Alzheimer's
Drug Discovery
Foundation

FROM

IDEA

TO IMPACT

2016
ANNUAL
REPORT

PAGE 7

Dr. Paul Newhouse | *Clinical Phase 1*
Dr. Newhouse and his colleague Dr. Rook are testing VU0467319, a drug that targets synapses and may prevent loss of cognitive function.

PAGE 8

Dr. Scott Turner | *Clinical Phase 2*
Dr. Turner's trial is using the cancer drug nilotinib, which has shown promise for treating Alzheimer's and many other neurodegenerative diseases.

PAGE 9

Dr. Michela Gallagher | *Clinical Phase 3*
Dr. Gallagher's drug, AGB 101, targets brain hyperactivity, an innovative approach that may slow or even prevent the onset of Alzheimer's disease.

"With $100 million invested in over 500 of the best ideas for Alzheimer's, our strategy is having an impact."

LETTER FROM OUR FOUNDERS

Dear Friends,

In 2016, we reached a remarkable milestone—$100 million invested in drugs to prevent and treat Alzheimer's disease.

When we founded the Alzheimer's Drug Discovery Foundation in 1998, there weren't many drugs being developed for this disease. We set out to change that.

Our strategy was to identify promising ideas to prevent and treat Alzheimer's, and then support the pioneering researchers who could pursue them. From the beginning, we offered funding globally to researchers working in academia and the biotechnology industry, because we never wanted to say no to a potential cure.

Today, with $100 million invested in over 500 of the best ideas for Alzheimer's, our strategy is having an impact. There are more treatments in clinical trials—the final stages of a drug's development—than ever before. The ADDF has supported over 20% of them, which is more than any other charity.

The generosity of our fellow Board members and all of the ADDF's donors ensures that the best ideas to treat Alzheimer's will make it into the hands of patients.

Together we will conquer Alzheimer's disease.

With our deepest thanks,

LEONARD A. LAUDER
Co-Chairman and Co-Founder

RONALD S. LAUDER
Co-Chairman and Co-Founder

"Our strategic investments have resulted in a diverse portfolio of drugs in clinical trials, which increases our chances of success."

THESE TARGETS ARE ONLY A FEW OF THE INNOVATIVE APPROACHES WE ARE ADVANCING

INFLAMMATION
Chronic inflammation in the brain can accelerate Alzheimer's, and may be a trigger for the disease. Scientists are developing drugs that protect against damage while preserving normal inflammatory responses.

NEUROPROTECTION
As Alzheimer's progresses, neurons begin to die, causing loss of memory and other cognitive functions. Neuroprotective drugs seek to shield these brain cells from damage and death.

NEUROTRANSMITTERS
As we age, certain cognitive functions decline, a process known as cognitive aging. Researchers are exploring several strategies to improve cognitive function, such as enhancing neurotransmitters and synaptic function.

MISFOLDED PROTEINS
In neurodegenerative diseases, misfolded proteins such as beta-amyloid, TDP-43, and tau accumulate, causing damage to brain cells. Scientists are pursuing several approaches to prevent or clear these toxic protein accumulations.

GENETICS & EPIGENETICS
APOE4 is the most significant genetic risk factor for late-onset Alzheimer's disease. New therapies may modify this risk as well as alter how certain genes are expressed (i.e., epigenetics).

LETTER FROM OUR EXECUTIVE DIRECTOR

Dear Friends,

This was an important year for the clinical development of Alzheimer's treatments. There were some high-profile failures, including Eli Lilly's aducanumab. But there were many more success stories, as promising drugs kept advancing.

In 2016, the Alzheimer's Drug Discovery Foundation invested over $16 million to fund 46 new drug programs. And for the first time in our history, we spent the majority of that annual investment on clinical trials.

The programs the ADDF supports are innovative. Most pharmaceutical companies have focused exclusively on anti-amyloid drugs, but the ADDF chose to follow another path. We know that aging is leading risk factor for Alzheimer's disease. And the drug programs we support are based on the biology of aging, with targets including inflammation, neuroprotection, and epigenetics.

