



AIDS ReSearch Alliance

2003 ANNUAL REPORT

*a national leader in fast-track
HIV/AIDS research*

About AIDS ReSearch Alliance

AIDS ReSearch Alliance (ARA)

VISION

ARA envisions a future in which HIV and its effects are eliminated from infected individuals, and a vaccine preventing new cases eradicates the virus.

MISSION

ARA's mission is to find and accelerate the development of effective treatments for HIV and its complications. We do this by conducting cutting-edge research and clinical trials in order to improve the longevity and quality of life for all people with immune deficiency.

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The Year in Review

The most exciting research conducted at ARA in 2003 remains its work on a drug called “prostratin”, isolated from Samoan rainforests over a decade ago after ethnobotanist Paul Alan Cox, Ph.D. observed Samoan healers using the plant to treat hepatitis. Cox immediately shipped a sample to the *National Cancer Institute*; NCI uncovered potent anti-HIV activity of the compound. Perhaps because prostratin is a plant-based medicine, no pharmaceutical company expressed interest in developing prostratin and it languished on NCI shelves until ARA expressed interest and began our research.

Our interest has paid off. We confirmed findings that prostratin packs two punches: it protects healthy cells from infection, but also “activates” the reservoirs of the virus that hide throughout the body preventing viral eradication.

2003’s progress moved the drug closer to human clinical trials. The promise in the one-two punch prostratin packs is its ability to flush the virus from its hiding places, while protecting uninfected cells. In theory, prostratin could be used in combination with current drugs that suppress HIV in the bloodstream. If we can force the virus out of hiding, it is possible that prostratin could provide an approach to eliminating HIV from the bodies of some infected with the virus.

Research in the last year makes this look more plausible. First,

through studying the drug in animal models, we determined the highest dose that could be administered to humans. Second, our collaborators around the globe showed that doses at this level activate reservoir cells in the way necessary for our eradication hypothesis to work. Third, even high levels of prostratin administered to animals resulted only in mild liver inflammation that quickly resolved when the drug was withdrawn. Fourth, for the first time

“If we can force the virus out of hiding, it is possible that prostratin could provide an approach to eliminating HIV from the bodies of some infected with the virus.”

the ability of prostratin to activate the reservoirs was confirmed in actual human tissue—not just in cells in test tubes.

This is all extremely heartening news. While it is too early to say that prostratin will be a key weapon against HIV/AIDS, all research into the compound has confirmed the presence of characteristics we hoped to find. This is indeed an exciting time.

In addition to our work on prostratin, ARA’s clinical trials accomplished important work in 2003.

Tackling neuropathy, a debilitating side effect of HIV-disease and its treatments, ARA performed three clinical trials seeking treatments to alleviate this sometimes crippling pain in the extremities. One trial attempted to find out if high dose, broad spectrum micronutrients could reverse neuropathy. Another used topical analgesics—including one made essentially from cayenne peppers. And the third uses new technology, testing a “nerve growth factor” that may restore damaged nerves. (So far, only the micronutrient study results are back: while supplementation did not reverse neuropathy, those receiving micronutrients rather than placebo had a 25% increase in their T-cells, a significant finding.)

A report on the last year must also include word of a new preventative vaccine trial. AIDS ReSearch Alliance is proud to be involved in this research. This novel vaccine uses adenovirus—often the culprit

in the common cold—to deliver three isolated genes from HIV, with hopes that the body will respond with an immune response strong enough to prevent infection with HIV.

Only time will tell whether this approach works. But you can know now that the support you provide AIDS ReSearch Alliance is funding research that may be instrumental in eradicating HIV from the body while also supporting our ability to research a vaccine to prevent new infections. That should come as exciting news.

