have infused this organization not just with funding support, but with the confidence and expectation that IPM will play a major role in accelerating microbicide development and access. Building upon our solid foundation, I look forward to a productive and rewarding 2005.

Zeda F. Rosenberg, Sc.D.
Chief Executive Officer
MISSION

The mission of IPM is to prevent HIV transmission by accelerating the development and availability of safe and effective microbicides for use by women in developing countries.

WHAT IS A MICROBICIDE?

Microbicides are products that could be applied topically to the vagina to reduce the transmission of HIV during sexual intercourse. Microbicides could take the form of a gel, cream, film, suppository, sponge or vaginal ring that releases the active ingredient gradually, or a new formulation or delivery method yet to be invented.
Overview

Since the first AIDS case was diagnosed in 1981, 20 million people have died from AIDS and 37.8 million people worldwide are living with HIV. If current trends continue, by 2020, AIDS will have claimed up to 100 million lives, making it the worst pandemic in human history.

Increasingly, in Africa, and in many developing countries in Asia and Latin America, AIDS is taking a disproportionate toll on women. As a result, AIDS has become one of the most serious women’s health issues globally.

An effective microbicide could not only protect women against HIV infection, but also interrupt the cycle of transmission from and to men and to newborns by preventing infection in the mothers. In order to protect individuals, preserve families and control the spread of the disease, IPM is focused on the population at greatest risk of becoming infected by HIV: women in developing countries.

IPM was created to identify and address gaps or bottlenecks in the development of and subsequent access to microbicides. Since its founding in 2002, IPM continues to establish collaborations based on cost-efficient and rapid approaches to development of highly promising drugs, conduct state-of-the-art research to optimize formulations and delivery methods, and develop clinical trial sites to facilitate the future conduct of large-scale efficacy studies.

IPM assists microbicide development in multiple ways. One is direct financial support to organizations involved in drug or formulation development. The second is drug development services provided by IPM’s extensive infrastructure. The third is through direct development, testing, and clinical trials of promising candidates by IPM.

PERCENT OF ADULTS (15-49) LIVING WITH HIV WHO ARE FEMALE, 1985–2004

Source: UNAIDS’ AIDS Epidemic Update: December 2004
### IPM INFRASTRUCTURE

**Antiviral screening laboratory**
- Initial testing of compounds for anti-HIV activity
  - St. George’s Hospital Medical School – UNITED KINGDOM

**Formulation support**
- Semisolids
  - Particle Sciences – UNITED STATES
- Vaginal rings
  - Queen’s University of Belfast – NORTHERN IRELAND
- Bioreactive polymers
  - University of Utah – UNITED STATES

**Animal facility**
- Animal efficacy testing
  - UNITED STATES

**Clinical trials material manufacturing facility**
- GMP facility with Phase I/II capacity for mixing and packaging
  - IPM – UNITED STATES

**Clinical trial capacity**
- New clinical trial sites
  - Family Health International – VIETNAM
  - Family Health International – KENYA
  - University of Ghent – KENYA
  - Gede Foundation – NIGERIA
- New collaborations and capacity building
  - FAMOVS-Parexel – SOUTH AFRICA
  - University of Witwatersrand, Reproductive Health and HIV Research Unit – SOUTH AFRICA
- Potential trial sites
  - Kilimanjaro Reproductive Health Programme and Harvard School of Public Health – TANZANIA
  - International Antiviral Therapy Evaluation Center and Rwandan Government – RWANDA

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### IPM growth

IPM grew tremendously as an organization, from a staff of two in 2002 to an international staff of 23 and a wealth of expert consultants in 2004. As of the writing of this annual report, the senior management team consists of Dr. Zeda Rosenberg as the Chief Executive Officer, with Dr. Mark Mitchnick, Chief Scientist, and Ms. Patricia Meier, Chief Operating Officer/Chief Financial Officer, reporting to her directly. The senior management team also includes Dr. Paul Coplan, Executive Director for Regulatory Affairs, Dr. Joseph Romano, Executive Director for Research and Development (R&D), and Mr. Martin Methot, Executive Director for External Affairs and Policy.