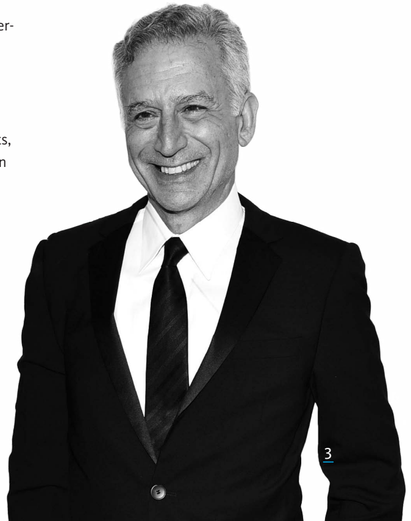
Our strategic investments have resulted in a diverse portfolio of drugs in clinical trials, which increases our chances of success. This is important because we believe that Alzheimer's is going to require a combination of drugs to effectively treat it, like heart disease or diabetes.

In 2016, our portfolio included 20 programs in clinical trials. Among them is a first-in-class drug targeting a critical pathway involved in cognition being developed at Vanderbilt University (featured on page 7), which just entered Phase 1 trials thanks to ADDF funding. And at Georgetown University, Dr. R. Scott Turner is already recruiting patients for his Phase 2 trial of nilotinib, a drug originally developed for cancer that has shown great promise for treating Alzheimer's and other neurodegenerative diseases (see page 8).

It takes a lot of determination and resources to go from an idea to a drug that has a lasting impact on patients' lives. Thanks to the commitment of our funded scientists, donors, and partners, we are closer than we've ever been to conquering Alzheimer's disease.

Howard

HOWARD FILLIT, MD
Founding Executive Director and Chief Science Officer



TAKING A DRUG FROM IDEA TO IMPACT

THE PIPELINE

Developing a drug is not easy. It takes, on average, 12 years and $2 billion to go from an idea in the head of a scientist to a pill in the hands of a patient.

1 Target ID & Validation

The process begins by identifying what you want the drug to do, what "target" it needs to affect to slow or stop Alzheimer's disease.

2 Screening

From there, you screen thousands or even millions of chemical compounds to find a precious few that interact with the target the way you want.

3 Lead Discovery & Optimization

Now you use medicinal chemistry to develop each compound into an actual drug. It has to be able to cross the blood-brain barrier to reach the parts of the brain damaged in Alzheimer's, which is no easy feat. You keep improving the compounds until you've got just a few drugs you can use in preclinical testing.

4 Preclinical Testing

You've made some potential drugs and now need evidence of safety and effectiveness. You have to address any issues with side effects or interactions with targets other than the one you intended. What worked in a Petri dish may not work in an animal, and if it doesn't, you go back a few steps.

5 IND Application

If your drug appeared to work in preclinical tests, you can submit an Investigational New Drug (IND) application to the FDA and, if approved, finally move to human clinical trials.

6 Clinical Trials

Not every idea advances this far, but more and more of the programs the ADDF supports are reaching the clinic. Clinical trials happen in three phases, and those with good results in Phase 3 can apply for FDA approval.

In the following pages, we highlight drugs in the final stages of development, being tested in patients who need them.

IND APPLICATION

Dr. Leen Kawas / M3 Biotechnologies

Before researchers can begin clinical trials of a drug, they must submit an Investigational New Drug (IND) application to the FDA and be approved. The process is designed to make sure that any treatment being tested on people is reasonably safe.

Submitting an IND is mandatory and expensive, but very few funders are willing to support the process. At the ADDF, we understand that every step in getting a drug closer to patients is important. Last year, we awarded $1.4 million to M3 Biotechnologies to complete its IND application and, if approved, advance to a Phase 1a clinical trial.

M3's founder, Dr. Leen Kawas, remarks: "M3 has one goal in mind—get an effective Alzheimer's drug into the hands of patients who need it. Thanks to this funding, we are one step closer."

Dr. Kawas has developed a small-molecule drug with the potential to restore cognitive function in Alzheimer's patients. The drug, NDX-1017, activates a specific type of neurotrophic growth factor in the brain. These growth factors help neurons survive, which could dramatically slow the progression of Alzheimer's disease.

CLINICAL PHASE 1

Dr. Paul Newhouse and Dr. Jerri Rook / Vanderbilt University

In Phase 1 clinical trials, a drug is tested in people for the first time. These early-stage trials evaluate a drug's safety and potential side effects and try to determine the optimal dose. These trials are short, involve a small number of (often healthy) people, and cost an average of $4 million[1] in Alzheimer's and other neurological diseases.

