



INTERNATIONAL  
PARTNERSHIP *for*  
MICROBICIDES



MICROBICIDES

PREVENTION THROUGH PARTNERSHIP



ANNUAL REPORT 2007

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Vaginal microbicides are products being developed to prevent sexual transmission of HIV to women. Because they are initiated by women, these products promise to give women an important new option for protecting their health and well-being. The International Partnership for Microbicides plays a lead role in microbicide development, including research, clinical testing, advocacy and planning for eventual product access. This report summarises progress made in 2007 in developing safe and effective microbicides that we hope will be available soon to women worldwide.

*Cover photos by Geoff Oliver Bugbee*

*Top: Lab technicians at the Projet Ubuzima Research Centre in Kigali, Rwanda*

*Bottom: Mavis Both and son Onele take a walk in Mbkweni, South Africa, township*

## Dear Friends and Colleagues:

*If there were any doubts about the challenges facing the microbicide field, the year 2007 put them resoundingly to rest.*

*On both scientific and political fronts, 2007 was a difficult year for the microbicide development community. In the wake of several “early generation” candidates’ failure to show effectiveness, the field is experiencing greater scrutiny, greater collaboration and greater self-examination. And greater expectations. The calls for “When?” grow louder each year. As they should.*

*Against this backdrop, the International Partnership for Microbicides has stepped up its efforts to develop safe and effective products that are acceptable to the women who need them most. During 2007, we acquired promising new compounds for development, made progress with studies of previously-acquired compounds, expanded our staff in multiple regions, and continued preparing for multi-country trials to determine the effectiveness of antiretroviral-based microbicides.*

*Our work each day is reinforced by a commitment to helping women take greater control of their own health and well-being. Women in South Africa, young mothers in India, and widows in Haiti all understand the same reality: They are at greater risk of acquiring HIV than men and they need more options to stay free of HIV.*

*We extend sincere thanks to IPM’s board of directors, our scientific advisory board, and our staff for the long hours they invest daily in advancing our agenda.*

*But we reserve our foremost gratitude this year for our partners — those people and organisations who stepped forward in the truest spirit of collaboration to help IPM change lives. All are invaluable, especially the women who volunteer to participate in our studies. Our other partners include the private-sector companies that contribute drug compounds for study; the host country governments that assist in our research; the global health leaders whose influence furthers this research; and our donors, who have demonstrated great foresight in continuing to support such a vital, promising technology during a difficult time.*

*We are happy to tell you about some of these partners in the subsequent pages.*

*Please join us in celebrating our partnerships, in recognising the progress made in 2007, and in anticipating even more accomplishments in 2008.*



**Els Borst-Eilers, MD, PhD**  
Chair of the Board

A handwritten signature in black ink that reads "Els Borst-Eilers".

1



**Zeda Rosenberg, ScD**  
Chief Executive Officer

A handwritten signature in black ink that reads "Zeda F. Rosenberg".



# THE POWER OF PARTNERSHIP

The International Partnership for Microbicides, now in its sixth year, is bringing vaginal microbicides closer to reality by galvanizing individuals and institutions worldwide. Today, IPM is the only organisation exclusively dedicated to creating safe, effective and accessible microbicide products, and to bringing global scientific, political and financial resources to bear on all phases of microbicide development.

2



*Residents participate in a Community Advisory Group meeting at Projet Ubuzima in Kigali, Rwanda (Geoff Oliver Bugbee)*



**JOINED AGAINST A GLOBAL FOE.** IPM builds on partnerships at every level — with governments, foundations, universities, researchers, pharmaceutical companies, policymakers, advocates and, most especially, with women living in communities most affected by HIV. Working with so many different partners, IPM has the perspective to see beyond obstacles, mobilize partners' strengths and find solutions.

The urgency of the mission is enormous. The AIDS epidemic continues to devastate the developing world. More than 33 million people are living with HIV, and as many as 3 million more adults become infected each year. These aggregate numbers mask the personal tragedies that have come to define life in so many communities. Women, who are particularly vulnerable and disproportionately affected, bear the added tragic risk of passing the virus to unborn children.