Clinical Trials 2003

STUDY	DESCRIPTION
Pre-clinical & basic research AIDS ReSEARCH ALLIANCE	ARA pursues an extensive pre-clinical research agenda not reflected in this chart. We include this information here to ensure that our supporters know that this chart reflects only a part of our mission-driven work to ameliorate and, we hope, one day end the epidemic. (Various)
Experimental HIV Vaccine MERCK & CO., INC.	A Phase I dose-ranging study of the safety, tolerability and immunogenicity of the Merck trivalent adenovirus serotype 5 HIV-1 gag/pol/nef vaccine in a prime boost regimen in healthy adults. (Preventative HIV Vaccine)
C0603 SAVIENT PHARMACEUTICALS, INC. & THE NEURO-AIDS RESEARCH CONSORTIUM	A study testing the safety and efficacy of a new medication called prosaptide for the relief of HIV/AIDS-associated neuropathic pain. (Pain alleviation)
C107 NEUROGESX, INC.	A study testing the safety and efficacy of a new treatment called a capsaicin patch for the relief of HIV/AIDS-associated neuropathic pain. (Pain alleviation)
BMS AI266-406 BRISTOL-MYER SQUIBB	Vest-QD: a Phase IV, open-label, randomized, multicenter study switching HIV-1 infected subjects with a viral load <50 copies/ml on a first PI-based regimen to an efavirenz substitution regimen. (Antiviral therapy)
BMS AI424-067 BRISTOL-MYER SQUIBB	A Phase IIB, open-label, randomized, multicenter study evaluating the effect on serum lipids following a switch to the protease inhibitor (PI) atazanavir in HIV-1 infected subjects evidencing virologic suppression on their first PI-based antiretroviral therapy. (Antiviral therapy)
Micronutrient Neuropathy Study INTEGRATIVE HEALTH CONSULTING, INC.	Broad-spectrum micronutrient supplementation in HIV-infected patients who develop peripheral neuropathy while taking stavudine and/or didanosine antiviral therapy. (Pain alleviation)
Capravirine A431 I002 PFIZER/AGOURON	A double-blind, randomized, placebo controlled study of capravirine (AG1549) in combination with Viracept™ and two nucleoside reverse transcriptase inhibitors in HIV-infected patients who have failed an initial nonnucleoside reverse transcriptase inhibitor-containing regimen. (Antiviral therapy)
Capravirine A431 I006 PFIZER/AGOURON	A Phase II, randomized, double-blind, dose-ranging study of capravirine (AG1549) in combination with Kaletra™ and at least 2 nucleoside reverse transcriptase inhibitors in HIV-infected subjects who have failed antiretroviral regimens containing protease inhibitors, nonnucleoside reverse transcriptase inhibitors and nucleoside reverse transcriptase inhibitors. (Antiviral therapy)
Serostim® SERONO LABORATORIES	A study testing the safety and effectiveness of a growth hormone in treating HIV-associated lipodystrophy. (Fat redistribution therapy)
Zerit® (Stavudine, d4T) BRISTOL-MYERS SQUIBB	A study to evaluate and compare the safety and efficacy of extended-release stavudine compared with standard stavudine for antiviral activity. (Antiviral drug/improved dosing)

Out and About

AIDS ReSearch Alliance (ARA) outreach was extensive and productive in 2003. New community partnerships were formed, existing partnerships were strengthened and ARA reached additional population groups regarding our important HIV/AIDS research.

Clinical Trials 101

ARA made significant contacts in the diverse HIV/AIDS community and gave our "Clinical Trials 101" presentation at numerous AIDS Service Organizations (ASO) including: the **Alcohol and Drug High Gain Council, Orange County AIDS Services Foundation, Antelope Valley Hope Foundation, Tarzana Treatment Center** and the **APLA Women's Program**. "Clinical Trials 101" covers basic information about clinical trials, including the drug development process, the pros and cons of participating in clinical trials, definitions of terms and how to access clinical trials. ARA was invited back to several ASO to give a presentation regarding the results of the VaxGen vaccine study.

