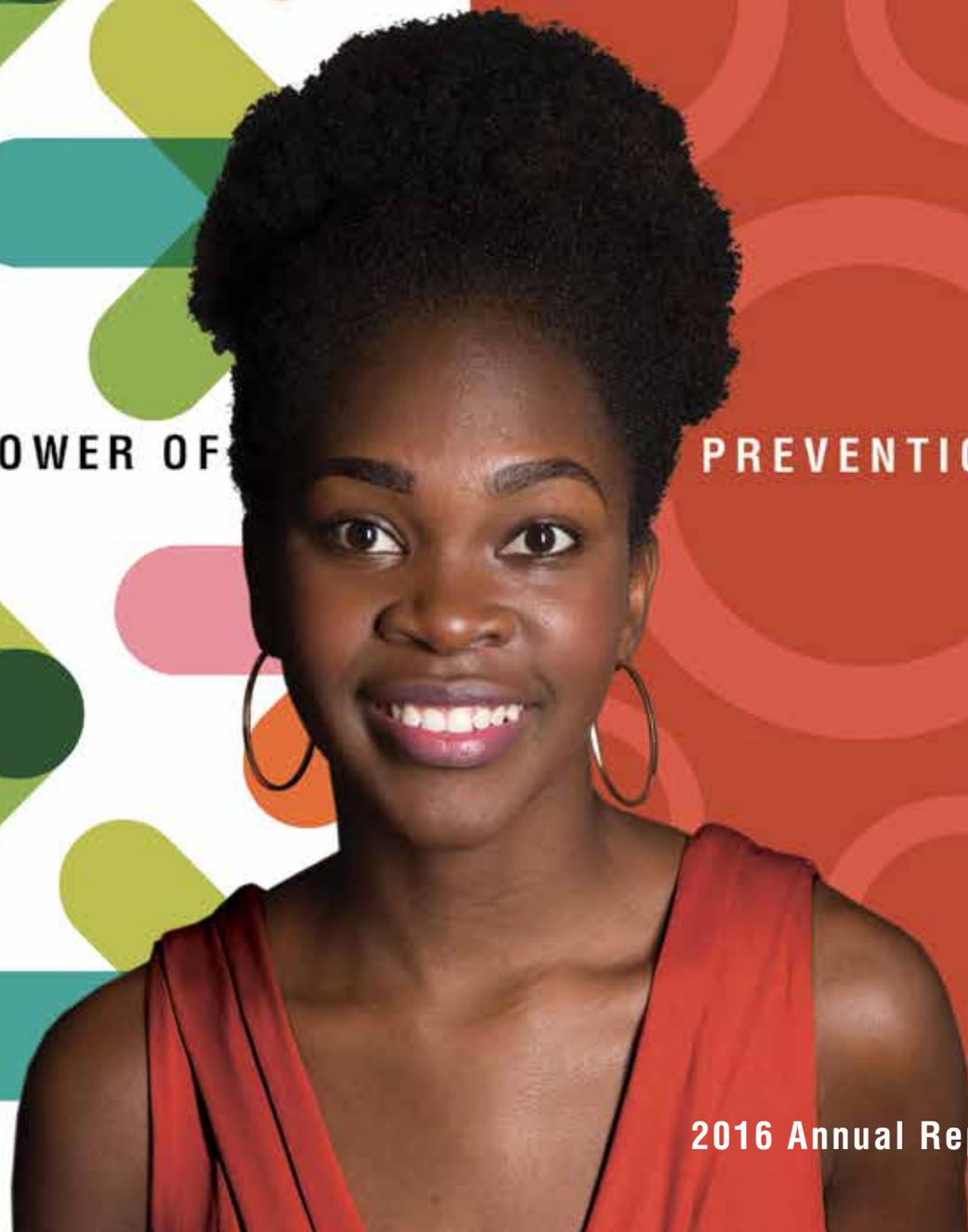




INTERNATIONAL
PARTNERSHIP FOR
MICROBICIDES

HOPE, PROGRESS AND THE POWER OF PREVENTION



2016 Annual Report



Dear friends and colleagues,

Last year, we shared the inspiring news that IPM's monthly dapivirine ring helps to safely reduce a woman's risk of HIV infection. We were encouraged by the enthusiasm of many women who participated in The Ring Study when they heard the primary results, which was so nicely summed up by one participant: "I wish that the ring can be approved and be available to all women who are sexually active and want to use it to protect themselves against HIV."