Richard Lord



*Senior Process Engineer Timothy Muehleise works the vaginal ring press at IPM's facility in Bethlehem, Pa. (Andrew Loxley, Felt Photography)*





**FOCUSED ON ARVs.** IPM and its partners have focused their microbicide development efforts on antiretroviral drugs (ARVs). Because ARVs are already proven effective in *treating* HIV — they define treatment standards globally — they hold great promise as “next generation” microbicide candidates for *preventing* HIV. Unlike “early generation” candidates, ARVs specifically target HIV. IPM is conducting safety and acceptability trials of dapivirine, one of the most advanced ARVs in its pipeline, and anticipates beginning a large-scale efficacy trial in 2010.



SOURCE DOCUMENT: PROTOCOL IPM-100

LINE MEDICAL HISTORY

Please record relevant medical history which includes but is not limited to:  
- history of STIs  
- gynaecological conditions  
- hospitalizations  
- surgeries  
- allergies  
- any conditions requiring prescription or chronic medication, i.e. > 2 weeks in duration, and acute conditions occurring prior to enrolment.

If the subject cannot provide the exact year of onset, please write "UNK."

Condition (One per line)	Year of onset	Yes
fever	2008	<input type="checkbox"/>
flu	2008	<input type="checkbox"/>
menstruation	2008	<input type="checkbox"/>
...	...	...

Progress in developing a microbicide of any kind has been complicated by increasingly difficult political environments in countries where trials are taking place, and by the failure of several early generation compounds to demonstrate efficacy. Against this complex backdrop, IPM and its partners have persevered, bolstered by the promising nature of dapivirine and other ARV-based candidates and knowing that efficacy trials will be more critical than ever.

**VIGOROUSLY COMMITTED TO MICROBICIDES . . . AND RESULTS.** IPM received important support totalling US\$48 million in 2007, including grants for specific studies.

Donors, like all organizations that partner with IPM, share IPM's belief that, especially now, there simply is no alternative to perseverance. Microbicides have the potential to accomplish nothing less than improve the lives of millions of women and families.

Geoff Oliver Bugbee



## PARTNERING WITH DONORS

**Nicola Brennan, Senior Development Specialist, Irish Aid, Dublin**

Overseeing the Irish Government's funding to the International Partnership for Microbicides since 2003 has given me insight into their vision and work. In a world where women and girls remain the most vulnerable to HIV infection by virtue of their sex, their lack of status in society, and their lack of power in sexual relationships, an effective

microbicide will give women hope, protection and control over their own bodies. As a woman I know how important that is.

I am very impressed with the work of the International Partnership for Microbicides. They have maintained their vision of an effective and accessible microbicide, have

developed strong partnerships with a range of agencies and have responded to our concerns.

I am keen to see an effective microbicide that is affordable and accessible by women who need it. The International Partnership for Microbicides can make that happen.

## RESEARCH: **Building on Worldwide Findings**

**IPM's research programme has several objectives: Bring new ARV candidates to the research and development pipeline; advance development of IPM's lead ARV-based microbicide candidates; and create new and different drug delivery mechanisms for women to choose from. IPM also supports applied biology research to add to the field's body of knowledge on HIV infection, ARVs and potential drug resistance.**

As with all IPM efforts, partnerships are key to progress in research. IPM helps coordinate the work of diverse researchers, furthering their ability to build on each other's achievements. In addition to its own research and development studies, IPM provides support to independent academic and research institutions. IPM has arranged novel partnerships with pharmaceutical companies that, under royalty-free licensing agreements,

allow IPM to develop and manufacture compounds such as microbicides, and distribute any resulting product in resource-poor countries at the lowest possible cost.

*Clinic Pharmacist Elizabeth Ngowi works in the temperature-controlled pharmacy in Moshi, Tanzania (Geoff Oliver Bugbee)*







**NEW COMPOUNDS, NEW OPPORTUNITIES.** In 2007, IPM received access to several ARVs that block the virus' access to a protein called CCR5, the part of the human cell to which HIV must bind to cause infection. Pfizer provided IPM quantities of its new therapeutic drug maraviroc for formulation work and early study (leading to a full royalty-free license in 2008), while Schering Plough provided three different CCR5 blockers for early-stage evaluation. During the year, IPM supported discovery and development of other promising ARV compounds at Imquest, Locus Pharmaceuticals and Drexel University Medical School, and continued to screen new compounds worldwide.

