
International Partnership for Microbicides
MICROBICIDES:
NEW SCIENCE
NEW HOPE
2009 ANNUAL REPORT

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INTERNATIONAL PARTNERSHIP FOR MICROBICIDES

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Dear Friends and Colleagues:

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Chair of the Board

Dr. Zeda F. Rosenberg
Chief Executive Officer

Recently, we have been encouraged by a renewed emphasis on women in global health discussions. This is an important focus, especially given the millions of women who are still unable to protect themselves against the persistent threat of HIV infection — particularly in sub-Saharan Africa. Microbicides provide hope that women can one day empower themselves against HIV. IPM's mission is to turn that global health goal into a scientific reality.

The announcement in December 2009 that PRO 2000, an early-generation microbicide candidate, was safe as tested but did not provide protection against HIV, closed the chapter on early-generation products. Fortunately, microbicide development has already entered a new phase. The field in recent years has focused on one of the world's best hopes for female-initiated HIV prevention: next-generation microbicides. These newer candidates are based on the same antiretroviral (ARV) drugs used successfully in HIV treatment.

From its inception, IPM has worked to develop these next-generation products and in 2009 made important advances toward that goal. During the year, IPM initiated four clinical trials to evaluate the safety, acceptability and pharmacokinetics of dapivirine vaginal gels and rings, including our largest expanded safety studies to date. We began our second market research/product acceptability study assessing preferences for microbicide formulations among women and their partners. We also continued our work on HIV incidence studies in several African communities.

IPM prioritized its product pipeline in 2009, focusing work on products with the most potential. Our most clinically advanced candidate, a long-acting monthly dapivirine ring, continues to progress and is scheduled to enter Phase III evaluation in 2011.

IPM also invested extensively in the development of multiple clinical research centers in sub-Saharan Africa, with 15 research centers planning or conducting trials.

While remaining deeply committed to the development and distribution of microbicides, IPM expanded its scope in 2009 to develop new approaches to systemic ARV-based prevention (known as "pre-exposure prophylaxis," or PrEP), which could expand the world's toolkit of ARV-based prevention options. The Bill & Melinda Gates Foundation awarded IPM a grant to collaborate with Tibotec Pharmaceuticals on initial development of its PrEP candidate, TMC278 LA, a long-acting injection that would potentially be administered monthly. This new approach could augment ongoing work of organizations evaluating daily oral PrEP products by providing individuals with the option of a monthly product.

We continue to be deeply grateful to our donors, who understand that microbicide and PrEP research will not only help reduce the burden of death and disease among women — and indirectly among men and children — but will also produce global development benefits as we move toward our ultimate goal: saving millions of lives. The road to developing effective HIV prevention options is long and complex, and will require continued resolve, patience and hard work.

We also are indebted to our Board of Directors, our Scientific Advisory Board with its long-standing leadership, our staff, our partners, the communities and nations that host our clinical research, and most importantly, to the women who volunteer for IPM clinical trials.

Women may be at greater risk of HIV, but they are resourceful and dependable. They simply need the right tools to protect themselves — and their families.

New Science, New Hope

IPM seeks to close one of the most significant gaps in HIV prevention — the lack of an effective, affordable strategy that women can use on their own to protect themselves from infection. An effective microbicide used to prevent HIV in women would markedly lower the rate of new HIV infections in the developing world and across the globe.

Behind the daunting statistics on the global HIV epidemic are millions of lives cut short, millions of households and countless communities threatened.

In 2009, IPM made notable advances in efforts to develop safe and effective microbicides to prevent HIV transmission that offer new hope for women and their families around the world.

ANDREW LOXLEY

What are microbicides?

Vaginal microbicides are biomedical products being developed to reduce the transmission of HIV to women during sex with an infected male partner. These products could take many different forms, such as a vaginal gel or film that women would use once a day, or a long-lasting ring that would provide protection for up to a month at a time.

The pressing need for microbicides

Far too many women and girls are at high risk of HIV infection. Each day, more than 3,000 women and girls become infected with HIV.

The epidemic is exacting a high price in developing countries, especially in sub-Saharan Africa, where women represent nearly six out of every 10 new infections. In 2008, 2.7 million people became newly infected with HIV — two-thirds of them in sub-Saharan Africa.

Treatment alone has not sufficiently lowered the rate of new infections. For every two people started on antiretroviral (ARV) therapy, five new HIV infections occur.

Almost all improvements in life expectancy in Africa over the past 15 years have been reversed by the epidemic. In the most heavily affected countries in Southern Africa, the epidemic has reduced average life expectancy by two decades or more. In the absence of HIV, there would have been more than 60,000 fewer maternal deaths in 2008.

These statistics tell the story of why HIV/AIDS is one of the world's most serious threats to public health, poverty reduction and international development — and the drive behind IPM's mission to help turn the epidemic around.

In September 2000, global leaders pledged in the UN Millennium Declaration to halt and begin to reverse the HIV epidemic by 2015. Achieving this goal will require dramatically greater progress in preventing new infections.

Scientific advances provide hope

The first microbicides to be tested were known as "early-generation products" and were primarily composed of large molecules without direct activity against HIV. None of those products proved effective in preventing HIV transmission.

Fortunately, however, research in the field in recent years has opened a new and potentially promising chapter in microbicide development focused on products based on the same types of powerful ARVs that are being used successfully today to treat HIV/AIDS and prevent mother-to-child transmission. Adapting these highly potent treatments to create female-initiated prevention technologies has the potential to transform the global response to HIV infection.

Work is under way to identify the most promising ARV drugs or combinations of drugs that would be suitable for use as microbicides. ARV-based microbicides would work in a

GEOFF OLIVER BUGBEE

Lab technicians at Projet Ubuzima, an IPM research center partner in Kigali, Rwanda.

variety of ways by either preventing HIV from attaching to or entering a healthy human cell, or by preventing the virus from making copies of itself once it is inside a cell. There is great hope that ARV-based microbicides are following the precedent set by other life-saving prevention technologies that have been adapted from treatments for other diseases such as malaria and pneumonia.

Microbicides would come in a variety of product formulations, with the goal of giving women greater choice and convenience.

The microbicide formulation most commonly tested in early-generation trials were gels that needed to be applied shortly before sexual intercourse. Newer formulations currently under development in the field include once-daily vaginal gels, films and tablets, as well as vaginal rings that would provide up to one month's protection from HIV. All of these formulations could potentially be used independently of sexual activity, offering more convenience and providing protection during anticipated or unanticipated sex. Working in partnership with other researchers, IPM is a leader in this new frontier in microbicide research. As of December 2009, IPM was investigating seven antiretroviral drugs for use as microbicides and scaling up for Phase III evaluation to begin in 2011.

BACKGROUND: ISTOCKPHOTO/FRANKVANDENBERGH
WOMAN AND BABY: GEOFF OLIVER BUGBEE

The PDP model in advancing global health: Partnering for success

IPM is one of a group of nonprofit enterprises that is providing an important new model to advance the global health field. Known as product development partnerships, or PDPs, these organizations manage resources and partnerships across public, private and philanthropic sectors to drive development of new health tools that advance global development goals and promise to save millions of lives.