As we learned more about the ring's potential from additional analyses, we heard similar expressions of enthusiasm from women and partners around the world. Bolstered by this global commitment to addressing women's urgent HIV prevention needs with innovative technologies, we are optimistic that the ring results mark an important milestone on the road to offering women an effective long-acting prevention method.

The dapivirine ring can serve as an example of what the product development partnership (PDP) model can achieve. Yet our work is far from done. For IPM, the "D" in PDP stands for development and delivery. IPM is providing the ring to former Phase III trial participants as well as young women using the ring for the first time through open-label studies that may help us better understand adherence challenges and ways to address them. IPM is submitting the first applications this year and in 2018 for the ring's regulatory approval — a critical next step toward expanding women's options.

As IPM works to make an affordable dapivirine ring available to women, we remain just as focused on developing a pipeline of next-generation products to stay ahead of the virus, including a three-month dapivirine ring, a three-month ring that combines dapivirine with a contraceptive, and three-month rings that combine multiple ARVs.

There is a saying that sticks in a bundle are unbreakable. Indeed, our work is only possible with continued — and even more focused — collaboration on a variety of fronts across countries and sectors, from supporting uptake and use of effective prevention methods to integrating new options into health systems and financing their affordable access. We are enormously grateful to our donors and partners, who, like us, believe that women deserve HIV prevention options that meet their needs, including oral PrEP and rings as well as next-generation methods being developed. In 2016, our hope was renewed that such a future is indeed possible.

Dr. Zeda F. Rosenberg

Founder and Chief Executive Officer

Dr. James McIntyre

Chair of the Board



HIV/AIDS remains the leading cause of death among women ages 15-44, with nearly one million women and girls newly infected worldwide in 2015. In sub-Saharan Africa, where the epidemic has taken its greatest toll, nearly 60 percent of new infections among adults ages 15 and older are in women.

These stark statistics — which represent millions of women's lives — drive our work to develop and deliver new HIV prevention approaches for women, for whom existing methods are not doing enough to reduce their risk of infection. Women urgently need solutions that meet their needs, which can change throughout their lives.

In 2016, IPM made promising strides toward fulfilling its founding mission to provide women with products they could use themselves to prevent HIV. We look back at milestones from 2016 — and the next steps to come — that could help usher in a new era: one where women have the range of options they need to stay healthy and HIV-free.



Dapivirine ring becomes the first microbicide to show efficacy in two Phase III trials

In early 2016, IPM's monthly dapivirine ring was found to safely help reduce HIV risk in two Phase III trials — making it the first microbicide and the first long-acting prevention product to confirm efficacy.



Building the HIV prevention evidence base

IPM and MTN published primary Ring Study and ASPIRE results, respectively, in the *New England Journal of Medicine*, and jointly announced the findings at a press conference and sessions at the 2016 Conference on Retroviruses and Opportunistic Infections in Boston. IPM presented on dapivirine ring research at major scientific conferences throughout the year, including the 2016 International AIDS Conference (AIDS 2016) in Durban and the 2016 HIV Research for Prevention (R4P) Conference in Chicago.

The ring was found to safely reduce infection among more than 4,500 women in Malawi, South Africa, Uganda and Zimbabwe by approximately 30 percent overall. Additional analyses showed that HIV risk reduction was greater among women who used the ring consistently.

Dapivirine ring: At-a-glance

- Vaginal ring made from flexible silicone
- Slowly releases ARV drug dapivirine
- Self-inserted monthly
- Assessed for safety and efficacy in The Ring Study, led by IPM, and ASPIRE, led by the US National Institutes of Health-funded Microbicide Trials Network (MTN)

SPREADING THE WORD



IPM and MTN gathered Phase III participants, trial communities and civil society advocates to share the results and our plans for open-label follow-on studies now ongoing in the four Phase III countries.



To increase public awareness of the dapivirine ring results and the role the ring could play in broadening the toolkit for women's HIV prevention, IPM conducted briefings for stakeholders across Africa, Europe and North America, and hosted events at the Women Deliver conference in Copenhagen and the United Nations High-level Meeting on HIV and AIDS in New York.