In 2016, we awarded $1.27 million to Paul Newhouse, MD and Jerri Rook, PhD at Vanderbilt University to support a Phase 1 trial of their drug, VU0467319. We began funding this program in 2011, when it was just an idea for a drug.

Dr. Newhouse explains: "One of the most gratifying parts of this research is making it to the clinic. After years and years of development, you finally have a drug and can give it to people. The ADDF's funding was instrumental in getting VU0467319 to this point."

VU0467319 targets synapses, the spaces where signals pass between our brain cells. Current drugs for Alzheimer's disease increase levels of a transmitter that carries the signals, but these only alleviate symptoms temporarily. VU0467319 instead focuses on a synaptic receptor, called M1, which "catches" those signals. Previous drugs targeting M1 failed due to negative side effects. With ADDF funding, Dr. Newhouse and Dr. Rook tried a different approach to M1, which appears to alleviate symptoms and prevent losses in cognitive function without the side effects.

After this trial, they will know whether their drug is safe enough to be tested in Alzheimer's patients.

[1] *https://aspe.hhs.gov/report/examination-clinical-trial-costs-and-barriers-drug-development*

CLINICAL PHASE 2

Dr. R. Scott Turner / Georgetown University Medical Center

In Phase 2 trials, drugs are tested for effectiveness. If earlier trials proved that the drug was safe, it can then be given to small groups of patients. In this stage, researchers evaluate whether the drug affects its target and if that helps slow or stop the disease.

The cost of a Phase 2 trial can range from a few million to tens of millions of dollars, depending on its scope and duration. These costs include manufacturing the drug and placebo, recruiting and reimbursing patient volunteers, and performing diagnostic tests, (e.g., PET scans, MRIs, blood tests), as well as covering physician, nurse, and administrative staff time, study site fees, and data collection and analysis.

In 2016, we made a $2.1 million grant to R. Scott Turner, MD, PhD, of Georgetown University Medical Center to test whether a cancer drug could be repurposed to treat Alzheimer's disease. Dr. Turner and his colleagues are planning a trial of low-dose nilotinib—a drug already FDA-approved for leukemia. Earlier research at Georgetown found that nilotinib triggers a process (called autophagy) that clears out toxic protein aggregates, including tau and beta-amyloid, from neurons in the brain. By repurposing an already approved drug, the team used available safety data, including completed Phase 1 studies, to markedly accelerate the drug discovery process.

Dr. Turner and his colleagues are already recruiting patient volunteers in the Washington, D.C. area. If they find evidence of effectiveness in this trial, the next step is a larger Phase 3 trial conducted at multiple research sites across the country.

CLINICAL PHASE 3

Dr. Michela Gallagher / Agenebio

If a Phase 2 trial finds evidence that a drug is effective, it can move ahead to phase 3 clinical trials. Very few drugs have made it this far in Alzheimer's, though the ADDF's investments are changing that.

Phase 3 trials can cost hundreds of millions of dollars, involve thousands of patients, and last five years or more. Because of the cost and complexity, many late-stage drug trials are supported by pharmaceutical companies and governments.

AGB 101—a drug developed by Dr. Michela Gallagher at Agenebio that we first funded in 2010—is now planning Phase 3 trials. To accelerate this process, the ADDF has committed funding to Agenebio to formulate an extended release daily pill at the effective dose found in an earlier stage trial.

Most Alzheimer's drugs that have advanced to phase 3 trials in recent years have all had the same target—beta-amyloid. And so far, all have failed. But we are optimistic. AGB 101 is targeting brain hyperactivity, an innovative approach that has shown a lot of potential to slow the progression of mild cognitive impairment (MCI) to Alzheimer's disease. There are currently no treatments approved for MCI, and AGB 101 may slow this early stage enough that patients never develop clinical Alzheimer's.

Cognitive Vitality

BUILDING A PREVENTION BLUEPRINT

Alzheimer's prevention is a critical part of our mission. In 2016, we launched a new and expanded **CognitiveVitality.org.** The streamlined, easy-to-navigate site provides credible, science-backed information on ways to improve brain health and prevent dementia.

CognitiveVitality.org features clear, unbiased ratings on food and drinks, drugs, and vitamins and supplements that may benefit the brain. The site also features a blog with in-depth articles on potential risks, lifestyle factors, and emerging science.