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A senior process engineer operates the vaginal ring press at IPM's Clinical Trial Materials (CTM) facility in Pennsylvania, USA.

PDPs like IPM aim to combine the business model of the private sector with the public sector's commitment to improving global public health.

PDPs are flexible and efficient, and can focus their resources on a single public health objective. IPM works with an array of other PDPs to ensure support for this innovative approach, which can uniquely mobilize scientific know-how to improve health outcomes in developing countries.

Since 2004, IPM has obtained six non-exclusive, royalty-free license agreements from pharmaceutical companies to develop, manufacture and distribute eight ARV products as microbicides in developing countries. These royalty-free licenses ensure that any new product will be most affordable in the settings where such new tools are most urgently needed. These agreements serve as a model of public-private partnership in fostering global health solutions.

2009: A Year of Progress

In 2009, IPM focused on building capacity to advance its goal of developing safe and effective ARV-based microbicides for HIV prevention.

IPM began four clinical trials to evaluate dapivirine vaginal gels and rings in Africa, Europe and the United States, including its largest expanded safety studies to date. IPM also continued its work to assess the product preferences of women and their partners with the start of its second market research study on vaginal films, tablets and soft-gel capsules in West, East and Southern Africa. Through its continued work on HIV incidence studies in several African communities in 2009, IPM is identifying settings that are suitable for microbicide efficacy trials while also building the case for the pressing need to fight HIV/AIDS among women.

With substantial investment in new research center site development in 2009, IPM is now collaborating with more than 20 research center partners in Africa, Europe and the United States.

Like many other organizations, IPM has been affected by the global economic recession. IPM took steps in 2009 to streamline and prioritize its microbicide product pipeline to focus on achieving a timely launch in 2011 of its Phase III program.

IPM is carefully shepherding resources, enhancing operational efficiency, and seeking to build its donor base. As a PDP (see box at left), IPM works continuously to ensure that resources are available to fulfil the promise of new scientific advances that will increase women's hope for a healthy future.

IPM-licensed compounds

Compound	License	Mechanism
Dapivirine	Tibotec/Johnson & Johnson	Reverse transcription: Stops virus from copying its genetic material inside human cells
L167, L872, L882	Merck	Cell Attachment: Prevents virus from attaching to human cells
BMS793	BMS	Cell Attachment: Prevents virus from attaching to human cells
Tenofovir (IPM & CONRAD)	Gilead	Reverse Transcription: Stops virus from copying its genetic material inside human cells
Maraviroc	Pfizer	Cell Attachment: Prevents virus from attaching to human cells
L'644 peptide	Merck	Cell Fusion: Prevents virus from entering human cells

R&D: Breaking New Ground

IPM's research and product development activities support the earliest possible product approval and access to new tools for HIV prevention. By accelerating product development and mobilizing industry expertise to focus on one of the world's most pressing public health and global development priorities, IPM directs its resources toward its singular scientific mission: to provide women with an affordable and self-initiated prevention strategy to reduce the cycle of HIV infection.

Prioritizing and advancing the pipeline

IPM advances products that are the most promising in terms of their potency, stability, ease of application and acceptability to the women who would use them. As a result of its flexible licensing agreements and multiple chemical compounds and product formulations, IPM implemented a decision algorithm to prioritize candidates and product forms in its pipeline with the goal of developing the best products and delivering them to women as quickly as possible.

Developing new HIV prevention products, including microbicides, requires many years of sustained investment. No organization, whether commercial or nonprofit, has the resources to progress every possible drug candidate to a registered product.

This is why it is very important to design and carry out a series of scientific studies that will allow product developers to prioritize the candidates in their pipeline. These studies permit developers to gather data as early as possible to decide which candidates will have the most chance of ultimate success, which are unsuitable for continued development, and which should be delayed until sufficient resources will be available to progress them effectively.

In 2009, IPM's scientific team studied a variety of different compounds as potential microbicides and prioritized dapivirine and maraviroc, concentrating its resources on those two advanced products.

IPM also prioritized current approaches to formulating its microbicides, moving ahead with a novel monthly vaginal ring as a lead formulation as well as a daily vaginal gel.

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Vaginal ring press at IPM's CTM facility.

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An automated machine fills applicators with vaginal gel manufactured at IPM's CTM facility.

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Novel technology: The microbicide ring

IPM is leading the field in research on novel formulations designed to provide more choices for women and to enhance the effectiveness of microbicides in the real world, including work on microbicide vaginal rings. As of today, ring technology has been successfully used only to deliver contraceptives and hormonal therapy in Europe and the United States. Now IPM is developing new ring technology that will deliver drugs to prevent HIV infection in women and help save lives in the developing world.

Advantages

Vaginal rings have a number of potential advantages: They would need to be replaced only once a month or less frequently, and are easy to use. Preliminary data from IPM's placebo ring safety and acceptability study show that rings appear to be safe to use and acceptable to women in Africa. Rings also hold the promise of greater versatility in dosing, including the potential to deliver combinations of ARV drugs or to formulate an ARV drug with a contraceptive.

First in trials

IPM is currently the only organization to have progressed microbicide rings into clinical evaluation: four clinical trials to evaluate the safety, PK and feasibility of dapivirine vaginal rings have been completed. Two additional safety trials are ongoing, with an initial efficacy trial in the planning stages.

Contraception benefit

IPM is also collaborating with the Population Council to develop a prototype vaginal ring that combines dapivirine and the hormone levonorgestrel that could provide both HIV prevention and contraceptive properties in the same product.

Products in the pipeline

Dapivirine-based products: In 2009, IPM's most clinically advanced drug candidate, dapivirine, continued to progress through the pipeline and is scheduled to be tested in Phase III trials in 2011. As a non-nucleoside reverse transcriptase inhibitor, or NNRTI, dapivirine works by preventing HIV from replicating its genetic material after the virus enters a healthy cell.

IPM has studied dapivirine in eight clinical safety and pharmacokinetic (PK) trials that are designed to measure the vaginal and systemic concentrations of the compound in the body. Tibotec Pharmaceuticals, a subsidiary of Johnson & Johnson, that licensed the product to IPM, previously conducted 11 safety and PK trials of oral formulations of dapivirine, along with one gel trial.

All these trials suggest a favorable safety and tolerability profile, providing the basis to move toward efficacy trials that will test if a microbicide product containing dapivirine is effective in preventing HIV. IPM is pursuing dapivirine-based products in two formulations, including a long-acting monthly vaginal ring, currently its lead product, and a once-daily gel.

Maraviroc-based products: Maraviroc is an FDA-approved ARV treatment for HIV/AIDS that is licensed to IPM from Pfizer. Known as a CCR5 blocker, maraviroc works by blocking a protein on the surface of human cells that is used by HIV to attach to and enter the cell. Developing a maraviroc-based product, both as a stand-alone and as a combination product, is a high IPM priority. IPM continued its work on maraviroc in 2009 and plans to initiate Phase I safety studies in late 2010.

Vaginal gel manufacturing at IPM's CTM facility.