In addition to expanding its headquarters in Silver Spring, Maryland, USA, IPM Belgium established an office in Brussels, Belgium in September 2004. With a presence in Europe, IPM is now positioned to strengthen links with European countries and the European Union institutions, and to reach out to other constituencies in Europe.
OPPORTUNITIES FOR ACTION

Help ensure widespread availability & adoption

BASIC RESEARCH > DISCOVERY > PRE-CLINICAL > CLINICAL TRIALS > LICENSURE > LAUNCH

Help identify the “next generation” of microbicides
Assess and fund across the microbicide portfolio
Provide common capabilities or supports for the field
Maximize clinical trial capacity
Help create regulatory pathways and capacity

- Multiple mechanisms/targets/products
- Formulation capacity
- In vitro and in vivo models
- Regulatory
- Manufacturing
Collaboration with the Pharmaceutical Industry

In March 2004, IPM and Tibotec Pharmaceuticals Ltd., a subsidiary of Johnson & Johnson, signed a groundbreaking agreement empowering IPM to develop the promising compound TMC120 as a microbicide. This agreement marked the first collaboration in the microbicide field between a major pharmaceutical company and a public-private partnership such as IPM.

Building upon Tibotec's Phase I TMC120 gel study, IPM sponsored a safety trial of TMC120 formulated in a vaginal ring in collaboration with Tibotec and the Population Council. This was the first human trial of a microbicide in a vaginal ring. The trial was completed in early 2005.

In late 2004, the R&D team undertook reformulation of the gel, which will be tested in an expanded safety trial in Rwanda, Tanzania and South Africa, scheduled to begin in mid-2005. Although the development efforts have been transferred to IPM, Tibotec is an active member of the TMC120 development team. IPM and Tibotec continue to work collaboratively on projects as they arise and hold regular joint development team meetings. This is seen as a model of best practices and will hopefully encourage other pharmaceutical companies to follow suit.

Microbicidal Vaginal Ring

The TMC120 vaginal ring trial was the first time a microbicide ring formulation was tested clinically. This study took nine months from concept until the last participant completed the study. The purpose of the trial was to evaluate whether a vaginal ring can be feasibly used to deliver TMC120 to the entire vaginal mucosa. Results from this study will be available in 2005.

As a product moves from R&D to clinical testing, the handoff between the two teams can be cumbersome especially for a new organization. In its first such experience, IPM’s R&D and Clinical teams worked seamlessly to bring this trial to the clinic in record time. Production, in cooperation with the Population Council, protocol design, subcontractor relationships and regulatory support all required participation by many team members.
IPM has examined the microbicide pathway, from drug discovery to development, and has identified ways to accelerate efforts to get safe, effective microbicides in the hands of women in developing countries.

IPM is applying new discoveries in HIV science to the identification and screening of promising drugs and concentrating resources on the highest priority second- and third-generation microbicide candidates—highly-active antiretroviral single agents as well as combinations. In collaboration with pharmaceutical companies, biotechnology companies, non-profit organizations and academia, IPM is funding, in whole or in part, the development of several microbicide products and enabling technologies. IPM will continue to seek and add promising approaches to the portfolio of candidates.

One critical factor for success is the engagement of the private sector and academia in identifying new potential microbicides. In 2004, IPM entered into several critically important agreements.

In March 2004, IPM signed a non-exclusive licensing agreement with Tibotec Pharmaceuticals Ltd., a Belgian-based subsidiary of Johnson & Johnson, to develop TMC120 as a microbicide (see page 8). Quickly following, in September 2004, IPM signed an agreement with GlaxoSmithKline to test promising new anti-HIV compounds as potential microbicides. IPM also has entered into contracts with Biosyn, Inc. for development of Cyanovirin-N, an HIV fusion inhibitor and with Warner Chilcott and Queen’s University of Belfast for investigation of microbicide-containing vaginal rings.

Finally, IPM has an agreement with the University of Utah to pursue controlled-release technologies. These collaborations are precedent-setting ventures based on innovative intellectual property strategies that will serve as models for future negotiations and partnerships to accelerate microbicide development. IPM continues to actively seek out collaborations with the pharmaceutical industry.

"The development and marketing of an effective microbicide could have a great impact on the well-being of our country’s women, and consequently on the children they bear."