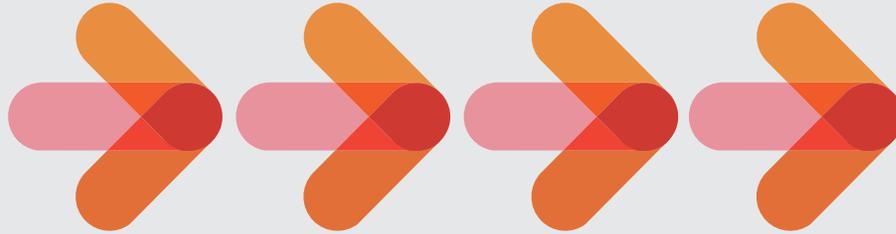
IPM was also a sponsor of the inaugural Women Now! conference to elevate women's sexual and reproductive health and rights and justice issues in the lead-up to AIDS 2016.



POTENTIAL ACCESS

REGULATORY PATHWAY

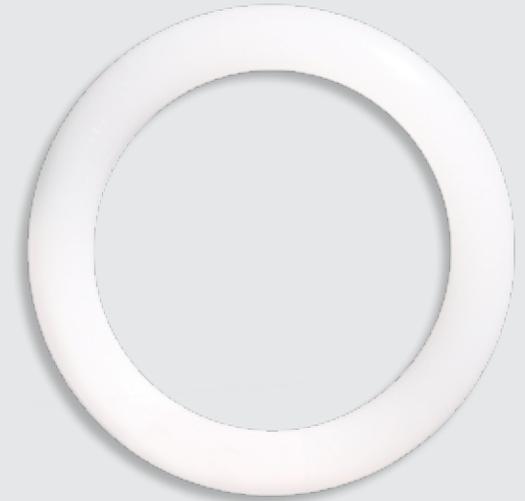
Applications for regulatory approval to be submitted starting mid-2017



PATHWAYS TO ACCESS FOR THE RING

PUBLIC HEALTH PATHWAY

Open-label studies to provide the ring to women of reproductive age, support consistent use and collect additional safety data



Launch of first open-label studies for an HIV prevention ring

The first open-label studies of a vaginal ring shown to reduce HIV transmission began in July 2016. The two studies, DREAM and HOPE, are providing the dapivirine ring to former Ring Study and ASPIRE participants, respectively. The data collected will help us understand how women use the ring now that they know its safety and efficacy.





IPM's DREAM study recently expanded enrollment to include 600 young women ages 18-25 who have not previously used the ring. Given that 4,500 young women in Africa are newly infected every week, this expansion will provide crucial insights into how young women might incorporate the dapivirine ring into their lives and will help inform adherence support strategies. In all, DREAM is expected to enroll about 1,700 participants.

Taking place at six former Ring Study locations in South Africa and Uganda, IPM's DREAM study is exploring the feasibility of a three-monthly follow-up schedule where women visit the clinic to receive a new ring and take two new rings to insert at home. Similarly designed, MTN's HOPE study is implementing a three-monthly schedule among an expected 1,500 to 2,000 women at 15 former ASPIRE sites in Malawi, South Africa, Uganda and Zimbabwe. Both studies will collect data on why some participants choose not to use the ring, and HOPE will also explore alternative markers of adherence. Building on the foundation laid by the Phase III trials, community briefings, information sessions and sporting events will continue to play an important role in engaging women and trial communities in both open-label studies.



“I feel very protected and more relaxed with the ring with medication in it. That makes my sex life more interesting. I am very happy to be in the DREAM study.”

– DREAM participant



In addition, to better understand HIV prevention product preferences and adherence challenges among adolescent girls and young women, IPM is partnering with MTN to conduct a new study called REACH. To begin in 2017, the study will assess the safety of and adherence to the monthly dapivirine ring and daily oral pre-exposure prophylaxis (PrEP) among 300 young African women ages 16-21. This important study will support platforms for conversations about young women’s lives and HIV prevention needs.



Preparing the first regulatory applications for an HIV prevention ring

As the regulatory sponsor for the dapivirine ring, IPM is pursuing regulatory approval for the ring's use in countries where women are at high risk of HIV infection. If approved, the ring would be the first microbicide and first vaginal ring licensed for HIV prevention.