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Other products: IPM in 2009 also worked on BMS 793, an entry inhibitor licensed from Bristol-Myers Squibb. This drug disrupts HIV infection by binding to a protein called gp120 on the surface of the virus, which prevents it from binding to the healthy cell. Results of preclinical studies IPM conducted in 2009 suggested that BMS 793 was safe in the formulation tested.

In addition, work continued in 2009 on L'644 peptide, a fusion inhibitor licensed from Merck that acts by binding to a glycoprotein called gp41 on the surface of the virus. This prevents HIV from fusing with the healthy cell. IPM completed several preclinical assessments, including virology laboratory studies conducted at St. George's, University of London.

Combination products: Consistent with advances in HIV/AIDS treatment regimens that now combine antiretrovirals from different classes, experts anticipate that microbicides based on a combination of ARVs that target HIV at different points in the life cycle may maximize their protective effect.

IPM conducted preclinical studies in 2009 to evaluate the safety and PK of a combination microbicide composed of dapivirine and maraviroc, and investigated various formulations for this product. In addition, the organization carried out work on formulating BMS 793 as a combination drug and continues to evaluate new prototype formulations.

Expanding IPM's research focus with PrEP

In 2009, after extensive consultation with stakeholders, its Board of Directors, and its Scientific Advisory Board, IPM expanded its scope of work to include development of novel, ARV-based prevention products called pre-exposure prophylaxis, or PrEP. Like microbicides, PrEP is a strategy for using antiretroviral drugs to prevent healthy, HIV-negative people from becoming infected with HIV.

IPM currently is working on developing a long-acting injectable formulation of TMC278 (rilpivirine), a highly potent ARV owned by Tibotec Pharmaceuticals. TMC278 is from the NNRTI class of ARVs that block HIV from reproducing its genetic material within human cells. The long-acting formulation IPM is working with Tibotec Pharmaceuticals to develop is known as TMC278 LA.

Powerful potential: **Just as timely administration of oral ARV drugs to HIV-positive pregnant mothers significantly reduces the risk of mother-to-child transmission, researchers believe that taking ARVs as PrEP could similarly help lower the odds of becoming HIV-infected. Involvement in next-generation, long-acting injectable PrEP research supports IPM's mission to develop new HIV-prevention technologies and complements its work on microbicides. TMC278 LA represents a potentially powerful new tool that both women and men could use to protect themselves from HIV. IPM's collaboration with Tibotec Pharmaceuticals on TMC278 LA is supported by a two-year grant from the Bill & Melinda Gates Foundation.**

Current study results: **In expanded safety trials, a once-daily oral formulation of TMC278 for HIV treatment has been shown to be safe and well-tolerated. In addition, two pivotal Phase III studies Tibotec Pharmaceuticals conducted to evaluate TMC278 as a treatment for HIV have met their efficacy objectives, with results to be published this year. Regulatory filings for TMC278 are scheduled for Q3 2010.**

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Manufacturing strategy

IPM considers manufacturing feasibility from the earliest stages of product development. An early understanding of the future manufacturing needs is key to determining each candidate's prospects for successful product development.

In its production facility in Pennsylvania, USA, IPM has successfully manufactured multiple batches of vaginal rings and gels. IPM's facility can produce products to supply safety trials and can be configured to provide initial supplies for Phase III trials if needed.

Refining Ring Manufacturing

In 2009, IPM further evaluated and refined its platinum-catalyzed matrix ring manufacturing process in preparation for dapivirine ring safety trials that were initiated during the year. These refinements will minimize variability and ensure that all batches of vaginal ring products are chemically and physically alike.

Partnering with manufacturers

IPM also undertook planning in 2009 to identify potential partners to help manufacture the much larger quantities of products that will soon be needed for Phase III efficacy trials and eventual commercialization. The identification of candidate partner organizations for this activity was completed in 2009.

Creating efficiency, saving resources

IPM and its partners are scaling up processes now to a level that will support cost-effective manufacturing of new products once they are approved. These scaled up processes will also be used to manufacture materials for Phase III trials, which will circumvent the need for post-trial compatibility studies. Such studies would be required to get approval for alternative manufacturing processes, if needed, to produce products for post approval distribution. This strategy will therefore ultimately speed up access to approved products.

Because the projected demand for a successful microbicide is likely to be larger than could be supplied by a single manufacturing site, additional sites will eventually be needed. Consideration will be given to future expansion of manufacturing capacity in Africa, India and possibly other parts of the world to help maximize product availability and minimize cost. A key component of IPM's access strategy, which IPM began devising in 2009, is to identify partners who help ensure access of new products to the women who need them. The final selection of manufacturing partners is targeted for 2010.

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IPM employees at the CTM facility carry supplies through a sterile room.

Developing products, overcoming challenges

The drug development process is long and complex. This is true for all drug candidates and especially innovative, first-time products like microbicides. Outlined below are the challenges IPM is seeking to overcome to ensure that its products, once they are available, reach the women who need them the most as quickly as possible. Saving millions of lives is a result worth waiting for.

Dosage: Determining correct dosages for any product is an exacting process. The amount of drug delivered to the vagina, its distribution and retention time depend on a number of factors, including the form the product takes. Researchers also carefully study the product's absorption and safety in the body along with the drug's efficacy — all of which are influenced by the product's formulation.

Formulation: Microbicides are being formulated in a variety of ways — with the goal of giving women maximal choice and convenience. Factors such as ease-of-use, women's preferences, manufacturing feasibility and cost all affect which formulations move forward in development. The primary formulation tested in early-generation products were vaginal gels that needed to be used shortly before or at the time of sex. Next-generation products being developed can be used less frequently, providing protection for both anticipated and unanticipated sex. It is thought that formulations that release the active drugs over prolonged periods may help avoid side effects and make the products easier to use.

Acceptability: We know from experience that offering product choice increases the chances that products will be used. IPM places high importance on identifying products that address women's preferences. Even the most efficacious and safe product will not work if women do not use it. IPM is learning more about the preferences of women — and their partners — in market research and acceptability studies that will help ensure future microbicides will be used in the real world to prevent HIV.

Adherence: Measuring whether clinical trial participants are correctly using the product being tested is usually self-reported by participants. But self-reports are not always dependable. It is critical to assess product use as much as possible so that safety and efficacy can be adequately evaluated. Some products IPM is developing, such as long-acting monthly vaginal rings, are designed to help facilitate correct product use. IPM is also testing a method called "daily monitored adherence" to help women establish a consistent routine for using the once-daily gel during clinical trials.

Clinical trial location and size: Testing HIV prevention products such as microbicides can be costly and time-consuming because it requires the recruitment of a large population of individuals in regions that have a high number of new infections in a given time period. Researchers then measure if the rate of new infections, or HIV incidence, has been reduced and assess whether the microbicide is working to prevent HIV.

Determining HIV incidence can be difficult but it is a prerequisite to ensuring that efficacy trials deliver meaningful data and minimize the risk that a trial might need to be stopped early because of lower-than-anticipated incidence. IPM is addressing this issue by conducting HIV incidence studies in potential host communities profoundly affected by HIV to ensure that clinical trials can demonstrate results as quickly as possible in those regions. The ultimate goal is to develop and deliver products to women and communities with the greatest need for HIV prevention.