The neuroscientists behind **CognitiveVitality.org** constantly review new research, which they use to update the site and inform our efforts to advance effective drugs for Alzheimer's disease. Over the next year, we plan to build on what we've learned and push the field forward by funding more studies in prevention.

BRINGING GREAT MINDS TOGETHER

Each year, the Alzheimer's Drug Discovery Foundation organizes several conferences to increase the number of researchers working on Alzheimer's drugs and support those already in the field.

In February, we hosted **NEW YORK CITY DRUG DISCOVERY: AN EDUCATIONAL COURSE ON TRANSLATING RESEARCH INTO DRUGS.** This one-day session helped to foster the city's growing biotechnology sector and provided a drug discovery primer to local academic scientists.

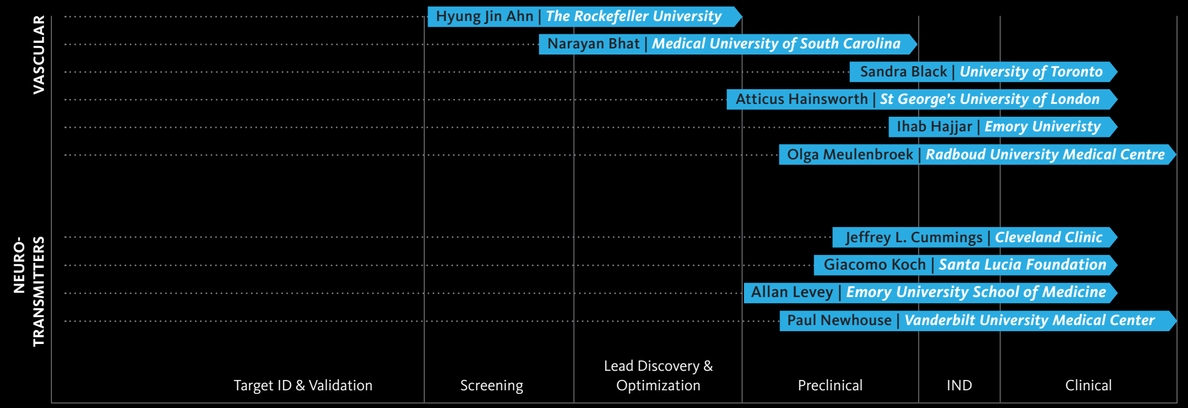
A month later, we convened the **10TH DRUG DISCOVERY FOR NEURODEGENERATION CONFERENCE** in Miami, FL. It is designed as an educational course and delves into the process of creating a drug. Sessions covered how to obtain funding and get started, overcome challenges in pharmacology and medical chemistry, create clinical drug candidates, navigate the FDA, and commercialize an approved drug. Representatives from biotechnology companies shared case studies and Voyager Therapeutics' Steven Paul, MD delivered a powerful keynote: "Gene Therapy Strategies for Treating or Preventing Alzheimer's Disease and Related Neurodegenerative Disorders."

In May, we brought the **DRUG DISCOVERY FOR NEURODEGENERATION CONFERENCE** to Europe for the first time. This iteration, which was held in Budapest, focused on drug discovery challenges unique to researchers working outside the U.S. and featured presenters from leading European universities, pharmaceutical companies, and biotechs, including AbbVie and Oryzon Genomics.