IPM partners made substantial progress in 2007 working on compounds acquired in previous years. Manufacturing processes have been established, and kilogram quantities are now available to support early studies. A complex synthesis process was simplified in 2007 to allow for kilogram-scale manufacturing of clinical trial grade material in 2008. Virology studies of dapivirine in combination products, such as with compounds acquired from Bristol-Myers Squibb and Merck & Co., also continued.

In addition, IPM and its partners made progress on a compound acquired last year from Gilead, 1 percent tenofovir gel. IPM supported early studies of the gel and provided material to other groups, such as the U.S. National Institutes of Health's Microbicide Trials Network, based in Pittsburgh, Pa., for future studies aimed at developing a combination product.



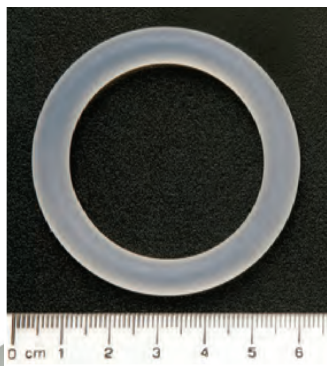
Richard Lord

## GEL AND RING FORMULATIONS

A drug's specific form (gel or tablet, for instance) helps determine its efficacy and cost — and, ultimately, its acceptability to the user. All of the early generation microbicide candidates were formulated as gels that must be applied shortly before sexual intercourse; for this reason, they are known as “coitally dependent.”

An important advantage of the ARV-based microbicides IPM is developing is that they can be formulated in longer-acting gels, vaginal rings, vaginal tablets and other means that can be used once a day, or even less frequently, and independent of sex. This would provide protection against HIV infection even during unanticipated sex.

Any effective compound must be transformed into a product that women find acceptable and are likely to use. IPM has focused exclusively on formulations that provide sustained, long-acting release of the active ingredient, which means the products need not be applied at time of sex. For example, IPM is developing gels that would be applied only once daily as part of routine hygiene activities. In 2007, IPM made progress on four base prototype gels of dapivirine. In 2007, IPM's Clinical Trial Material facility (CTM) in Pennsylvania produced two of them for a safety and pharmacokinetics trial (studying how the body absorbs, uses and releases the material) that took place in Belgium. Two additional prototype gels are being tested as backups.



*The next generation takes shape: Intravaginal rings are a leading option for microbicide delivery. In 2007, IPM began establishing its own intravaginal ring manufacturing capacity in Bethlehem, Pa., to prepare for upcoming large-scale trials. A ring could deliver an effective microbicide for up to 30 days. (Andrew Loxley, Felt Photography)*





Intravaginal rings (IVRs) are another promising technology that would allow for sustained HIV protection. The intravaginal rings that IPM and its partners are pursuing would not need to be replaced for a month or longer. In 2007, IPM added ring-producing capabilities to its CTM facility in Bethlehem, Pa., to guarantee the large quantity of rings that will be needed for upcoming clinical trials. IPM also studied the safety, drug distribution dynamics and PK of both the “matrix” and “reservoir” ring configurations. Because studies

concluded that the matrix configuration releases the most drug vaginally, IPM is now focusing on matrix ring improvements and manufacturing. A new option may be the biodegradable polyurethane IVR. This design offers the dual advantage of manufacturing speed and low environmental impact.

**NEW DOSAGE TECHNOLOGIES.** To learn which approaches women prefer, IPM’s partners are also exploring vaginal tablets, soft gel capsules for vaginal delivery, and thin dissolvable vaginal films.

## PARTNERING WITH PHARMACEUTICAL COMPANIES

**Julie McHugh, Company Group Chair, Global Virology Business Unit, Tibotec, Yardley, Pa.**



“ At Tibotec, there is incredible energy to identify opportunities to use our products to address the health concerns of the developing world. HIV poses an unparalleled global challenge. And curbing the epidemic will in part require providing women with discreet tools that will protect them from HIV infection even if they can’t insist on condom use. Microbicides are one such tool.