BACKGROUND: GEOFF OLIVER BUGBEE
WOMAN AND CHILD: ISTOCKPHOTO/MANOAFRICA

Clinical Trials: Advancing the Pipeline

IPM initiated and planned for an array of clinical trials in 2009 — including its largest trials to date. As IPM works with its research center partners to scale up for its efficacy program in 2011, it is advancing its mandate to develop products that would save millions of women's lives, and give families hope for a healthier future. Embarking on these trials requires the engagement of thousands of researchers, local health workers, communities and clinical trial volunteers at multiple research centers across Africa, Europe and the United States. By building local capacity and infrastructure, IPM's work is also designed to benefit the communities where trials are held, seeking to improve lives today as it works to prevent HIV tomorrow.

By the end of 2009, IPM was collaborating with more than 20 research centers in Africa (Kenya, Malawi, Rwanda, South Africa, Tanzania, Zambia and Zimbabwe) and additional centers in Belgium and the United States. These research partners are implementing IPM HIV incidence studies and microbicide safety trials, and preparing for Phase III efficacy trials.

The true heroes in the fight against HIV are the women who participate in microbicide trials around the world. More than 4,700 women were enrolled in IPM research studies by the end of 2009, including 565 women in clinical trials, nearly 1,070 in market research studies and 3,100 in HIV incidence studies.

Clinical trials: moving forward

IPM launched several new trials in 2009, including three Phase I/II expanded safety trials of dapivirine vaginal gel in Africa and the United States, which are its largest trials to date. These trials will provide additional safety data on dapivirine as well as data on women's preferences regarding a once-daily dapivirine gel and their adherence to the product.

In addition, the trials are assessing the feasibility of using a "daily monitored adherence" design that helps women in establishing a routine to ensure daily use of the microbicide gel during the clinical trial. Community outreach workers monitor participants' use of the products by collecting gel applicators on a daily basis through home visits or at a separate drop-off center in addition to asking women about their experience with the gel. Great care is taken to ensure

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IPM-sponsored research and activities in Africa

broad community support for the trials and the confidentiality of all the women participating.

In 2009, IPM was also making preparations to initiate a six-country Phase I/II expanded safety trial of a dapivirine vaginal ring in Africa. A separate Phase I safety trial in Europe, completed in December 2009, collected data on the safety and PK of IPM's new platinum-catalyzed matrix ring containing dapivirine. Data from these various trials will inform IPM's decisions regarding the design of its Phase III program scheduled for 2011.

GEOFF OLIVER BUGBEE

The study investigator from Qhakaza Mbokodo, an IPM research center partner in Ladysmith, South Africa, points out areas where women participate in microbicide studies.

Acceptability studies: understanding what women want

To identify the types of microbicide products that will be used the most in the future, IPM conducts acceptability studies that gather information on women's and their partners' likes and dislikes about various formulations.

To learn about women's preferences for a microbicide vaginal ring, IPM continued work on a clinical trial to collect safety and acceptability data on a placebo vaginal ring at research centers in Africa. Study results will be available in 2010.

IPM also launched and completed a market research study in 2009 to assess the acceptability of placebo vaginal tablets, films and soft-gel capsules among more than 500 women and some of their partners in Burkina Faso, Tanzania and Zambia. Results will be published in 2010.

HIV incidence:

Number of new HIV infections that occur during a specific period of time.

HIV prevalence:

Number of people living with HIV infection in a population (new and existing infections).

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HIV incidence studies: preparing for Phase III

Laying the groundwork for a Phase III program begins with conducting incidence studies that measure the rate of new HIV infections in certain areas, which helps to determine where future efficacy trials will be held (see page 9). These incidence studies also aid national and local authorities in devising strategies to address the needs of women at risk of infection.

In 2009, IPM was in the final stages of conducting an HIV incidence study in five communities in South Africa that involved more than 4,400 women who volunteered for a one-time HIV test (cross-sectional study), with 1,500 women further choosing to enroll in a one-year follow-up study involving quarterly HIV tests (cohort study). In some of these areas, HIV prevalence rates were found to exceed 40 percent among young women ages 18-35. Early analyses suggest that HIV incidence may be above 5 percent in one of the communities studied. Full results are expected in 2010.

A similar IPM study among female sex workers in Rwanda also found a high rate of new infections as well as several strong predictors of HIV infection, with results to be available in 2010.

In 2009, IPM began preparations for additional HIV incidence studies in Kenya, South Africa and Zimbabwe.

IPM Clinical Trials with Activity In 2009				
TRIAL	DESCRIPTION	PHASE	COUNTRIES	STATUS AT THE END OF 2009
IPM 024	Dapivirine vaginal ring PK/feasibility	I	Belgium	Data analysis
IPM 011	Placebo vaginal ring safety and acceptability	n/a	South Africa, Tanzania Kenya	Ongoing, in final stages Site closure
IPM 020	Dapivirine vaginal gel safety	I/II	United States	Ongoing
IPM 014B	Dapivirine vaginal gel safety	I/II	South Africa	Ongoing
IPM 014A	Dapivirine vaginal gel safety	I/II	South Africa Kenya, Malawi, Rwanda, Tanzania	Ongoing In late planning stages
IPM 015	Dapivirine vaginal ring safety	I/II	Kenya, Malawi, Rwanda, South Africa, Tanzania, Zambia	In late planning stages
IPM 013	Dapivirine vaginal gel PK	I	Belgium	In late planning stages
IPM 007	Seroconverter protocol	n/a	Kenya, Malawi, Rwanda, South Africa, Tanzania, Zambia	In planning stages
IPM 010	Dapivirine gel male tolerance	I	TBD	In early planning stages
IPM 009	Dapivirine ring efficacy	III	TBD	In early planning stages
IPM HIV Incidence Studies with Activity In 2009				
TRIAL	DESCRIPTION		COUNTRIES	STATUS AT THE END OF 2009
IPM 100	Cross-sectional and prospective cohort	n/a	South Africa	Ongoing , in final stages
IPM 100.1	Cross-sectional and prospective cohort	n/a	Kenya, South Africa, Zimbabwe	In late planning stages
IPM Market Research Studies with Activity In 2009				
TRIAL	DESCRIPTION		COUNTRIES	STATUS AT THE END OF 2009
PAS II	Product acceptability study (vaginal tablet, film and soft gel capsule)	n/a	Burkina Faso, Tanzania, Zambia	Data analysis

Building capacity, promoting development

To achieve success in mounting complex research studies, IPM invests heavily in building skills and research capacity in the countries where it works. This involves constructing new research centers, developing infrastructure and providing professional development opportunities, and requires close collaboration between IPM and research center partners.

Capacity-building not only facilitates research efforts but also stands to benefit the women who participate in IPM studies, and the communities and countries that host the studies.

