Translating **science**
into **global** health impact

IAVI

Annual Report

2020

Letter from the CEO

Dear friends of IAVI,

My colleagues and I at IAVI are pleased that we were able to make significant progress in advancing our discovery and product development efforts across our research and development portfolio, and advanced global discussions on access to vaccines and antibody-based products despite the numerous challenges posed by the COVID-19 pandemic. I am deeply grateful to all of our colleagues and partners who worked through difficult circumstances to enable us to make important advances.

Over the past years, IAVI scientists have built on decades of research on HIV in Africa to characterize broadly neutralizing antibodies (bnAbs) that develop in some people after infection. Researchers are now designing sequential immunogens to trigger bnAb development in a stepwise fashion, starting with the activation of B cells expressing germline receptors from which specific bnAbs ultimately arise. At a 2020 scientific meeting, IAVI/Scripps Research scientist William Schief presented promising results from a Phase I trial (IAVI G001) that, for the first time, validate this "germline-targeting" vaccine approach. The results have renewed optimism that a pathway to rationally design effective HIV vaccines is feasible.

IAVI and partners are now poised to begin clinical studies of HIV immunogens intended to initiate and shape the development of bnAbs. These immunogens will be delivered by recently validated mRNA vaccine approaches in hopes of establishing a rapid, iterative approach to accelerate vaccine design and evaluation, in partnership with Moderna, the Bill & Melinda Gates Foundation, and the U.S. Agency for International Development (USAID).

Several IAVI Phase I clinical trials are evaluating other aspects of this sequential HIV vaccine approach, including IAVI C101, which vaccinated its first volunteer in October.

Results from the Antibody-Mediated Prevention trials validated continued research into using bnAbs for HIV prevention. IAVI, the Serum Institute of India, and the Vaccine Research Center of the U.S. National Institute for Allergy and Infectious Diseases continue to collaboratively develop bnAbs with characteristics to increase their accessibility to target populations, with important support provided by the President's Emergency Plan for AIDS Relief and USAID.

Our publication of the Global Call to Action on Monoclonal Antibodies in August 2020, in partnership with Wellcome, advocates for a creative approach to product development and to partnerships to enable global access to tools for solving health inequities. We tied the call to action to a comprehensive outreach and engagement plan to support access to new HIV prevention technologies and other biomedical tools.

The 2019 formal renewal of USAID's support to our core HIV program led us in 2020 to develop a refocused vision for the future and strategic six-year work plan for the ADVANCE Program, including hiring new leadership to promote African research and empower African scientists.

Our core HIV R&D program also enabled IAVI's ability to rapidly respond to the COVID-19 pandemic with the initiation of innovative vaccine and monoclonal antibody development programs. In February 2020, IAVI scientists began applying one of our HIV vaccine technologies — recombinant vesicular stomatitis virus (rVSV) as a vaccine vector — to COVID-19. After we partnered with Merck (known as MSD outside the U.S. and Canada), a clinical trial of this vaccine candidate administered intramuscularly began in October. While results from this trial were disappointing, we continue to explore alternate routes of administration, especially those that elicit protective immune responses at mucosal surfaces where the virus establishes initial infection. In parallel with the COVID-19 vaccine work, scientists at IAVI's Neutralizing Antibody Center at Scripps Research, in close partnership with Scripps and UC San Diego colleagues, helped identify potent neutralizing antibodies from recovered COVID-19 patients. This portfolio of antibodies is the foundation of a comprehensive program with potential application to COVID-19 research and to new coronaviruses that may arise.

We have also continued to expand the rVSV platform to other emerging infectious diseases. Prior investment by funders and support from new funders such as CEPI and the European and Developing Countries Trial Partnership is allowing us to advance vaccine candidates while also strengthening capacity at clinical research centers across Africa. New funding achieved in 2020 guarantees development to Phase II of the Lassa fever vaccine candidate and supports continued research on the Marburg virus disease vaccine candidate.

Our support for TB vaccine clinical results has continued unabated through the year, with IAVI deeply involved in three clinical trials of promising TB vaccine candidates.

This progress would not have been possible without your support, partnership and passion for global public health and equitable access. Thank you so very much.