We view IPM as a leading expert in microbicide development. So when we determined that Tibotec’s product dapivirine showed significant potential for a microbicide, it was an easy decision to partner with IPM and grant it a royalty-free license to use the compound to manufacture a microbicide. With its mission to develop a safe, effective vaginal microbicide that eventually will help

millions of women in resource-poor settings prevent HIV infection, IPM embodies Tibotec’s commitment to use science to advance humanitarian interests. And through its partnerships with governments, donors and other organizations, IPM has created a favorable landscape that allows major pharmaceutical companies to use their research for the benefit of underserved populations. ”



# CLINICAL STUDIES: Working with Women and Communities

Laboratory screening and testing to determine if a potential microbicide has an adequate “safety profile” before being tested in humans, no matter how rigorous, can take microbicide research and development only so far. Once these laboratory tests have been performed satisfactorily, microbicide candidates can advance through a series of human clinical trials designed to assess their safety in women, as well as their ability to prevent HIV infection.

Testing in the field is essential to determine the real-life safety and effectiveness of a possible product. Four basic kinds of studies in women must take place for microbicides to become a reality:

- trials that evaluate the **safety** of a microbicide candidate in humans
- **acceptability** studies that identify which formulations women are inclined to use
- **incidence** studies to determine whether the rate of new HIV infections in a given locale is sufficiently high to support future large-scale trials
- large-scale trials involving thousands of volunteers that determine whether the candidate microbicide is **effective** in protecting women against HIV infection

Behind each study is a tremendous amount of collaboration with countries, communities and

women who volunteer to participate. The future of microbicides depends on these partners.

The studies use the latest technology to produce the most accurate data possible. IPM is developing “smart” devices that may confirm the active ingredient is delivered in the body — a valuable aid in evaluating trial participant compliance and ensuring accurate trial results.

## **SITE DEVELOPMENT, HUMAN DEVELOPMENT.**

Before any trial goes forward, IPM and its partners work closely with communities to understand their concerns, with the hope of developing a shared rapport, trust and open communication. IPM invests time and resources to strengthen and build infrastructure, as well as to keep communities informed of important developments in HIV research generally and in IPM clinical trials specifically.



For many communities, the presence of research centres can yield substantial benefits. Community members can acquire greater understanding of health research in general and of HIV and microbicides in particular. Local researchers implementing IPM studies often gain new technical expertise and career skills. Communities sometimes receive new or updated equipment, and may experience greater access to health services. And where trials require more advanced medical or clinical research facilities, countries hosting clinical trials benefit from those investments.

**TOWARDS FUTURE TRIALS.** IPM laid the groundwork this past year for a large-scale, multi-year effectiveness trial that it hopes to launch in 2010. Based on incidence studies, infrastructure assessments and other important criteria, it has identified potential research centre sites across southern and eastern Africa that could support an upcoming efficacy trial.

At various research centres, IPM-supported organisations leased, purchased and renovated buildings for use as clinics; acquired and installed medical, telecommunications and office equipment; established medical referral networks; hired and trained staff;

and expanded education and engagement activities. IPM has concluded agreements with a number of organisations to help strengthen research centre infrastructure and prepare for additional clinical studies.

IPM took several steps in 2007 to ensure effective, ongoing collaboration with research centres. It adopted measures for more open communication with study participants, local and national leaders, the media and health advocates. It hosted an October gathering in Cape Town of key research centre personnel to discuss scientific developments, community engagement, recruitment, regulatory matters and ethical practices. And it met with government officials in southern and east African nations to discuss issues of concern, especially participant safety.

To better manage all regional efforts and upcoming trials, IPM established an office in South Africa in January 2007. Outside of Cape Town, the office had a staff of more than 30 a year later.