Community Forums

- In 2003, ARA proudly entered into partnerships with other ASO to co-sponsor community forums. In January, ARA and **Being Alive** co-sponsored one such forum featuring **Dr. Jon Kaiser**, who covered his approach to treating HIV and his study of micronutrients as treatment for peripheral neuropathy. Approximately 160 people were in attendance.
- In March, ARA's Medical Director **Dr. Stephen Brown** spoke about HIV vaccines to 150 people at a community forum sponsored by **UCLA** and **Being Alive**. Dr. Brown specifically addressed the preliminary results of the VaxGen study.
- ARA, **Being Alive** and **APLA** held their first of many co-sponsored community forums in October. This forum was an update of the 2003 ICAAC and IDSA conferences. The forum took place at the West Hollywood Park Auditorium and ARA was proud to host the satellite Spanish language forum in our conference room. This fruitful collaboration has continued into 2004 and ARA is proud to work with **Being Alive** and **APLA** to bring much-needed information to the community.

Women At Risk

On June 1, ARA was involved with the annual **Women at Risk** fundraiser at the **House of Blues**. Outreach Coordinator Michelle Simek represented ARA on the event planning committee which met for several months prior to the fundraiser. ARA proudly sponsored four HIV+ women to attend the event. ARA's logo was prominently displayed during the fundraiser which included a sumptuous brunch, an educational program by the clients of Women at Risk and gospel music.

Women's Caucus On HIV/AIDS, Los Angeles County

ARA continues to play a strong role in the **Women's Caucus on HIV/AIDS**, Los Angeles County. The mission of the Caucus is to empower women infected and affected by HIV/AIDS and is comprised of HIV+ women as well as women who work in the HIV/AIDS field. In 2003, ARA hosted several Caucus meetings in our conference room as the group planned its activities and ARA staff member Michelle Simek served as Secretary. In 2003, the Caucus was involved in strategic planning and a membership drive (*Currently, Michelle Simek is the interim Co-Chair of the Caucus. Her position is expected to last until the end of 2004.*)



**Volunteer Herminio Reyes
at the Concrete Blonde benefit.**



ARA's booth at CSW 2003.

Christopher Street West 2003

On June 21-22, ARA appeared once again at the **Christopher Street West (CSW)** gay pride celebration in West Hollywood Park. Our booth was staffed by a crew of dedicated ARA employees and volunteers, who set up and manned the booth, and distributed flyers about our enrolling studies, copies of our publications, event brochures, condoms, and ARA pens, chip-clips and t-shirts. Volunteers also spoke to CSW attendees about the Merck preventative vaccine study (*see related story on page 5*) and collected many names of potential study volunteers. (*For full coverage about CSW 2003, please see the Fall 2003 edition of Spotlight.*)

Concrete Blonde Benefit

On July 10, the alternative rock band **Concrete Blonde** headlined a benefit concert for ARA at the **Hotel Café** in Hollywood, increasing awareness about our research and raising over \$2,000 for ARA. The Hotel Café was standing room only, packed with ARA supporters and Concrete Blonde fans. (*For full coverage of the Concrete Blonde benefit, please see the Fall 2003 edition of Spotlight.*)

ARA In The Community

ARA was also represented at the following local and international events and coalitions:

- *The Global Fund to Fight AIDS, TB and Malaria*
- *Southern California HIV Advocacy Coalition (SCHAC)*
- *Activate U! (SCHAC)*
- *Being Alive Los Angeles/Being Alive Long Beach's Spring Fling*
- *South Bay AIDS Network*

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*"Your bounty is beyond my speaking;
But though my mouth be dumb,
my heart shall thank you."*