DR. MANTO TSHABALALA-MSIMANG, MINISTER OF HEALTH, SOUTH AFRICA
IPM now has several key resources including a formulation facility dedicated to microbicides and a manufacturing facility capable of producing clinical trial material under good manufacturing practices for Phase I and Phase II trials. In addition, IPM supports a dedicated staff at St. George’s Hospital Medical School in London, UK for the candidate screening programme, and a preclinical testing facility for non-human primate efficacy studies.

Other candidates also exist, including many proteins with multiple mechanisms of action and reverse transcriptase inhibitors.
Clinical Trials and Capacity Building

To adequately demonstrate efficacy of a candidate microbicide, clinical trials involving large numbers of women need to be conducted in locations where new HIV infections occur at a high rate. Additionally, in order to enable clinical trials to lead to product registration, it is necessary that these studies be conducted according to universally accepted regulatory guidelines, so as to guarantee the ethical and scientific integrity of the results and protect trial participants.

IPM’s goals include accelerating the clinical development of promising candidate microbicides; expanding clinical trial capacity for HIV prevention trials by identifying and developing new sites; working with local communities where trials are conducted so that they have a voice and sense of ownership in the clinical trials; and, building political support and national regulatory authority awareness regarding microbicide clinical development.

"[Microbicides are] a product still in development. A lot of research is done and it will take a few years before they can come on the market. But I don’t know of any other technology that would make such a difference to stop the heterosexual spread of HIV."

DR. PETER PIOT, EXECUTIVE DIRECTOR, JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS

The Clinical Team began in 2004 to prepare for a 42-day TMC120 vaginal gel safety trial expected to start in mid-2005 in three African countries: South Africa, Rwanda and Tanzania. The trial will be conducted in South Africa in collaboration with FARMOVSParexel in Bloemfontein and the University of Witwatersrand’s Reproductive Health and HIV Research Unit; in Rwanda, with Projet Ubuzima, a non-governmental organization, and the Netherlands-based International Antiviral Therapy Evaluation Center (IATEC); and with the Harvard School of Public Health and the Kilimanjaro Reproductive Health Programme in Moshi, Tanzania.

IPM is also preparing to conduct an extended safety study on TMC120 gel in Uganda to begin in late 2005. This will be conducted in collaboration with the MRC/UVRI Uganda Research Unit and the Medical Research Council Clinical Trials Unit. In 2005, IPM will also conduct a second vaginal ring study using a new ring formulation.
## IPM CLINICAL STUDIES

IPM has been working on the following TMC120 studies.

<table>
<thead>
<tr>
<th>STUDY</th>
<th>STUDY NAME</th>
<th>COLLABORATORS</th>
<th>n*</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPM001</td>
<td>Vaginal ring trial</td>
<td>Population Council&lt;br&gt;SGS-Medisearch International N.V.&lt;br&gt;University of Ghent</td>
<td>12</td>
<td>Completed</td>
</tr>
<tr>
<td>IPM002</td>
<td>HIV incidence studies</td>
<td>Family Health International</td>
<td>2,250</td>
<td>Planned 2005</td>
</tr>
<tr>
<td>IPM003</td>
<td>Gel safety trial</td>
<td>Central Laboratory Services&lt;br&gt;FARMOVS-Parexel&lt;br&gt;Harvard School of Public Health&lt;br&gt;International Antiviral Therapy Evaluation Center&lt;br&gt;Kilimanjaro Reproductive Health Programme&lt;br&gt;Projet Ubuzima&lt;br&gt;Quintiles - South Africa&lt;br&gt;Triclinium&lt;br&gt;University of Witwatersrand, Reproductive Health and HIV Research Unit</td>
<td>112</td>
<td>Planned 2005</td>
</tr>
<tr>
<td>IPM004</td>
<td>Gel pharmacokinetic trial</td>
<td>FARMOVS-Parexel&lt;br&gt;Triclinium</td>
<td>18</td>
<td>Planned 2005</td>
</tr>
<tr>
<td>IPM005</td>
<td>Gel expanded safety trial</td>
<td>MRC/UVRI Uganda Research Unit&lt;br&gt;Medical Research Council Clinical Trials Unit - UK&lt;br&gt;Quintiles - South Africa</td>
<td>200</td>
<td>Planned 2005</td>
</tr>
<tr>
<td>IPM006</td>
<td>Gel male tolerance trial</td>
<td>CONRAD&lt;br&gt;Family Health International</td>
<td>36</td>
<td>Planned 2005</td>
</tr>
<tr>
<td>IPM007</td>
<td>Seroconverter protocol</td>
<td>Quintiles - South Africa&lt;br&gt;Triclinium</td>
<td>N/A</td>
<td>Planned 2005</td>
</tr>
<tr>
<td>IPM008</td>
<td>Vaginal ring trial</td>
<td>SGS-Medisearch International N.V.&lt;br&gt;University of Ghent&lt;br&gt;Warner Chilcott</td>
<td>13</td>
<td>Planned 2005</td>
</tr>
<tr>
<td>IPM009</td>
<td>Gel efficacy trial</td>
<td>Various</td>
<td>9,824</td>
<td>Planned 2006</td>
</tr>
</tbody>
</table>