In 2016, IPM continued the intensive process of assembling a dossier containing all data on the dapivirine ring for its first regulatory reviews.

IPM plans to submit first to the European Medicines Agency (EMA) through Article 58, a mechanism that provides scientific opinions on products that will be marketed outside of the European Union in low- and middle-income countries, in consultation with the World Health Organization (WHO). A positive opinion from the EMA under Article 58 would help facilitate the ring's WHO prequalification, which many African regulatory authorities rely on for their own reviews and approvals. IPM also plans to submit applications to the South African Medicines Control Council (MCC) in late 2017, and to the US Food and Drug Administration (FDA) in 2018. First approvals in Africa could come as soon as early 2019.



IPM meets with African national regulatory authorities from Ghana, Kenya, Malawi, South Africa, Uganda, Zambia and Zimbabwe in 2016 in Cape Town.

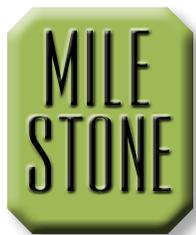
A peek into the regulatory process



Applying for approval of a new drug like dapivirine involves careful planning and an enormously synchronized effort. Vice President for Regulatory Affairs Patricia Mayer offers some insights into IPM's approach:

Over the past decade, IPM has generated a tremendous amount of data on the dapivirine ring, from early work to optimize the formulation and nonclinical testing to clinical safety and efficacy. After comprehensive data analyses are conducted, they are compiled into a dossier according to each regulatory agency's specific application format. The process of assembling the dossier started last year, and is an "all hands on deck" operation as we near our target submission date following a series of meetings with European regulators to ensure we submit as comprehensive a package as possible. After we submit the EMA application, we will immediately start assembling the country-specific applications to the MCC, FDA and each targeted African country.

Only with a committed team will we be able to reach our goal to potentially offer women this promising tool as soon as possible.



Partnering for potential rollout of the first HIV prevention ring

The dapivirine ring could add an important component to a future prevention toolkit as a long-acting and self-initiated option for women. Leveraging the partnerships that helped advance the ring through Phase III trials, IPM is collaborating across public, private and civil society sectors to increase widespread awareness, and to encourage demand and uptake if the ring is approved and incorporated into HIV prevention strategies.

IPM works with both governmental and traditional leaders in South Africa and Uganda to ensure that discussions on national HIV prevention policies include the dapivirine ring as an important potential option for women. National strategic plans continue to support microbicide research and eventual introduction.



PARTNERING FOR ACCESS





Courtesy of 3P Innovation Ltd.

Activities in 2016 included:

- Purchasing the new inspection and packaging equipment needed to meet the manufacturing scale for the ring's potential launch. IPM worked with its ring manufacturing partner, QPharma (Sweden), to install and prepare the equipment for process validation in 2017 to ensure the ring's quality.
- Exploring how human-centered design approaches could encourage dapivirine ring uptake and adherence among young African women, in partnership with Dalberg's Design Impact Group and USAID's Center for Accelerating Innovation and Impact.
- Building a brand identity for the ring by conducting market research on potential brand names for the ring among health professionals in the US and Africa, and preparing for focus group discussions with potential end-users in 2017. IPM will include the selected brand name in its MCC submission currently planned for late 2017.
- Partnering with USAID's OPTIONS project to advocate for the ring's inclusion in WHO guidelines and policies, and to develop an investment case for policymakers and global donors that demonstrates the ring's potential public health impact and cost-effectiveness.

IPM expanded its partnership with Janssen Sciences Ireland UC, one of the Johnson & Johnson Pharmaceutical Companies, which granted IPM exclusive worldwide rights to dapivirine. Janssen committed to a multi-year secondment of a staff member whose commercial marketing expertise will help guide IPM's market introduction activities for the dapivirine ring.

“Innovation can help rewrite the script for girls and young women affected by HIV.”

– Jaak Peeters, global head, Global Public Health, Johnson & Johnson



Planning for future milestones to expand women's options

Any strategy to slow, and ultimately end, the epidemic must include a diverse prevention pipeline that addresses women's comprehensive sexual and reproductive health needs. Using the dapivirine ring as a platform technology, IPM is steadily advancing a range of promising next-generation products that could offer women more effective and convenient tools to protect their health.