Best regards,

Mark Feinberg, M.D., Ph.D.
President and CEO

About IAVI

IAVI is a nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges including HIV, tuberculosis (TB), and emerging infectious diseases. Our mission is to translate scientific discoveries into affordable, globally accessible public health solutions. In 2020, we extended our decades of experience in HIV toward vaccine development and antibody discovery efforts for the COVID-19 pandemic. Those efforts continue in tandem with our mission-critical activities. Defeating COVID-19 will likely require multiple vaccines and treatments and most certainly will benefit from the kinds of global collaborations in which IAVI excels.

At the heart of IAVI's working model is deep expertise in convening public, private, and community partners to accelerate development of new candidates in areas where the need is greatest and there is no traditional market incentive. Together, we're advancing the next generation of vaccines and long-lasting injectable antibodies to prevent HIV infection and conducting clinical trials of promising TB vaccine candidates in partnership with high-burden communities. We apply our HIV expertise to develop cheaper, safer, more potent antibody products that target venoms of medically important snakes in India and Africa as well as vaccines for emerging infectious diseases that pose bioterror threats. And we help other product developers avert the "valley of death" so today's laboratory concepts become tomorrow's public health solutions.

IAVI is headquartered in New York City, with offices in six countries and four laboratories across the world. Supported by a longstanding partnership with the U.S. Agency for International Development through the U.S. President's Emergency Plan for AIDS Relief, we also collaborate with a robust network of clinical research center partners at leading academic institutions in sub-Saharan Africa.

Whether studying epidemics at the community level, innovating against new outbreaks, understanding local barriers to effective treatment, or working with governments to support optimal health policies and access, we foster lasting partnerships to transform lives and communities.

Our mission

To translate scientific discoveries into affordable, globally accessible public health solutions

Our vision

A world where all people have equitable access to innovative vaccines and therapeutics

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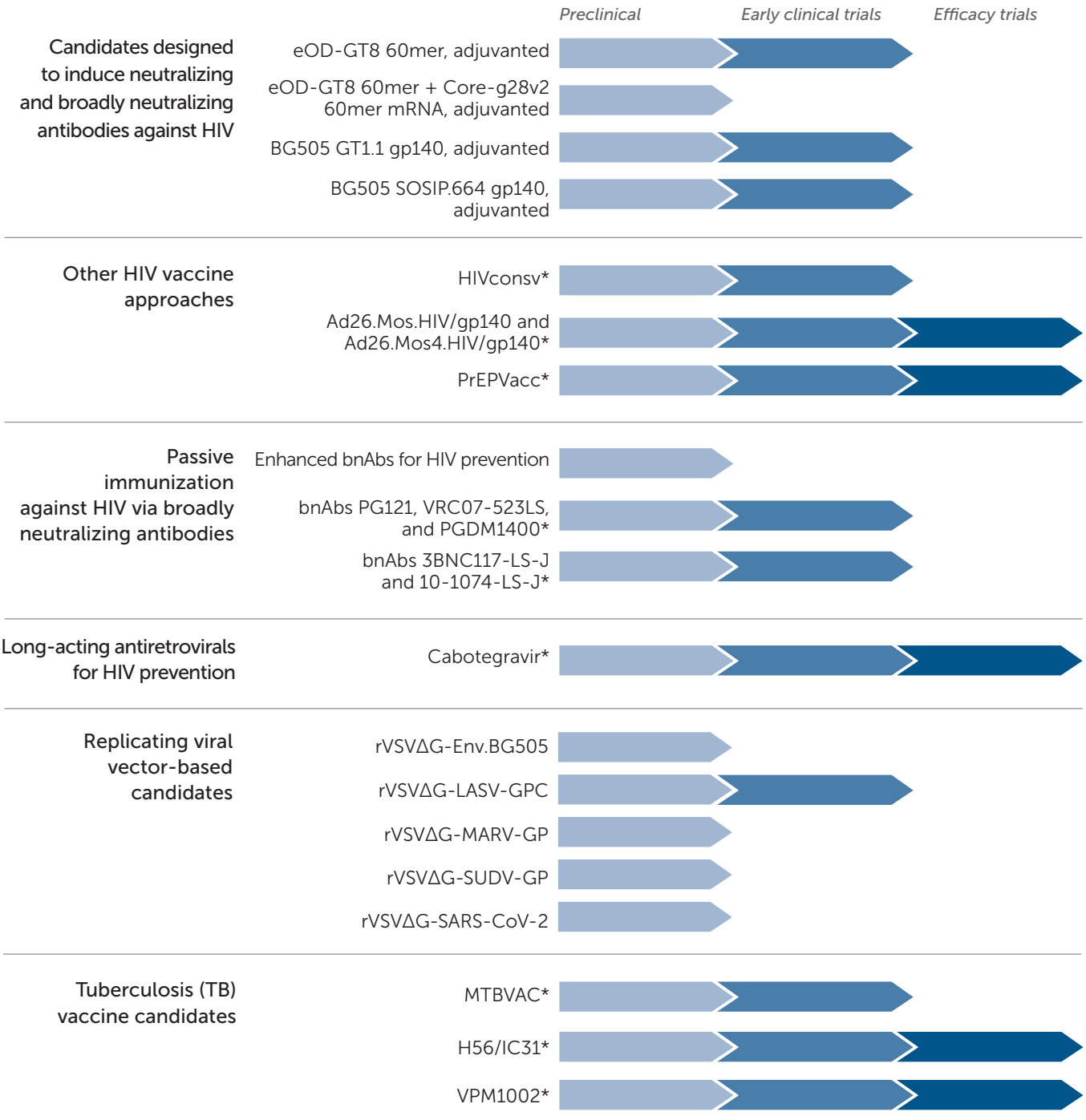
Pipeline