– Nicholas Rowe

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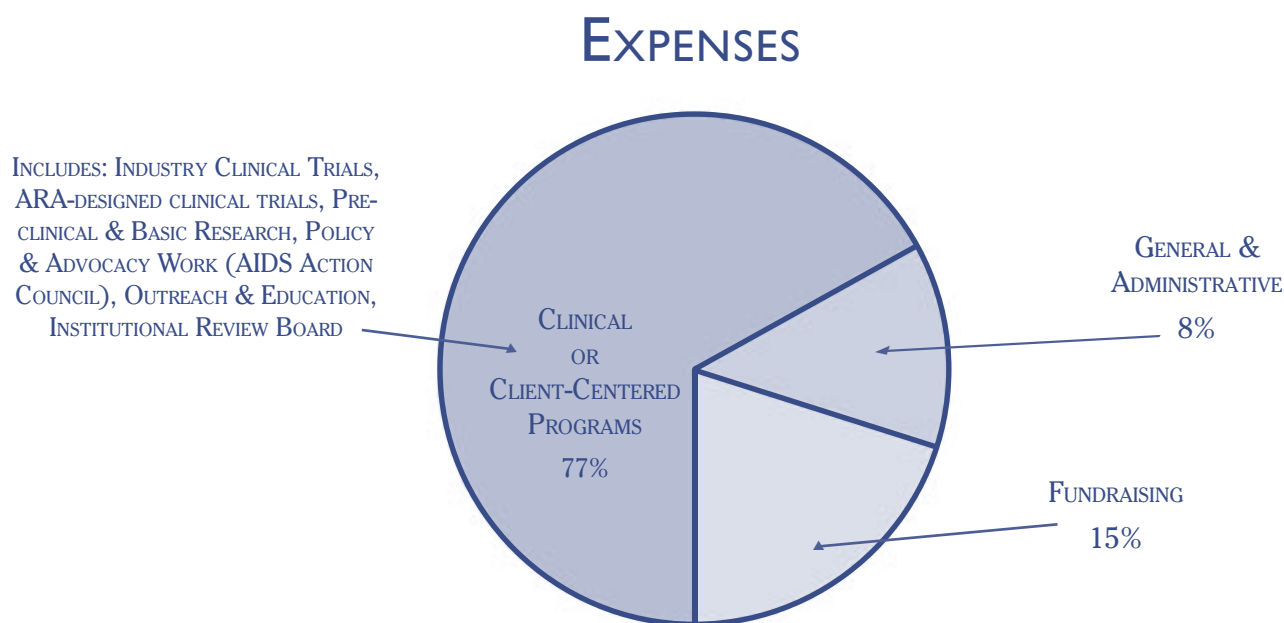
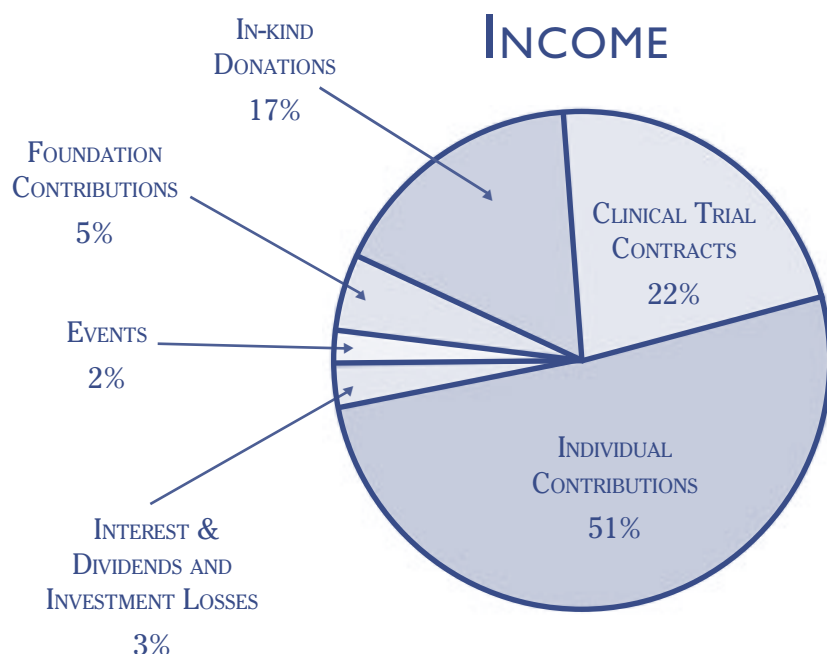
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*"To accomplish great things,
 we must not only act but also dream.
 Not only plan but also believe..."*

– Anatole France

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DESIGN & PRODUCTION:

Karen J. Wellenkamp

PRINTING:

Acuprint

PRINTED ON RECYCLED PAPER

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“The best scientist is open to experience
and begins with romance—
the idea that *anything* is possible.”

Ray Bradbury

“Nothing in life is to be feared.
It is only to be understood.”

Marie Curie

“Every great advance in science has issued
from a new audacity of imagination.”

John Dewey



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