In 2016, IPM and MTN prepared for a Phase I study of IPM's **three-month dapivirine-only ring** that would offer women longer-lasting protection. The study is planned for 2017 and will evaluate the safety and pharmacokinetics of rings with different doses of dapivirine.

“HIV infection cannot be undone or reversed. The ring can save their lives. The ring can give young women back some power. The ring could become an important arsenal in the fight against HIV among young women, so I'll be keeping my eye and ear close to its further development. The ring has in me a new advocate!”

– Gqibelo Dandala, chief executive officer, Future of the African Daughter

“We need new prevention tools if we are to escape this epidemic. Investment in research and development for new prevention tools remains a critical goal for us all.”

– Naledi Pandor, minister of science and technology of South Africa

IPM and MTN also planned for a Phase I trial of IPM's **three-month dapivirine-contraceptive ring** that is designed to prevent HIV and unintended pregnancy, two leading contributors to death and disability among women of reproductive age. Initiated in 2017, the trial is assessing the ring's safety and pharmacokinetics and includes the three-month dapivirine-only ring for comparison. Results from both Phase I studies will inform next steps for the dapivirine-contraceptive ring and help define the possible regulatory pathway for the three-month dapivirine-only ring.



Under agreements with leading pharmaceutical companies, IPM is also exploring products that would combine the potency of different ARVs with mechanisms of action that have not been used for prevention. Introducing new routes of attack and disabling the virus in multiple ways in a single product could help reduce the chance of acquiring drug-resistant HIV and improve the product's overall effectiveness.

Data analysis began in 2016 for a Phase I safety and tolerability trial of a vaginal tablet containing DS003, a gp120 entry inhibitor licensed from Bristol-Myers Squibb. Results are expected in 2017 and will inform the development of a **DS003-dapivirine vaginal ring**. In addition, IPM is planning analytical and preformulation studies of darunavir — a protease inhibitor licensed from Janssen that is currently used for HIV treatment — to inform future prototypes of a **darunavir-dapivirine vaginal ring**.

IPM Donors

2016 Donors

Bill & Melinda Gates Foundation
Ministry of Foreign Affairs of Denmark
Flanders Department of Foreign Affairs
German Federal Ministry of Education and Research (BMBF) through the KfW Development Bank
Irish Aid, Department of Foreign Affairs
Ministry of Foreign Affairs of the Netherlands through the Netherlands Enterprise Agency
Norwegian Agency for Development Cooperation, Norwegian Ministry of Foreign Affairs
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United States Agency for International Development through the United States President's Emergency Plan for AIDS Relief

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2016 FINANCIAL CONSIDERATIONS

IPM's cash, cash equivalents and short-term investments as of Dec. 31, 2016, totaled USD 11.5 million. In 2016, IPM advanced three major programs:

- Support to clinical research center partners and clinical activities to transition from The Ring Study, one of two Phase III clinical trials of the dapivirine ring, to DREAM, an open-label extension study that launched in July 2016 to provide the ring to approximately 1,400 former Ring Study participants and 600 young women using the product for the first time. Comprehensive analyses of Ring Study data continued in 2016. IPM also supported chemistry, manufacturing and control activities to support the regulatory filing to the EMA, to automate some aspects of the ring manufacturing process and scale up capacity in preparation for the ring's potential launch in African countries where women face high HIV risk.
- Regulatory activities to assemble a comprehensive dossier of data on the dapivirine ring and to prepare applications to license the ring that IPM currently plans to submit in mid-2017 to the EMA, late 2017 to the MCC and in 2018 to the FDA.
- Pipeline products, including the conduct and data analysis of the first clinical trial of DS003 and manufacturing of supplies for the first clinical trial of IPM's three-month dapivirine-contraceptive ring, which began in 2017. This work is conducted in consultation with IPM's Scientific Advisory Board using a highly disciplined approach to product prioritization that advances only the most promising self-initiated HIV prevention tools and other sexual and reproductive health technologies for women.