Once a research center partner is identified, IPM conducts a comprehensive readiness assessment that includes evaluating the quality and accessibility of medical and social support services in the community, and then providing funding and technical support to build physical infrastructure and human resource capacity where it is needed. A few additional examples of this work follow:

- By renovating or building research centers and providing technical support and advice, IPM research can improve infrastructure and professional development in communities that will last long beyond IPM's endeavours.
- IPM-supported trials can help contribute to the broader HIV response by increasing HIV awareness through community engagement activities, supporting HIV prevention and testing, and referring individuals who test HIV-positive to follow-up care.
- Risk-reduction, family planning and general health counseling provided to IPM study volunteers enhances health-seeking behaviors.
- More than 15,000 women in Africa have received HIV testing through participation in IPM incidence studies and clinical trials.

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A nurse performs a test at the Reproductive Health and HIV Research Unit, an IPM research center partner in Edendale, South Africa.

GEOFF OLIVER BUGBEE

An IPM staff member trains members of the Kilimanjaro Christian Medical Centre study team, an IPM research center partner in Moshi, Tanzania.

Training and professional development

IPM provides extensive training and professional development for approximately 300 full-time staff at research centers in Africa.

- In 2009, IPM's clinical, site development and community engagement teams intensified their training sessions in preparation for expanded dapivirine gel safety trials initiated during the year. This included a series of capacity building visits designed to enhance each research center site's readiness for these trials.
- IPM conducted more than 135 trainings for research staff in Africa in 2009, including courses in Good Clinical Practice, Good Clinical Laboratory Practice, and Good Pharmacy Practice, as well as HIV rapid testing, clinical safety and study-specific trainings.
- Non-clinical staff also received professional training in financial management, community education, counseling, behavioral science and communications.

In 2009, IPM's Clinical Affairs Annual Meeting in Nairobi, Kenya, also provided a training and idea-exchange forum to more than 70 research center attendees from a variety of countries in Africa.

Community education

- In 2009, IPM sponsored 30 community engagement workshops and trainings to help prepare research centers to communicate with a wide variety of stakeholders about the research taking place in their communities and to build support for microbicide trials.
- Significantly, IPM research centers are involving men in research and prevention efforts, serving as vital community resources to promote healthy sexual behavior for both men and women.
- IPM also helps support research centers in their efforts to build or strengthen the capacity of community advisory boards or groups, which serve as liaisons between the research center and the community. IPM conducted two regional day-long workshops in 2009 in South Africa and Rwanda for community advisory groups operating in several African countries.

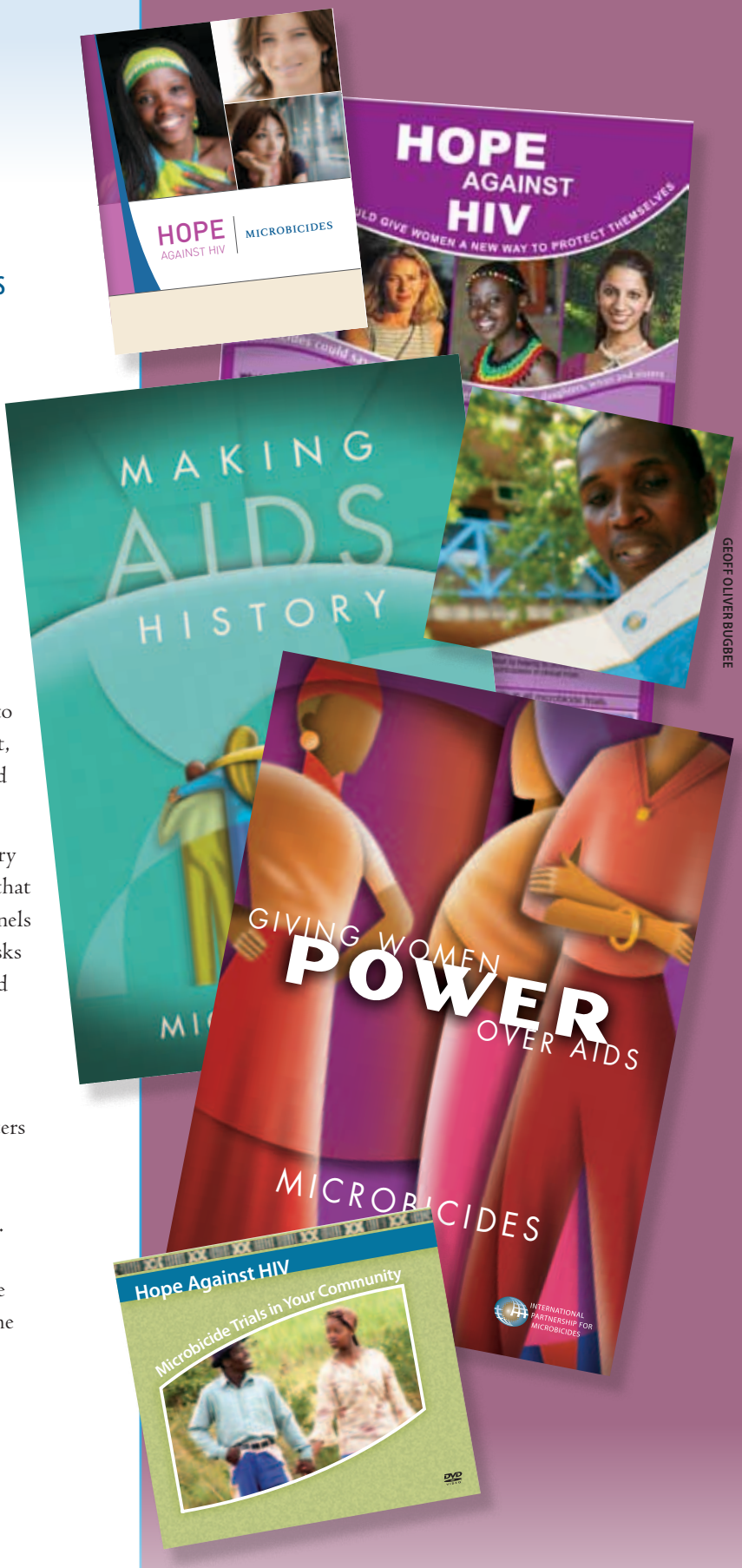
Using innovative tools to reach communities

Communicating effectively about microbicides and clinical trials is key to deepening public support for and understanding of microbicide development efforts. In 2009, IPM crafted a variety of communications tools for use by research center partners in Africa and the United States to reach communities successfully.

New educational video: *Hope Against HIV: Microbicide Trials in Your Community* is a new educational video produced in 2009 in five languages to answer basic questions about microbicides and clinical trials taking place in Africa. Developed in collaboration with the Population Council, the video uses an interactive question-and-answer format to describe the clinical trials process, what women can expect, and the risks and benefits of enrolling in a trial. Download or request a video at *www.ipmglobal.org/edu_videos.htm.*

Adherence/informed consent project: To ensure that every woman who enrolls in a trial provides individual consent that is truly informed, IPM has created an illustrated set of panels to educate clinical trial participants on the benefits and risks of microbicide research and to help ensure they understand trial procedures.

Communications toolkit: IPM has also developed a standardized public education toolkit for clinical trials in Africa and the United States that includes brochures, posters and presentations. The toolkit has been translated into more than 10 local languages. IPM also developed a web portal designed specifically for its research center partners. It centralizes all materials related to clinical trials and communications activities, and makes them easily available online to research center partners in Africa, Europe and the United States.