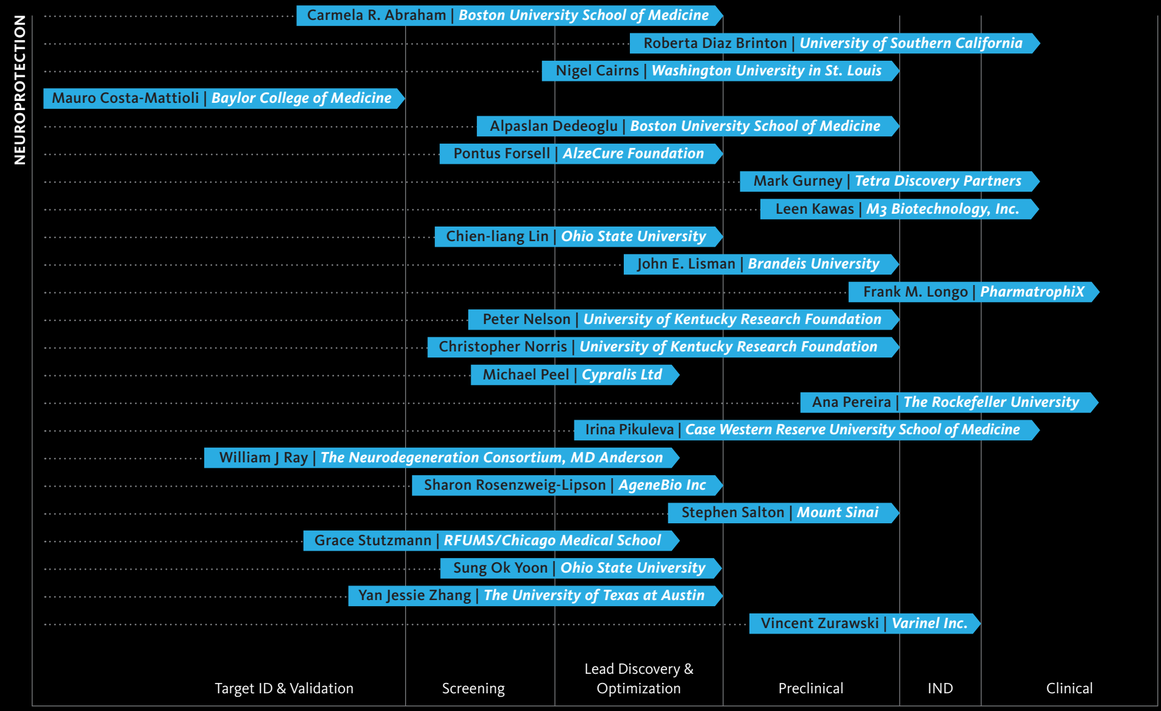
Our final conference was also our largest. We welcomed researchers to Jersey City, NJ, in September for our **17TH INTERNATIONAL CONFERENCE ON ALZHEIMER'S DRUG DISCOVERY.** This year's conference focused on two pioneering approaches to treating Alzheimer's: inflammation and neuroprotection. We also devoted a full day to sessions on clinical trials. The ADDF is uniquely positioned to offer such an innovative program because we have supported more Alzheimer's clinical trials than any other nonprofit and began funding fresh approaches over a decade ago. An attendee noted that we presented "new Alzheimer's disease targets long before 'big pharma' tackles them."