*Top: Nurse Elizabeth Makena meets a patient at the Mombasa, Kenya, research centre*

*Bottom: A meeting in Stanza Bopape, South Africa, to train people who will recruit study participants (Geoff Oliver Bugbee)*



### IPM CLINICAL TRIALS WITH ACTIVITY IN 2007

Study	Description	Location	Status in 2007
IPM003	Dapivirine gel safety	Rwanda, South Africa, Tanzania	Data analysis ongoing
IPM004	Dapivirine gel PK	South Africa	Data analysis ongoing
IPM005B	Dapivirine gel safety	Belgium	Data analysis and study completed
IPM008	Dapivirine intravaginal ring safety	Belgium	Data analysis and study completed
IPM009	Dapivirine efficacy	TBD	In planning stages
IPM011	Placebo intravaginal ring safety & acceptability	Kenya, South Africa, Tanzania	Study initiated and ongoing
IPM012	Dapivirine gel PK	Belgium	Study initiated and ongoing
IPM014	Dapivirine gel safety	Malawi, South Africa, Tanzania	In planning stages
IPM015	Dapivirine intravaginal ring safety	South Africa, Tanzania	In planning stages
IPM017	Dapivirine intravaginal ring safety	Belgium	In planning stages
IPM018	Dapivirine intravaginal ring PK	Belgium	Study initiated and data analysis ongoing
IPM020	Dapivirine gel safety	United States	In planning stages
IPM021	Dapivirine intravaginal ring safety	Europe	In planning stages

### IPM HIV INCIDENCE STUDIES WITH ACTIVITY IN 2007

KCMC	Cohort	Tanzania	Data analysis ongoing
ICRH	Cross-sectional	Kenya	Data analysis ongoing
Protocol 002	Cohort	Kenya	Study ongoing and data analysis initiated
IPM002A	Cross-sectional	Kenya	Data analysis and study completed
IPM002B	Cross-sectional	Nigeria	Data analysis and study completed
HIVINC	Cross-sectional and cohort	Rwanda	Study ongoing
IPM100	Cross-sectional and cohort	South Africa	Study initiated and ongoing
IPM101	Cross-sectional	Mozambique	In planning stages

### IPM MARKET RESEARCH STUDIES WITH ACTIVITY IN 2007

PAS 2	Product attribute study (vaginal tablet, film, soft gel capsule)	Burkina Faso, Mozambique, Tanzania, Zambia	In planning stages
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## SAFETY, THE TOP PRIORITY

IPM is strongly committed to generating data that will support licensure in the shortest time period possible. Specifically, in light of compliance and incidence obstacles encountered by the early generation Phase III microbicide trials, we must all reconsider the most effective way to proceed in testing products for licensure.

Keeping women healthy is the overriding purpose of microbicides — and fundamental to the process of developing successful microbicide products. In 2007,

IPM began developing a novel, two-stage Phase III trial design that features compliance monitoring and demands early trial termination should harm or futility be detected. IPM convened numerous meetings to elicit community input on the trial design, a process that is ongoing in 2008.

In support of IPM safety studies and future efficacy trials, IPM developed new communication measures that will help research centres more quickly detect and respond to any problems that might emerge.

## PARTNERING WITH WOMEN

**31-year-old mother of two and past clinical trial participant (study 011), Johannesburg, South Africa \***



“ Quite some time ago, I was in a taxi with two other women who were discussing their participation in a study for a product to help women prevent HIV. I wanted to learn more about the study, so I went to the clinic where the workers told me about the International Partnership for Microbicides and its work to find

an HIV prevention tool specifically for women.

I agreed to enrol in the study because I know that HIV is a big problem in South Africa. Women need a product because oftentimes your partner may find it insulting if you ask him to use protection.

Because of this, too many women are getting infected with HIV and too many children are being born with HIV. I have two young sons, and I would like to see them and others of their generation remain HIV free. In some way, I think my participation in IPM’s study will help achieve that goal.”

*\* This participant asked that we not identify her by name.*

## ACCESS: Getting Ready Together

**What will happen when proven microbicide products are ready for market? How easily can women make them part of their everyday lives — especially economically disadvantaged women? IPM is establishing partnerships worldwide to pave the way for women’s access to microbicide products. This means working with national regulatory bodies to develop processes for expediting product approval; with researchers and manufacturers to ensure product availability and affordability; and with distribution, marketing and communication specialists to tailor product introduction and launch strategies to specific regions of Africa and Asia.**

Most facilities that are capable of manufacturing microbicides currently do so only in quantities too small for widespread product distribution, and are located in developed countries. Because little information exists on large-scale manufacturing options, IPM commissioned a survey of worldwide microbicide manufacturing capacity, with an emphasis on developing countries.