IAVI, in collaboration with partners in the public, private, and philanthropic sectors, develops vaccines and antibodies to address urgent, unmet global health challenges including HIV and tuberculosis. IAVI and its partners conduct and support preclinical work and clinical trials for vaccine and antibody candidates, as well as a long-acting antiretroviral for HIV prevention. Below is the pipeline as of August 2021. For the most updated version, go to www.iavi.org/our-science/pipeline.



* Includes third party candidates under development where IAVI is providing translational and/or clinical development support.

Our track record

Accelerate vaccine research with a pipeline of novel vaccine approaches and the development of new tools and technologies

29
HIV vaccine candidates advanced to clinical trials across 11 countries, with first ever Phase I trials in Kenya, Rwanda, Zambia, India, and Germany.

59
Epidemiology studies conducted that informed the design of HIV vaccine efficacy trials, improving future accessibility and acceptability of final product.

24
Potent and broad HIV neutralizing antibodies, identified from 2,300 samples collected from people living with HIV, are currently being used in research for vaccine design and other prevention treatment. Three IAVI isolated antibodies are being used in clinical studies.

4
IAVI-sponsored replicating VSV vector candidates advanced in novel portfolio toward clinical development (rVSV-HIV, rVSV-Marburg, rVSV-Lassa, rVSV-SARS-CoV-2).

1,222
Vaccine and epidemiology samples stored in an open access data warehouse maximize scientific advances.

Strengthen scientific leadership and collaboration for vaccine research and development and future access

40
Clinical research partners in Africa and India, including 11 state-of-the-art clinical research center partners with 12 GCLP-accredited laboratories capable of conducting clinical research at international standards.

832
Scientists in LMICs trained in GCP and GCLP to international standards for conducting clinical trials (2018 – 2020).

98.9%
Overall retention rate of HIV vaccine trial participants with an average of 53.8% participation by women, improving gender balance to garner research insights in communities most at risk.

80
Scientific papers published by IAVI and partners in 2020: 29 LMIC-led (36%); 44 female-led (55%), and 70 (88%) are open access.

42
Students and researchers furthered their HIV-related work: 20 early stage scientists supported with research grants; 42 students supported by the International Training Program. In 2020, 11 students were ongoing.

Work in partnership for continued support for HIV research and development

190
Partners from academia, biotechnology, and pharmaceutical sector, as well as civil society and global health initiatives.