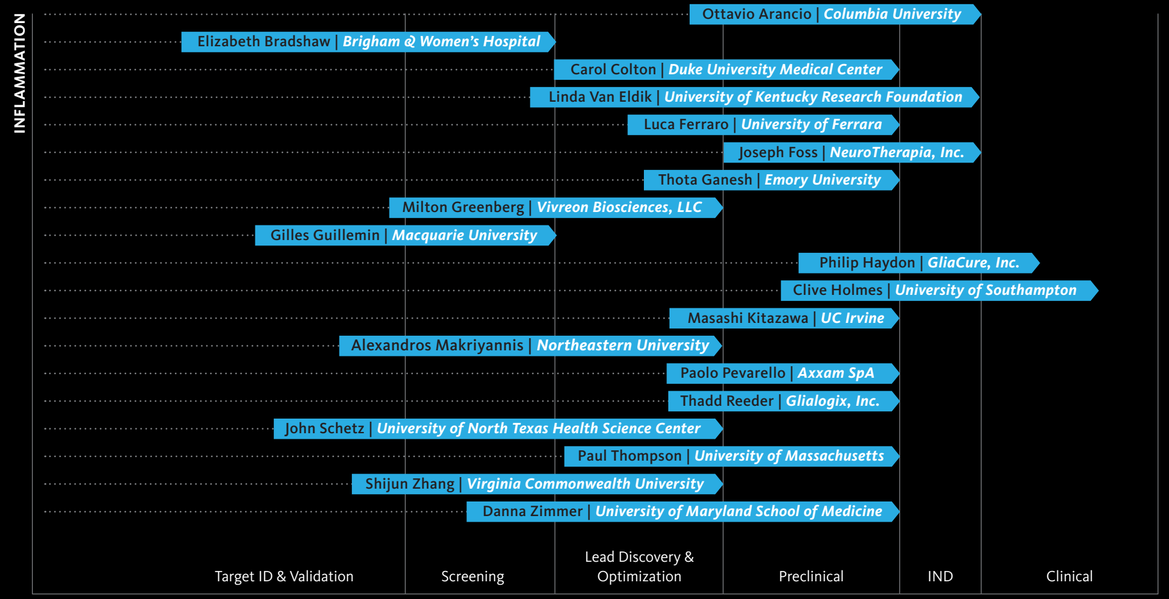
OUR PORTFOLIO

New & Ongoing Programs in 2016

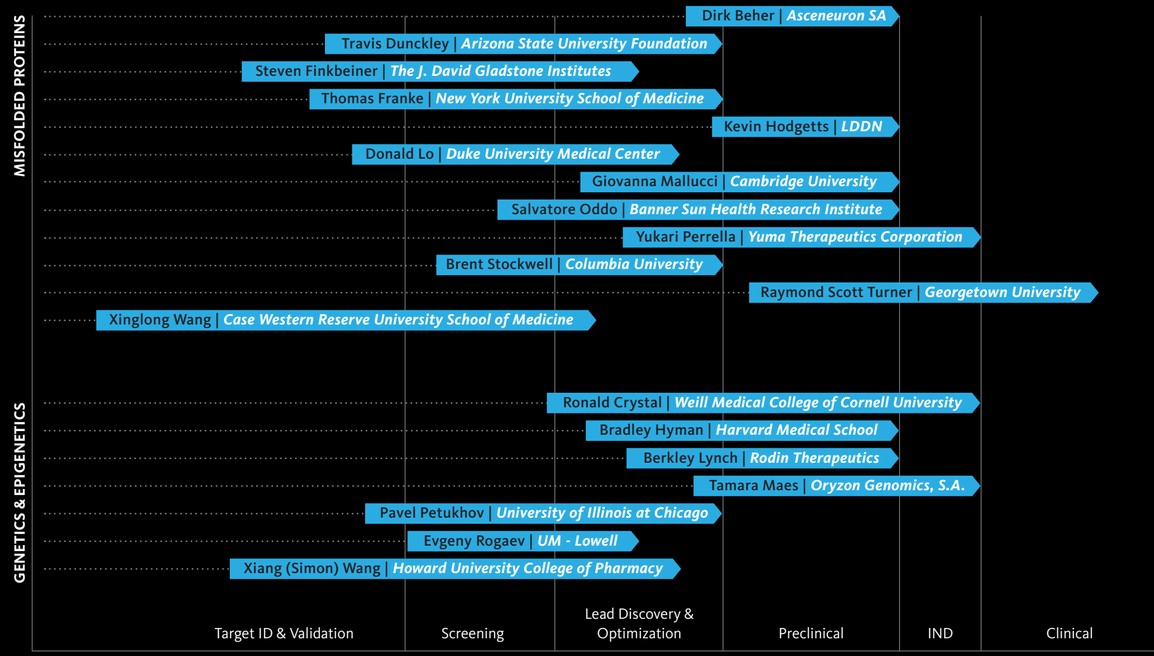


**Arrow points to stage of funding in 2016; length of arrow not indicative of duration of funding.*

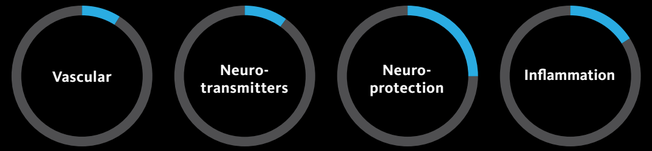


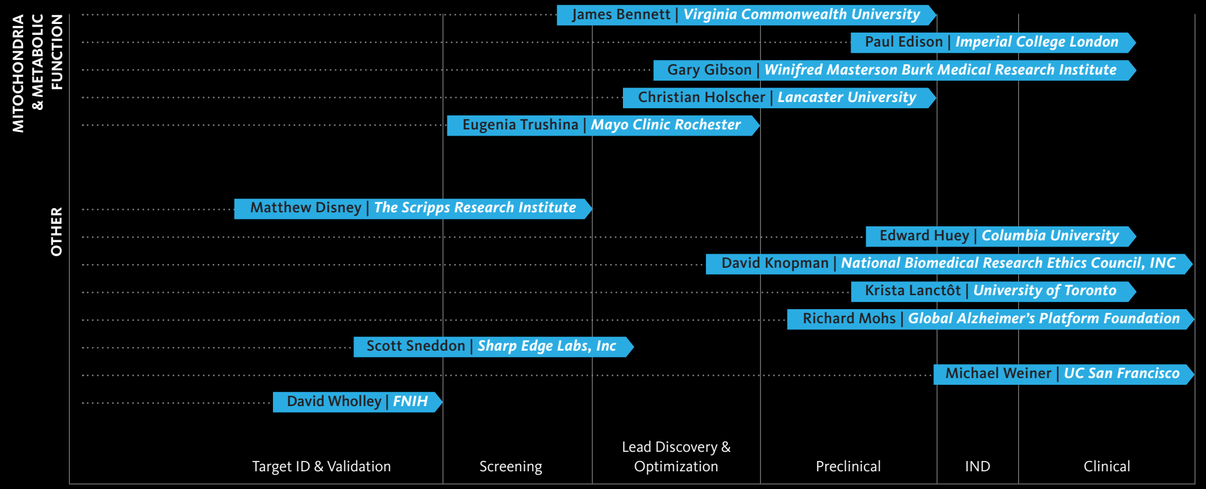


*Arrow points to stage of funding in 2016; length of arrow not indicative of duration of funding.



PORTFOLIO BY PERCENTAGE





**Arrow points to stage of funding in 2016; length of arrow not indicative of duration of funding.*

BIOMARKERS: *These tools assess the presence and progress of disease and are critical for conducting clinical trials.*

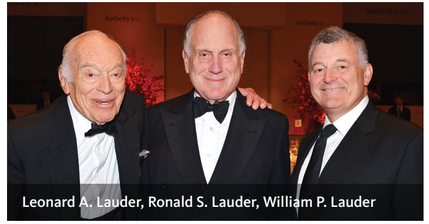
Adam Boxer | *University of California, San Francisco*
Mari DeMarco | *University of British Columbia*
Steven Estus | *University of Kentucky Research Foundation*
Els Fieremans | *New York University School of Medicine*
Massimo Filippi | *Fondazione Centro San Raffaele*
Sam Gandy | *Mount Sinai*
Lawrence Honig | *Columbia University*
Jacob Hooker | *Massachusetts General Hospital*
Sharon Inouye | *Hebrew SeniorLife*
Daniel Javitt | *Columbia University Medical Center*
Michelle Mielke | *Mayo Clinic Rochester*
Gerard Nuovo | *Gnome Diagnostics, LLC.*
Ashish Raj | *BrainWire LLC*
Blaine Roberts | *Howard Florey Institute*
Keith St. Lawrence | *Lawson Health Research Institute*
Charlotte Teunissen | *VU University Medical Center*