GEOFF OLIVER BUGBEE

Progressing Toward Product Access

The hope that microbicides could represent will only be realized if women who need them can obtain the products easily and affordably, and use them effectively once they are available. Ensuring future access to products is part of IPM's core mission. The organization plans for regulatory approvals and access strategies from the very outset of the development process. In addition to negotiating provisions in its license agreements to ensure royalty-free rights to distribute these products in developing countries, IPM prioritizes access initiatives through advocacy, focused research, and direct discussions with regulatory and oversight bodies as well as country governments.

ANDREW LOXLEY

Crafting a practical access strategy

At IPM, access is defined as women's ability to obtain and appropriately use good quality microbicides whenever and wherever women want and need HIV prevention.

To outline the challenges and opportunities IPM and other microbicide developers will face in creating strategies to provide access to microbicides, IPM commissioned an in-depth report in 2009 based on historical experiences that synthesizes the most recent data on access to products. *Access to Medicines in the Developing World: Lessons Learned from Antiretroviral Access Programs* identifies principles learned from the HIV prevention field and is being used broadly to create a coordinated and stepwise approach to ensuring access to future products.

From insights gained from the results of access-related activities during 2009, IPM also began developing a comprehensive five-year strategic access plan to be finalized in 2010. The plan will intensify IPM's strategic access focus, and identify objectives and milestones that will help ensure access to future microbicides.

GEOFF OLIVER BUGBEE

IPM recognizes five concepts central to understanding and achieving access to microbicides:

Architecture: The network of organizations at the global, national, and local levels that will support, connect and implement all microbicide access activities must be in place.

Availability: Sufficient high-quality production and supply of microbicide products, and reliable channels for distribution, to meet user demand is vital.

Acceptability: A microbicide product and how it is provided need to be satisfactory to end-users (women and their sexual partners), and to gatekeepers who control and facilitate availability.

Affordability: The costs of microbicides and programs to deliver them must be affordable to purchasers, financers and end-users.

Appropriate use: Microbicides need to be used properly as part of personal and programmatic strategies to achieve the desired health outcome: preventing HIV transmission.

Navigating regulatory pathways

IPM is interacting with African, European and US regulatory authorities, as well as the World Health Organization, to help define a global drug development plan that will enable regulatory decision-making for its novel products. IPM will continue to communicate with regulatory authorities frequently throughout the development process to ensure that it is collecting the appropriate data to support proposed product statements.

Refining best practices across agencies and countries

IPM hosted an annual meeting in 2009, sponsored by the European Commission, that brought together more than 40 representatives from national regulatory agencies and independent ethics committees from Kenya, Malawi, Rwanda, South Africa, Tanzania, Uganda, Zambia and Zimbabwe. The goal of the meeting, held in Nairobi, Kenya, was to build a common understanding of the key issues related to microbicide and other HIV prevention research throughout the region. Meeting participants shared information on a range of issues from access and standards-of-care to product safety, efficacy and community engagement.

IPM and WHO partner for the Microbicide Access Forum

In 2009, IPM and the World Health Organization partnered to co-convene the Microbicide Access Forum, an annual event supported by the US Agency for International Development, where participants gathered to advance strategies for future microbicide access.

Held in Cape Town, South Africa, the 2009 forum included more than 30 high-level stakeholders from global health organizations, African civil society groups as well as academic and research institutions.

Sixty percent of the participants were from countries in sub-Saharan Africa. These leaders in the field identified actions that could help shorten product development time lines, accelerate clinical research and help ensure the earliest possible delivery of safe and effective microbicides.

Forum participants shared results from acceptability studies conducted across the field that gauge women's preferences for future microbicides and will help ensure uptake of new products once they are available.

ISTOCKPHOTO/LUCIAN

Expanding IPM's Reach Through Partnership

Working in partnership is a core IPM value. Advancing the science of microbicides and effectively capturing those advances to produce real results for the world's women is not something IPM can achieve on its own. This commitment to synergy across country and organizational lines is reflected in IPM's collaborations with the HIV prevention field, other PDPs, research center partners, advocacy partners, pharmaceutical companies and industry, policymakers and regulators. Below are a few additional examples of IPM's partnerships in 2009.

Strengthening ties: Civil society & Advocates

IPM partners with nine civil society organizations based in eight European countries and Canada to support its advocacy and resource mobilization initiatives. Partners organize activities at the national level for key stakeholder groups to raise awareness and support for new HIV prevention technologies such as microbicides. IPM also works with its partners to strengthen their technical knowledge around the complexities of HIV biomedical research.

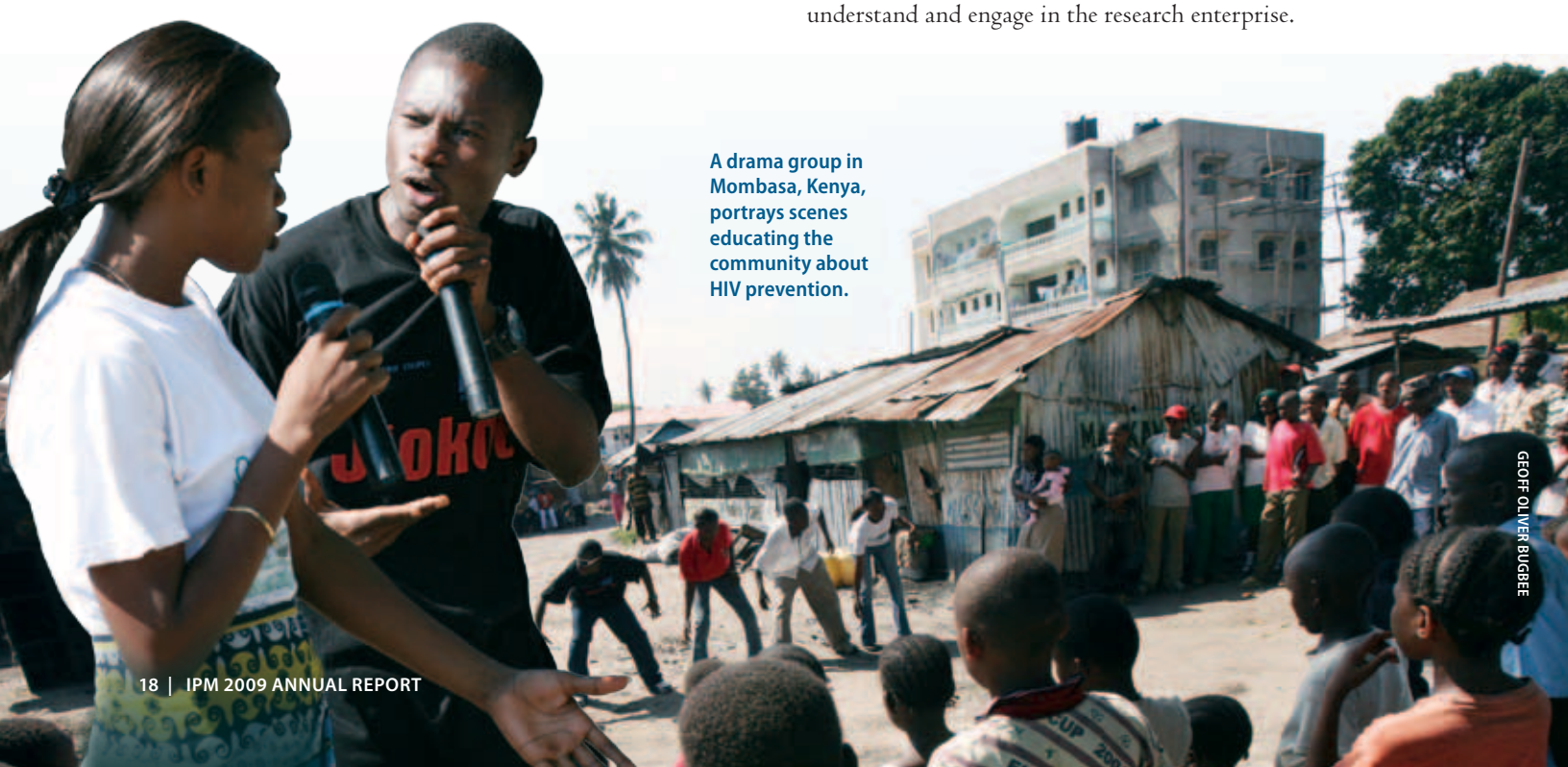
For example, during a visit to a research center in Nairobi, Kenya, as part of IPM's 2009 Clinical Affairs Annual Meeting, IPM partners received training to enhance scientific literacy and learn new ways to communicate about the science of microbicides to their constituents.