* Number of participants
Regulatory Pathways for Microbicides

Working towards regulatory approval of microbicides involves assessing the current approaches of regulatory agencies in Europe and the United States; reviewing regulatory requirements in key developing countries whose decisions often influence other countries; and developing review and approval strategies that appropriately consider risk/benefit analyses for microbicide products in settings where HIV incidence is high.

Among the regulatory challenges to testing and licensing microbicides is the limited experience in evaluating topical drugs designed to prevent intravaginal infection. Insufficient resources and expertise in national regulatory authorities (NRAs) in many developing countries are an added challenge. As a result, NRAs may have to rely on decisions by European and US regulators, whose decision-making criteria—especially with regard to risks and benefits—may not be appropriate in settings where HIV prevalence is much higher than in the populations of Europe or the United States.

In June 2004, IPM published a paper in Science magazine on regulatory pathways for licensure of microbicides. The article outlines the unique challenges that will be faced by microbicide developers in seeking licensure and calls for strengthening of national regulatory agencies to ensure country-appropriate risk-benefit assessment.

To overcome regulatory challenges, IPM is working to strengthen capacity in developing countries in collaboration with organizations, such as the World Health Organization, familiar with multi-country regulatory processes. In addition, to enable joint reviews of products, IPM is creating stronger collaborative links between NRAs in developing and industrialized countries. Finally, IPM is liaising with the US Food and Drug Administration (FDA) and the European Medicines Agency (EMEA) to facilitate regulatory approvals by these agencies and to ensure that microbicide development programmes meet these requirements.

"Women and girls need methods to protect themselves from HIV—methods that they can control. One of the most promising female-controlled prevention options on the horizon is microbicides …"

AILEEN CARROLL, MINISTER OF INTERNATIONAL COOPERATION, CANADA
IPM is also working with Social & Scientific Systems to establish a database of regulatory requirements for approval of microbicides in key developing countries, which will be available online.

IPM’s Regulatory Affairs Team made considerable progress in 2004 in researching and preparing the required documentation to begin clinical trials. IPM recently submitted a clinical trial application for approval to the Medicines Control Council in South Africa and is preparing to submit a pre-investigational new drug approval to the FDA. These documents and subsequent approvals are a first step in conducting trials.

Product Attribute Study

IPM has commissioned an acceptability study aimed at determining women’s preferences for a variety of gels. The goal is to take a consumer approach to ensure that once a microbicide is formulated into a gel, it will be acceptable to, and used by, women.

South African and US market research firms will team with local partners in Botswana, Nigeria, South Africa and Zambia to conduct the study. Not to be confused with a clinical trial that tests microbicide safety and effectiveness, or a hypothetical acceptability study, women will actually use different gels. These gels do not contain any active ingredients. To get a representative sample, different ethnic groups in each country will be included. Women will be asked to comment upon their likes and dislikes; rate each product on a range of comfort and aesthetic attributes; describe their likelihood of future use and whether they would recommend it to others; and provide suggestions for improvement.