Neil Vasdev | *Massachusetts General Hospital*
Dominic M. Walsh | *Brigham & Women's Hospital*
Peter Working | *Alzeca Biosciences*
Ying Wu | *NorthShore University HealthSystem Research Institute*

PREVENTION: *These investments include comparative effectiveness and clinical research of prevention strategies.*

Deborah Blacker | *Harvard Medical School*
Marek Brzezinski | *UC San Francisco*
Lenore Launer | *National Institute on Aging*
Nathalie Pochet | *Brigham & Women's Hospital*
Galit Weinstein | *Boston University School of Medicine*

EVENT HIGHLIGHTS

In 2016, we celebrated leaders in Alzheimer's philanthropy and research. We thank everyone who came together and supported our events.

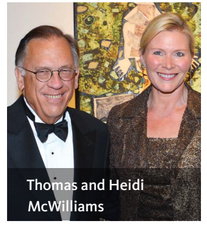

Leonard A. Lauder, Ronald S. Lauder, William P. Lauder

Tenth Annual

CONNOISSEUR'S DINNER

Our annual gala on April 28, 2016, in New York City honored Ronald S. Lauder for his leadership. The evening featured an exclusive art preview and wine pairings presented by Sotheby's.


Eleanora Kennedy, Judy Glickman Lauder, Sheila J. Robbins, Sharon Sager


Thomas and Heidi McWilliams


Jo Carole Lauder, Laurie Tritsch, Ronald S. Lauder

Sixth Annual

GREAT LADIES LUNCHEON & FASHION SHOW

On April 13, 2016, we gathered in Washington, D.C. to honor Trish and George Vradenburg. Trish sadly passed away in 2017, but we remain committed to continuing her important work.