More than 110 companies provided contact information, and 20 companies in North and South America, Asia and Africa completed the survey. Comprehensive audit reports have been assembled for 17 companies that were deemed capable of

commercially producing the drug substance and formulations (e.g., vaginal gels, rings, tablets). This information has been captured in a database that is available to the microbicide field. The survey concluded that although viable manufacturing resources are present in the developing world, they are relatively small and must be expanded. Bringing production closer to the intended market may reduce distribution costs and regulatory burdens.

This important survey was augmented by other activities to pave the way for access. IPM turned to the London School of Hygiene and Tropical Medicine to undertake a modelling effort to better



inform microbicide product introduction strategies. IPM participated in discussions convened by the Centre for Global Development on projecting product demand, and undertook a study to gather lessons learned from those who introduced contraceptive technology in developing countries. At its investigators meeting, IPM engaged African regulatory representatives in a day-long workshop on regulatory and ethical issues, including the need to build technical expertise and infrastructure for evaluating prevention technologies.

An ongoing facilitator of international discussions on access planning, IPM co-sponsored the Regional Meeting on Regulatory Issues in Microbicide Research in October 2007 in New Delhi with the Indian Council of Medical Research, the World

Health Organisation and the U.S.-based health research organisation CONRAD. That followed a July forum on microbicide access that IPM co-hosted with WHO in Nairobi, Kenya, supported by USAID. This gathering brought together more than 45 government representatives, program implementers, health advocates and social scientists, as well as HIV and reproductive health clinicians, to discuss approaches to microbicide introduction and delivery scale-up. The meeting was convened to try to reconcile the urgent need for female-initiated HIV prevention methods with realistic expectations about a timeframe for product approval and introduction. Participants discussed experiences with prior efforts to introduce contraceptive technologies, male circumcision and antiretroviral therapy, among other topics.

## PARTNERING WITH GOVERNMENTS

**Minister Gareth Thomas, Parliamentary Under-Secretary of State for International Development, United Kingdom**



The U.K. Government is a strong supporter of research to develop new prevention technologies and welcomes the important work of IPM. The U.K. recognises that microbicides

can make a significant difference to tackling the feminisation of the AIDS epidemic, and to women's health and well-being in the developing world.



# ADVOCACY AND COLLABORATION: The Voice of Partnership

Collaboration fuels IPM's work and advances in the broader microbicide field. At the same time, IPM galvanizes the financial, political and community support needed to overcome challenges facing microbicide development and to continue progress on all fronts.

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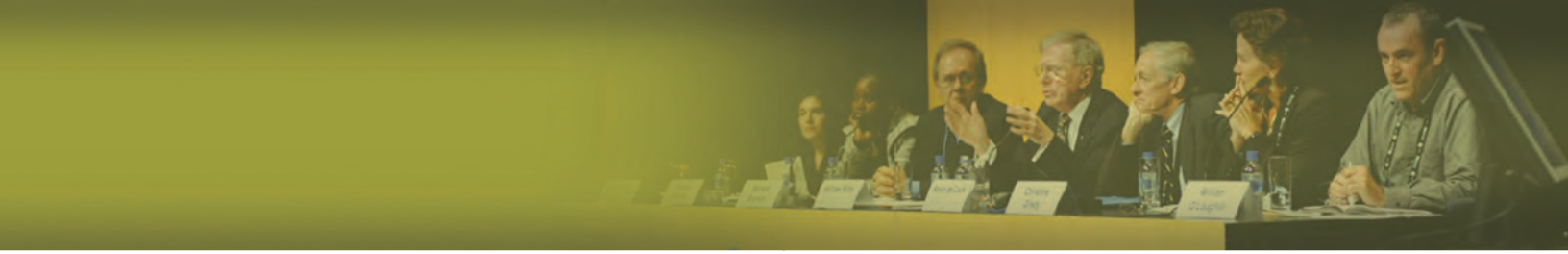
Towards this end, IPM in 2007 continued its ongoing outreach to the larger microbicide community. Staff briefed leading microbicide supporters, including Graça Machel of the Women's Leadership Network for Microbicides, representatives from the Bill & Melinda Gates Foundation, government officials in Europe and North America, and G8 leaders meeting in Berlin. IPM also brought the microbicide

development message to major conferences, including the International Women's Summit in Nairobi, the Conference on Retroviruses and Opportunistic Infections in Los Angeles, the Interscience Conference on Antimicrobial Agents and Chemotherapy in Chicago, the International AIDS Society conference in Sydney, and diverse sessions, seminars and workshops worldwide.