In addition, IPM collaborated in 2009 with a variety of international advocacy groups. Such efforts included supporting a new fellowship program created by the Global Campaign for Microbicides (GCM) and AVAC to expand the ranks and capacity of individuals who advocate on behalf of HIV prevention research throughout Africa. IPM also provided support for a GCM-AVAC African HIV prevention research forum designed to strengthen advocates' ability to understand and engage in the research enterprise.

Establishing new advocacy partnerships in communities hosting trials

Building on its successful European partner model, IPM began to identify formal partners in sub-Saharan Africa in 2009, including the Kenya Medical Women's Association and the Open Society Initiative for Southern Africa.

These partnership agreements will pave the way for ongoing advocacy collaboration with civil society organizations in the countries where IPM's clinical research efforts are concentrated. IPM engaged a wide variety of advocacy groups in activities in 2009 to discuss priorities and expectations for future progress in the field, and to increase awareness about HIV prevention research.



A drama group in Mombasa, Kenya, portrays scenes educating the community about HIV prevention.

GEOFF OLIVER BUGREE

IPM participation in scientific forums

To strengthen partnerships and to share information and new data with other stakeholders in the field, IPM played an active role in numerous international and regional meetings. Below are a few examples of IPM's activities in 2009:

- ***International AIDS Society Conference*** At this global scientific conference held in July 2009 in Cape Town, researchers shared developments in HIV research. IPM presented eight presentations on a variety of topics to inform the global response to the HIV epidemic, including promising research on IPM's microbicide candidate maraviroc, HIV incidence studies, PK studies, modelling and cost-effectiveness analyzes for microbicide access. IPM also held research literacy trainings for journalists to help improve accuracy in media coverage of microbicides and HIV prevention research.
- ***European and Developing Country Clinical Trials Partnership*** At this annual forum held in Tanzania in October 2009, IPM shared strategies for building capacities and partnerships in Africa to support global HIV prevention efforts.
- ***Microbicide Trials Network*** At this regional meeting in Cape Town in October, IPM shared its work on product acceptability with partners in HIV prevention across the field.
- ***American Association of Pharmaceutical Scientists*** At this November meeting of experts on drug formulations in California, USA, IPM shared advancements on its development of novel microbicide ring and film formulations.

GEOFF OLIVER RUGBEE

Site manager and study nurse at Be Part Yoluntu Centre, an IPM research center partner in Mbekweni, South Africa.

Mobilizing women in science

At the African regional congress of the Medical Women's International Association in Dar Es Salaam, Tanzania, in July 2009, IPM held a session to highlight shared goals across both organizations.

The women doctors who attended described the daily challenge of delivering the difficult news to women who test HIV positive. Their first-hand experience helping women through the devastation of discovering their HIV positive status reinforced the doctors' strong sense that women need the means to protect themselves from infection with HIV — something they believe microbicides could one day offer.

IPM employees and civil society partners visit with staff at the Kenya Medical Research Institute's Kisumu site, which hosts IPM clinical trials.

Financial Report

Assets

	Dec. 31, 2009	Dec. 31, 2008
Cash and cash equivalents	$8,337,020	$17,183,386
Investments	$77,252,592	$95,905,340
Accounts receivables	$2,267,701	$1,386,153
Prepaid expenses and other assets	$1,246,187	$1,238,691
Prepaid rent and maintenance, net	$305,684	$372,184
Property and equipment, net	$5,640,501	$5,040,274
Total Assets	**$95,049,685**	**$121,126,028**

Liabilities and Net Assets

	Dec. 31, 2009	Dec. 31, 2008
Liabilities		
Accounts payable and accrued expenses	$7,781,435	$7,719,170
Grants advances and deferred revenue	$63,537,516	$89,905,178
Total liabilities	**$71,318,951**	**$97,624,348**
Net Assets		
Unrestricted	$11,402,291	$10,102,417
Temporarily restricted	$12,328,443	$13,399,263
Total net assets	**$23,730,734**	**$23,501,680**
Total liabilities and net assets	**$95,049,685**	**$121,126,028**

Funding considerations

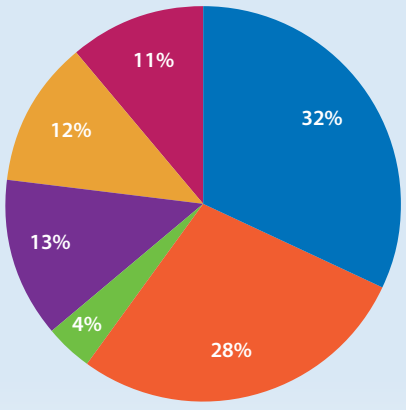
Between 2002 and the end of 2009, IPM raised $398 million, including $275 million in funds received and $124 million in commitments for 2010-2013.

Conducting clinical trials in developing countries requires substantial financial investment. An efficacy trial to support licensure for a single microbicide product requires enrolling thousands of women and following them for several years so that researchers can compare infection rates among those who use a candidate microbicide with those using a placebo. Depending on the sample size and number of clinical sites involved, the costs for pivotal data for licensure can be approximately $90 million. Given that ethical review boards generally will not approve a trial without evidence of sufficient funding, IPM undertakes resource development efforts with the understanding that funding commitments to complete efficacy trials should be in hand before trials commence.