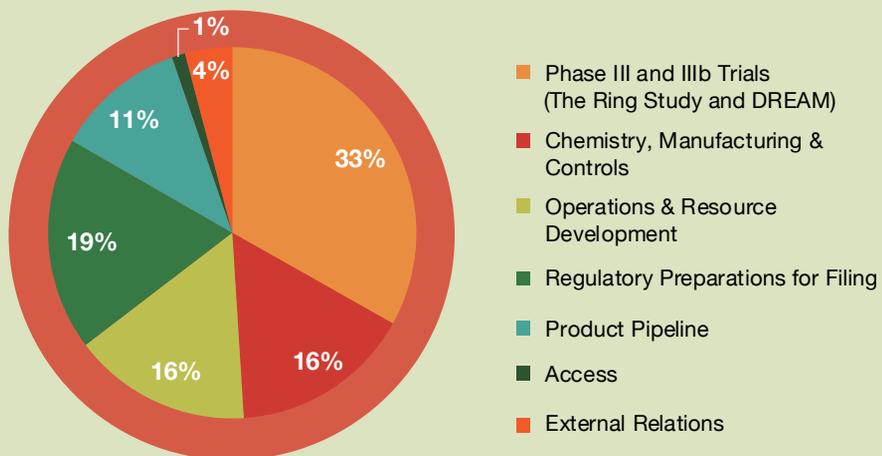
In 2016, IPM received significant support from donors including the Ministry of Foreign Affairs of Denmark, the Flanders Department of Foreign Affairs, the German Federal Ministry of Education and Research, Irish Aid, the Ministry of Foreign Affairs of the Netherlands, Norad, DFID, USAID and the Bill & Melinda Gates Foundation. IPM received approximately USD 29.7 million (cash receipts) in 2016.

IPM's 2016 financial audits continue a history of full compliance with all financial reporting requirements from all US and international government and private donors. In 2016, IPM again received unqualified, or clean, opinions on all audits in both its South Africa and US offices.

IPM's Board of Directors, management team and staff are committed to efficiently and effectively deliver on our mission to accelerate the development and availability of prevention products that women can use to protect against HIV infection. Women and girls continue to become infected at alarming rates, especially in sub-Saharan Africa, and new products like the dapivirine ring have the potential to make a significant public health impact. Sustained donor funding for IPM's activities is essential, and we continue to advocate for increased funds from existing donors and pursue new sources of support to achieve our goals.

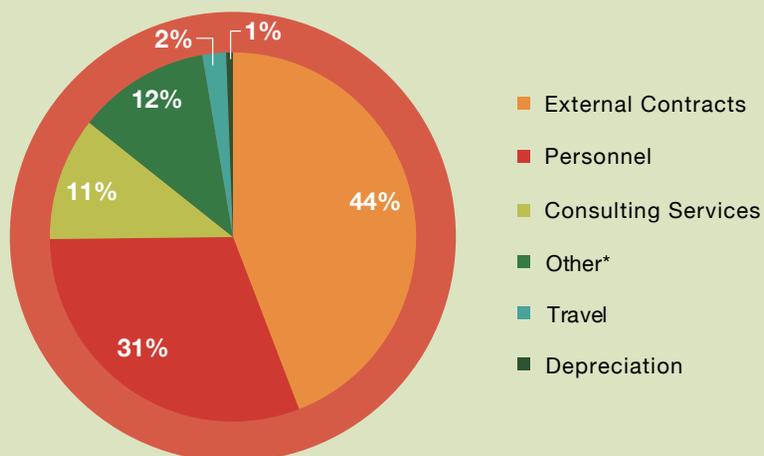
2016 Expenditures by Program

\$33.8M



2016 Expenditures by Functional Category

\$33.8M



*Includes rent, internet/phone, clinical trial insurance, legal fees, audit fees, regulatory fees and miscellaneous.

Statement of Financial Position

December 31, 2016

Assets

Cash and cash equivalents	\$6,311,229
Investments, at fair value	\$5,194,090
Grants receivable	\$4,823,974
Prepaid expenses and other assets	\$854,943
Property and equipment, net	\$2,875,959

Total Assets **\$20,060,195**

Liabilities and net assets

Liabilities

Accounts payable and accrued expenses	\$4,130,315
Accrued payroll liabilities	\$528,108
Grant advances and deferred revenue	\$831,193
Deferred rent liability	\$35,513

Total Liabilities **\$5,525,129**

Net assets

Unrestricted net assets	\$14,535,066
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Total Liabilities and Net Assets **\$20,060,195**



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