Gathering this type of information will help IPM produce gels that best meet women’s product preferences and will maximize product use. The results will be shared widely with all microbicide developers.
Preparing for Access and Use

Ensuring rapid and widespread access to microbicide products is a cross-cutting issue that influences all of IPM’s work. For example, agreements on intellectual property and pricing that facilitate availability and affordable pricing are conditions of IPM’s investment decisions. To further its access work, IPM has engaged an executive recruiting firm to assist in a search for a Senior Advisor for Access. The person who ultimately takes on this job will report directly to the Chief Executive Officer and will play an integral role across the organization.

IPM is working to ensure that women will have access to microbicide products once they have been tested and approved. Preparing for access considers all steps: from product selection to an individual woman’s interest and ability to use a microbicide product. In advance of the introduction of microbicides, IPM is helping to address financing, manufacturing, procurement, logistics, delivery and consumer education issues through preparedness studies. IPM is also exploring ways to use existing delivery or fulfillment systems for consumer products to distribute microbicides, and is conducting product attribute studies to determine women’s preferences for a variety of gel formulations (see page 14).

"I often feel like I have nothing real to offer women who want to protect themselves. When microbicides become a reality we will really have something to say to the women. I can’t wait!"

MERCY WAHOME, CO-ORDINATOR OF SOCIETY FOR WOMEN AND AIDS IN KENYA (SWAK)

A central element of IPM’s access work is a programme of country preparedness studies, designed to assess considerations in different country settings. It consists of three components: (1) a country preparedness assessment tool; (2) country assessments; and, (3) follow up actions. The country preparedness assessment tool identifies issues and actions at the country level to prepare for rapid availability of microbicides. The tool is being tested and adapted and will be applicable in a range of country settings. Results from its application will provide country-specific information and analysis, and map steps for expediting microbicide availability in each setting.

Working in partnership with a consortium of groups in Johannesburg, headed by Health and Development Africa, and JHPIEGO in Lusaka, IPM initiated the first two country assessments in South Africa and Zambia. These assessments are being conducted through programmatic research, policy review, and targeted interviews. The reports are being finalized and stakeholder meetings are being arranged for mid-2005 that will allow for review and dissemination of findings. IPM is also actively working to identify appropriate collaborators to conduct similar assessments in Nigeria and India, and anticipates initiating two additional country case studies in the coming year.
In 2004, IPM completed a collaborative project with EngenderHealth, the University of Cape Town and the Population Council to explore the views of South African community members, providers and policy makers about potential barriers and opportunities related to the introduction of microbicides. Through in-depth interviews and focus group discussions, this study and a subsequent publication explored and identified issues that could facilitate or undermine access to and use of microbicides. The study was presented at several meetings including Microbicides 2004, and has been submitted for publication.
Global Advocacy, Policy and Resource Mobilization

IPM is working to create awareness and support for microbicides and to pave the way for clinical trials in developing countries. IPM is actively mobilizing resources and seeking support from policy makers and advocates with the potential to influence national, international and multilateral decisions.

In 2004, IPM’s External Affairs and Policy Team focused on building strategic relationships with donors and collaborators to advance the microbicide agenda as quickly and efficiently as possible. IPM works with groups such as the UNAIDS’ Global Coalition on Women and AIDS, the Global Campaign for Microbicides and the Alliance for Microbicide Development to build an international network of champions and advocates. IPM aims to expand global recognition of microbicides as an essential component of a comprehensive response to the AIDS pandemic, attract financial support for microbicide research and development, and prepare for their introduction.

"I ask only that you see microbicides, not merely as one of the great scientific pursuits of the age, but as a significant emancipation for women whose cultural and social and economic inheritance have put them so gravely at risk."

STEPHEN LEWIS, UN SPECIAL ENVOY FOR HIV/AIDS IN AFRICA

IPM participated in the biennial microbicides conference, Microbicides 2004, held in London and attended by more than 700 researchers, public health workers and advocacy organizations from 50 countries. The biennial forum provided an important stage for sharing innovation and updates on research and development. In June 2004, IPM participated in a meeting in Dublin co-hosted by the then Irish Presidency of the EU and the Netherlands entitled, "New Preventive Technologies: Providing New Options to Stop the Spread of HIV/AIDS." There, the governments of the Netherlands, Luxembourg and the United Kingdom, the next three successive presidencies of the European Union, committed to continued emphasis on HIV during their presidencies.