40
Governments, foundations, and other donors, with work from across the globe on four continents.

45
Projects managed by the IAVI Product Development Center since its establishment in 2013, as an integrated platform to advance promising concepts from bench to clinic; 23 external investigators supported to date.

23
Phase I/II trials supported by IAVI's Product Development Center to assess external vaccine candidates and biologics.

Provide benefits for communities most impacted by HIV/AIDS

837,545
People in Africa received counseling services and health care referrals for treatment and care.

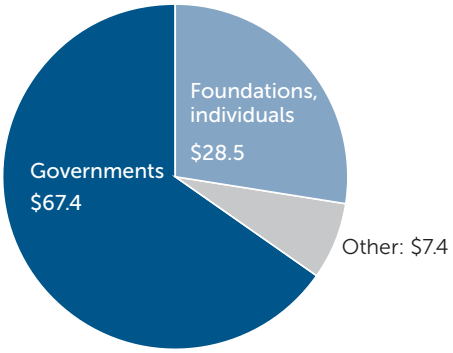
14
National and regional policies included HIV vaccine research, resulting in enhanced local ownership and an improved environment for research with at-risk populations.

2,400+
Volunteers enrolled in IAVI-sponsored HIV vaccine trials in Africa; more than 50,000 participants enrolled into epidemiology studies that not only helped HIV research, but also informed about other problems and health care issues relevant for each respective community.

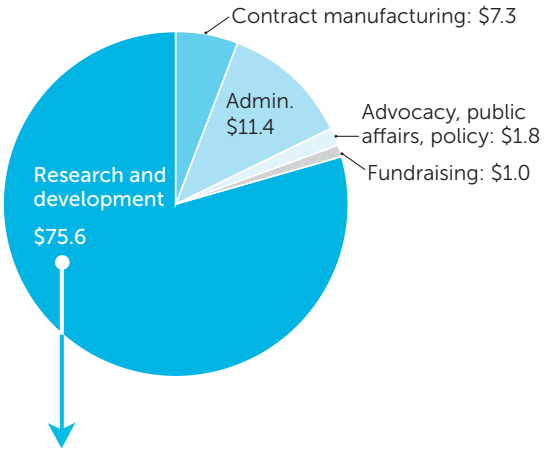
2020 financials

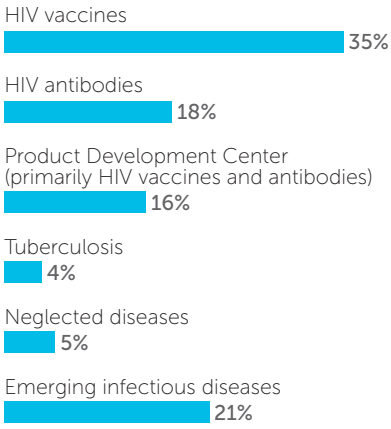
All figures in millions of U.S. dollars

	2019	2020
REVENUE		
Grants and contributions		
Governments	51.3	67.4
Foundations/individuals	35.0	28.5
Investment income and other	2.5	7.4
Total	**88.8**	**103.3**



EXPENSES		
Programs		
Research and development	63.4	75.6
Contract manufacturing – related activities	11.9	7.3
Vaccine advocacy, public affairs, and policy	2.3	1.8
Administration	9.9	11.4
Fundraising	1.3	1.0
Total	**88.8**	**97.1**





ASSETS		
Cash and investments	49.2	54.6
Grants & contracts receivables	23.8	27.0
Fixed assets	5.2	4.0
Other	0.5	0.7
Total Assets	**78.7**	**86.3**
Liabilities	37.3	44.1
Net assets	41.4	42.2
Total liabilities and net assets	**78.7**	**86.3**

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Donor acknowledgment

Thank you to all of our generous donors, whose support makes possible the advancement of research and clinical trials toward affordable, globally accessible public health solutions.

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PEPFAR U.S. President's Emergency Plan for AIDS Relief

USAID FROM THE AMERICAN PEOPLE

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And many other generous individuals and partners around the world

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iavi.org

GLOBAL HEADQUARTERS
125 Broad Street, New York, NY 10004
U.S.A.

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