Photos courtesy of International AIDS Society





### **AN IMPROVED AND EXPANDED IPM**

**INFRASTRUCTURE.** Coordination requires ongoing contact and efficient management. To increase its effectiveness, IPM moved to larger headquarters just outside Washington, opened a South Africa

office, enlarged its office in Belgium and expanded its manufacturing capacity in Pennsylvania. These developments position IPM well to advance the global pursuit of microbicides and hasten the day when new prevention products are readily available.

## **PARTNERING WITH GLOBAL LEADERS**

**Hilde Johnson, former Minister of International Development for Norway, current Deputy Director, UNICEF, New York**



*Photo credit: UNICEF*



In developing countries, particularly in sub-Saharan Africa, where the epidemic is hitting hardest, there is a growing feminization of the epidemic with young women having exponentially higher rates of HIV infection than young men. The harsh reality is that women too often can't negotiate sexual relations and thus existing behavioral interventions simply don't work for them. Microbicides hold immense promise for curbing the rate of new HIV infections because they oblige women's unique HIV prevention needs. IPM continues to

make progress toward developing a safe, effective microbicide. Its eventual success will reap significant returns for women and for the global community by preventing new HIV infections and saving lives.

In addition, it makes sound economic sense for donor governments to partner with IPM in its quest to develop a microbicide. If we fail to stymie the rate of new HIV infections, the human and macroeconomic costs will be enormous. Already, countries most harshly affected by HIV have

witnessed huge declines in life expectancy. The loss of adults during their most productive years will have devastating consequences for countries' GDP 10 or 20 years from now. Providing care and treatment for those affected by HIV or AIDS is essential — in accordance with universal access, but there are compelling humanitarian and economic reasons for devoting resources to preventing HIV infection in the first place. Developing microbicides must have priority in this regard.



# FINANCIAL REPORT

## ASSETS

	Dec. 31, 2007	Dec. 31, 2006
Cash and cash equivalents	\$98,105,608	\$81,897,654
Accounts receivable	1,367,232	812,017
Prepaid expenses and other assets	949,052	420,472
Prepaid rent and maintenance, net	527,679	522,461
Property and equipment, net	3,359,304	1,697,498
<b>Total assets:</b>	<b>\$104,308,875</b>	<b>\$85,350,102</b>

## LIABILITIES AND NET ASSETS

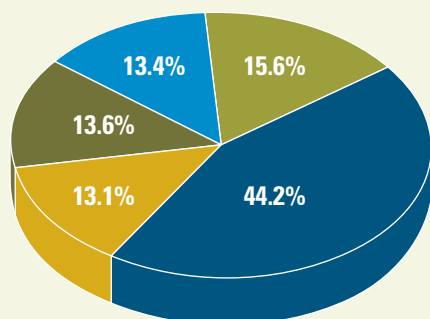
	Dec. 31, 2007	Dec. 31, 2006
<b>Liabilities</b>		
Accounts payable and accrued expenses	\$4,149,694	\$3,559,039
Deferred revenue	86,053,555	68,814,364
<b>Total liabilities</b>	<b>90,203,249</b>	<b>72,373,403</b>
<b>Net assets</b>		
Unrestricted	2,565,654	1,116,166
Temporarily restricted	11,539,972	11,860,533
<b>Total net assets</b>	<b>14,105,626</b>	<b>12,976,699</b>
<b>Total liabilities and net assets:</b>	<b>\$104,308,875</b>	<b>\$85,350,102</b>

## FUNDING CONSIDERATIONS

Conducting clinical trials in developing countries requires substantial financial investment. Since 2002, IPM has raised \$226 million (funds received plus commitments for future funding), almost \$100 million of which was available as of Dec. 31, 2007. In May 2007, IPM's board of directors designated all IPM funds for efficacy trial preparation and feasibility assessments for clinical sites in Africa and elsewhere, including the eventual conduct of efficacy trial(s). IPM continues to undertake resource development efforts with the understanding that funding commitments to complete efficacy trials should be in hand

before trials can commence, as ethical review boards generally will not approve a trial without evidence of sufficient funding for completion.