The XV International AIDS Conference in Bangkok in July 2004 provided a forum for microbicides, serving to dramatically increase awareness. Influential leaders such as UN Secretary General Kofi Annan called on the world to ensure that women have full access to practical prevention options, including microbicides.
Late in 2004, IPM was in the final stages of securing future funding commitments from Canada, the European Commission and the United States, adding to the support from Denmark, Ireland, the Netherlands, Norway, the United Kingdom, Sweden, the Bill & Melinda Gates Foundation, The Rockefeller Foundation, The World Bank and the United Nations, thus bringing total commitments to IPM to US $119 million for the period 2002-2007. After the close of 2004, early in 2005, IPM received formal commitments from Canada, the European Commission and the United States.

IPM will continue to raise awareness of microbicides in both developed and developing countries, as well as highlight the need for governments to invest in their development and access. IPM will take an active role in raising the profile in the international media and at the policy level by drafting policy papers on the relationship between microbicides and realization of the Millennium Development Goals, the importance of G8 support for microbicides as they develop their agenda in 2005 and the importance of advance purchase mechanisms for new prevention technologies such as vaccines and microbicides.
The XV International AIDS Conference in Bangkok, Thailand, was a watershed event for microbicides. The issue of women and AIDS and the potential for microbicides gained wide attention and, for the first time, provided a forum for microbicide advocates to be heard globally.

This was the ideal venue for IPM to introduce its mission to develop microbicides for women in the developing world. Through newly produced materials in English and French, including a brochure and website, IPM was able to begin sharing its message with a variety of key audiences including non-governmental organizations, press, policy makers and more.

IPM hosted a media briefing as well as an event for donors to update them on IPM’s progress and the state of the microbicide field. IPM CEO, Zeda Rosenberg, delivered a plenary address: “State of the Art Report on Development and Use of Microbicides,” and fielded interest from several international news organizations that ultimately covered microbicides in outlets as wide ranging as The Economist, Le Monde, The New York Times, The Guardian, the Globe and Mail and The Times of India.

"We must ensure [women] have full access to the practical options that can protect them from HIV—including microbicides, as they become available."

KOFI ANNAN, UN SECRETARY GENERAL
Financials

Statement of Financial Position Year Ending December 31, 2004

ASSETS

Current Assets
- Cash $11,079,043
- Short-term investments 25,529,609
- Pre-paid expenses 52,711
- Total Current Assets 36,661,363

Furniture, Equipment, and Leasehold Improvements
- less accumulated depreciation of $93,720
- Pre-paid Rent and Maintenance 590,916
- Security Deposit 73,750
- TOTAL ASSETS $38,216,961

LIABILITIES AND NET ASSETS

Current Liabilities
- Accounts payable $958,959
- Accrued expenses 37,792
- Payroll withholdings 7,020
- Total Current Liabilities 1,003,771

Net Assets
- Unrestricted 37,213,190
- Total Net Assets 37,213,190
- TOTAL LIABILITIES AND NET ASSETS $38,216,961

REVENUE

Unrestricted
- Contributions $29,088,989
- Interest and other revenue 108,290
- Unrealized gain on investments 61,577
- Unrealized currency translation 13,536
- TOTAL REVENUE $29,272,392

EXPENSES

Programme Services
- Access $170,076
- Clinical/regulatory affairs 2,248,149
- External affairs/policy 1,316,012
- Research and development 3,509,999
- Total Programme Services 7,244,236

Supporting Services
- General and administrative 1,681,396
- Fundraising 216,031
- Total Supporting Services 1,897,427
- TOTAL EXPENSES $9,141,663

CHANGE IN NET ASSETS $20,130,729

NET ASSETS AT THE BEGINNING OF YEAR 17,082,461
NET ASSETS AT THE END OF YEAR 37,213,190

IPM’s financial statements are audited by Kamerow, Weintraub & Swain, LLP.
The complete audited statements are available upon request to the Chief Financial Officer.
Board of Directors

Dr. Quarraisha Abdool Karim  Director - Columbia Southern African Fogarty International HIV/AIDS Training and Research Programme, SOUTH AFRICA

Dr. Els Borst-Eilers (Chair)  Former Minister of Health, Welfare and Sport and Deputy Prime Minister, THE NETHERLANDS

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