A consistent theme embedded in IPM's work plan is prudent pipeline management: limiting as necessary our product pipeline to allocate sufficient resources to an initial Phase III trial planned for 2011. This has required significant shifts in resources due to the fiscal reality created by the global recession and declining resources for 2010. With prospects from a new resource development strategy, a committed management team and aggressive actions to increase efficiency, IPM is confident that it can continue to advance the most promising microbicide candidates into the initial Phase III trial.

For all activities, IPM is committed to serving as a careful steward of public and private donor funds. IPM looks forward to continuing and increased funding from current donors as the recession subsides. We are also committed to increasing the diversity and number of donors in support of our mission. The result will be steady progress on safe and effective HIV prevention methods for women in developing countries.

Expenses by department



*Site development expenses: $8.1 million

Donors

Belgian Development Cooperation

Bill & Melinda Gates Foundation

Canadian International Development Agency

Ministry of Foreign Affairs of Denmark

European Commission

Ministry of Foreign Affairs, France

Federal Ministry for Economic Cooperation and Development, Germany

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Ministry of Foreign Affairs, the Netherlands

Norwegian Ministry of Foreign Affairs

Rockefeller Foundation

Ministry of Foreign Affairs and Cooperation, Spain

Ministry for Foreign Affairs, Sweden

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United Kingdom Department for International Development

United Nations Population Fund

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World Bank

This list includes all donors who have contributed to IPM since its founding in 2002 through 2009.

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BACKGROUND: GEOFF OLIVER BUGBEE
WOMAN: ISTOCKPHOTO/PETER-JOHN FREEMAN

Be Part Yoluntu Centre, an IPM research center partner in Mbekweni, South Africa.

Selected Scientific Publications & Presentations in 2009

Publications

Fletcher P., Harman S., Azijn H., Armanasco N., Manlow P., Perumal D., de Bethune M-P., Nuttall J., Romano J., Shattock R. "Inhibition of HIV-1 infection by the candidate microbicide, dapivirine, a nonnucleoside reverse transcriptase inhibitor." *Antimicrobial Agents and Chemotherapy* 53, no. 2 (2009): 487-95.

Garg A.B., Nuttall J., Romano J. "The future of HIV microbicides: challenges and opportunities." *Antiviral Chemistry and Chemotherapy* 19, no. 4 (2009): 143-50.

Nel A., Smythe S., Young K., Malcolm K., McCoy C., Rosenberg Z., Romano J. "Safety and pharmacokinetics of dapivirine delivery from matrix and reservoir intravaginal rings to HIV-negative women." *Journal of Acquired Immune Deficiency Syndromes* 51, no. 4 (2009): 416-23.

Nel A.M., Coplan P., van de Wijgert J.H., Kapiga S.H., von Mollendorf C., Geubbels E., Vyankandondera J., Rees H.V., Masenga G., Kiwelu I., Moyes J., Smythe S.C. "Safety, tolerability, and systemic absorption of dapivirine vaginal microbicide gel in healthy HIV-negative women." *AIDS* 23, no. 12 (2009): 1531-8.

Pal R., Nuttall J., Galmin L., Weiss D., Chung H-K., Romano J. "Characterization of vaginal transmission of a simian human immunodeficiency virus (SHIV) encoding the reverse transcriptase gene from HIV-1 in Chinese rhesus macaques." *Virology* 386, no. 1 (2009): 102-8.

Romano J., Variano B., Coplan P., Van Roey J., Douville K., Rosenberg Z., Temmerman M., Verstraelen H., Van Bortel L., Weyers S., Mitchnick M. "Safety and availability of dapivirine (TMC120) delivered from an intravaginal ring." *AIDS Research and Human Retroviruses* 25, no. 5 (2009): 483-88.

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Ampofo S.A., Warner S., Race S., Wilder S. "Comparative study of dissolution profiles of microbicide ring products prepared from different silicone elastomer sources." Poster presentation at the American Association of Pharmaceutical Scientists, Los Angeles, California, November 8-12, 2009.

Edwards K., Muehleisen T., Martindell J., Ampofo S., Sparks M.H. "Evaluation of content uniformity using a 3 stream vs. 2 stream mixing process to manufacture silicone based vaginal rings." Poster presentation at the American Association of Pharmaceutical Scientists, Los Angeles, California, November 8-12, 2009.

Sparks M.H., Edwards K-L., Malcolm K., Kiser P., Johnson T., Loxley A. "Drug release characteristics of dapivirine and tenofovir from vaginal rings consisting of ethylene vinyl acetate, silicone or polyurethane polymers: options for HIV prevention." Poster presentation at American Association of Pharmaceutical Scientists, Los Angeles, California, November, 8-12, 2009.

Engelbrecht A., Maleka M., Singh B., Puren A. "Evaluation of universal platform HIV rapid test controls." Poster presentation at 20th National Congress of the Society of Medical Laboratory Technicians, Durban, South Africa, September 6-10, 2009.

Nuttall J., Kashuba A., Wang R., White N., Allen P., Roberts J., Romano J. "The pharmacokinetics of tenofovir following intravaginal and intrarectal administration of tenofovir gel to rhesus macaques." Poster presentation at National HIV Prevention Conference, Atlanta, Georgia, August 23-26, 2009.

Rosenberg Z. "Overview of microbicides for HIV prevention." Oral presentation at 4th International Workshop on HIV Transmission, Cape Town, South Africa, July 17, 2009.

Mertenskoetter T. "PrEP and microbicides – new approaches to HIV prevention." Oral presentation at Swiss-Austrian-German AIDS Conference, St. Gallen, Switzerland, June 24-27, 2009.

Mertenskoetter T., Romano J., Kaptur P. "Microbicide formulations in development." Poster presentation at Swiss-Austrian-German AIDS Conference, St. Gallen, Switzerland, June 24-27, 2009.

Lambert A., Mutsambi J., Modikoe P., Isaacs M., Young K., Nel A. "Daily monitored adherence: process to develop novel design to improve adherence outcomes in phase III vaginal microbicide research." Poster presentation at 4th South African AIDS Conference, Durban, South Africa, March 31-April 3, 2009.

Malherbe M., Schley A., Herman C., Clement B., Parijs V., Nel A. "Use of good clinical practice (GCP) readiness assessment tool in multi-centre HIV prevention trials: assessment of GCP compliance." Poster presentation at 4th South African AIDS Conference, Durban, South Africa, March 31-April 3, 2009.

Nel A., Smythe S., Habibi S., Romano J. "Comparison of safety and pharmacokinetics of two formulations of dapivirine vaginal gel in healthy, HIV negative women." Poster presentation at 16th Conference on Retroviruses and Opportunistic Infections, Montreal, Canada, February 8-11, 2009.

Nel A. "Dapivirine vaginal gels for prevention of HIV transmission." Oral presentation at 16th Conference on Retroviruses and Opportunistic Infections, Montreal, Canada, February 8-11, 2009.

Please visit www.IPMglobal.org *for a full list of IPM supported publications and presentations.*

ISTOCKPHOTO/GUENTERGUNI

A production technician peers through a lens at the gel manufactured at IPM's CTM facility.

ANDREW LOXLEY

ISTOCKPHOTO/LOUIE SCHOEMAN

International Partnership for Microbicides

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