An efficacy trial necessary to support licensure for a single microbicide product requires enlisting thousands of women and following them for an extended period so that researchers can compare infection rates among those who use a candidate microbicide with those using a placebo. A single efficacy trial can cost as much as \$120 million. Multiple efficacy trials for microbicide products will be required, making IPM's future financial needs significant.



## EXPENSES BY DEPARTMENT

- Research and Development
- Clinical Programs
- Site Development
- External Relations
- General and Administrative



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**Xigo Nanotools**, United States

# SCIENTIFIC PUBLICATIONS AND ABSTRACTS SUPPORTED BY IPM IN 2007

Fairhurst D, Rowell R, Shattock R, McNeil-Watson F, Morfesis A. Electrophoretic characterization of particles under biologic conditions: Analysis of cells and viruses. Oral presentation at spring meeting of Materials Research Society, 9-13 April, San Francisco.

Fairhurst D, Rowell R, Monahan I, Stieh D, McNeil-Watson F, Morfesis A, Romano J, Shattock RJ, Mitchnick M. Electrophoretic fingerprinting of HIV-1 cell interaction: A novel tool for development of charge-based strategies. Oral presentation at Affinity 2007 Conference, International Society for Molecular Recognition, 8-12 July, New York.

Fairhurst D, Rowell R, Monahan JM, Key S, Stich, McNeil-Watson F, Morfesis A, Mitchnick M, Shattock RJ. Microbicides for HIV/AIDS. Electrophoretic fingerprinting of CD4+ T-Cell model system. *Langmuir*, 23: 2680-2687.

Geubbels E, Ingabire C, Braunstein S, Umulisa B, Ntirushwa J, Ford K, Gahiro E, Tuijn C, Sadat M, Vyankandondera J, van de Wijgert J. Estimating HIV incidence in high-risk women in Kigali in preparation for microbicide trials: Recruitment update and first results. Oral presentation at the Rwanda National AIDS Commission HIV/AIDS Dissemination Conference, 29-30 March, Kigali, Rwanda.

Nuttall, J. Development of a vaginal transmission model using a recombinant simian immunodeficiency virus encoding the human immunodeficiency virus type 1 reverse transcriptase gene in Chinese rhesus macaques. Oral presentation at 2nd International Workshop on HIV Transmission, 26-28 August, Washington.

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Romano J, Variano B, Coplan P, van Roey J, Douville K, Rosenberg Z, Temmerman M, van Bortel L, Weyers S, Mitchnick M. Sustained delivery of microbicide dapivirine using intravaginal rings: An independent clinical assessment of safety and drug delivery in women. Poster presentation at the Conference on Retroviruses and Opportunistic Infections, 25-28 February, Los Angeles.



[www.ipm-microbicides.org](http://www.ipm-microbicides.org)

**IPM HEADQUARTERS**

8401 Colesville Road,  
Suite 200  
Silver Spring, MD 20910  
United States  
TEL: +1-301-608-2221  
FAX: +1-301-608-2241

**IPM SOUTH AFRICA**

Main Street 121  
Paarl 7646  
South Africa  
*Mailing address:*  
P.O. Box 3460, Paarl, 7620  
South Africa  
TEL: +27-21-860-2300  
FAX: +27-21-860-2308

**IPM BELGIUM**

Rue du Trône, 98, 3rd floor  
1050 Brussels  
Belgium  
TEL: +32(0)-2-507-1224  
FAX: +32(0)-2-507-1222

**IPM – CTM FACILITY**

3894 Courtney Street,  
Suite 170  
Bethlehem, PA 18017  
United States  
TEL: +1-484-893-1050  
FAX: +1-484-893-1057