Elise and Marc Lefkowitz, Sheila C. Johnson, Martha Slagle

Trish and George Vradenburg, Nancy Goodes

Second Annual

GOODES PRIZE

We were proud to present the 2016 Goodes Prize to Daniel Martin Watterson, PhD on September 22 in New York City, for his discovery and development of novel therapies for Alzheimer's.


Dr. Daniel Martin Watterson, Nancy Goodes, Dr. Howard Fillit, Michelle MacDonald, Melanie Caceres, David Goodes


Stephen Toma, Randal Sandler


Leonard A. Lauder, Donald Newhouse

Seventh Annual

FALL SYMPOSIUM & LUNCHEON

Hosted by Paula Zahn, our luncheon on November 14, 2016, in New York honored philanthropist and President of Advance Publications, Inc., Donald E. Newhouse.


Paula Zahn


George Krupp, Leana Krupp, Liz Krupp


Gregor Medinger and Gary Lauder

OUR SUPPORTERS

We are deeply grateful to all those who supported our work in 2016. Your generosity gives us hope for a future without Alzheimer's disease.

$500,000 and above

Anonymous
Association for Frontotemporal Degeneration*
Judy and Leonard A. Lauder*
Jo Carole and Ronald S. Lauder*
The Lauder Foundation
Susan and Thomas Lowder*

$250,000–$499,000

Anonymous
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Nancy and Melvin R. Goodes
Carolyn and Malcolm Wiener

$100,000–$249,999

Caroline Fitzgibbons and Tad Smith
Roslyn Goldstein
Frances and Nathan Kirsh
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Lady Lynn Forester de Rothschild and Sir Evelyn de Rothschild
Lizabeth Furman Sandler and Randal Sandler
Charles and Helen Schwab Foundation
Joan Sutton Straus

$50,000–$99,999

Helen and Robert Appel
Renée and Robert Belfer
Blavatnik Family Foundation
The Chisholm Foundation
Joyce Cowin
Laurie Dowley and Cynthia Breen
Marlene Hess and James Zirin
A.P. Kirby, Jr. Foundation, Inc.
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Elise and Marc Lefkowitz
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Sharon and Robert Prince
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Yosun and Olivier Reza
Nathan E. Saint-Amand
Pam and Allen B. Swerdlick
Ann and Andrew Tisch
The Toma Family
Wendy Wilshin and Ronald Dickerman

$25,000–$49,999

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Rose Marie Bravo and William Jackey
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Caryn J. Clayman
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Ernst & Young LLP
Marilyn and Sam Fox
Georgia Melenikiotou-Garinois and Philippe Garinois
Julie and Philip Geier
Kamila and Munib Islam
Harry P. Kamen
Howard T. Kaneff
Amy and Mitchell Kaneff
Laura and Gary Lauder
The Ralph and Ricky Lauren Family Foundation, Inc.
Bonnie Englebardt Lautenberg
Beatrice Liu and Philip Lovett
Susan Lloyd
Macy's Inc.
Nancy and Howard Marks
The Northern Trust Company
Nucor Construction Corp.
Pfizer Inc.
Michael and Catherine Podell
Ingeborg and Ira Rennert
Margaret Rice
Lois Robbins and Andrew Zaro
Edmond Safra
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Janet Prindle Seidler Foundation
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Tishman Speyer Properties, LP
Staples Business Advantage
The Starr Foundation
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Giselle Wagner and Paul Myerson
Carol and Michael Weisman

$10,000–$24,999

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Arcade Beauty
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The Margaret and Daniel Loeb–Third Point Foundation
Alice and Thomas Tisch
Barbara and Donald Tober
Lorraine Wallace
Jane Lauder and Kevin Warsh
Jan Willinger and Robert Spiegel
Paula Zahn
Alison and Boniface Zaino
Aerin and Eric Zinterhofer
Salvatore Zizza

$5,000–$9,999

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Judy Angelo
Mercedes T. Bass
Belk, Inc.
Tina and Simon Beriro
Alecia and William Blake
Faith Bobrow
Evelyn Brandt
Jill and Daniel Brigati
Bobbi Brown and Steven Plofker
Bettina and Donald Bryant
Lynda and F. Davis Camalier
Caplan Family Foundation Trust
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JoAnn and John Mason
Nina B. Matis
Bettye Musham
Pamela J. Newman
Laura and Richard Parsons
Kathleen and Michael Pierce
Phebe Farrow Port and Thomas David Port
Principal Building Services
Cobey and Robert Rapaport
Sharon and Daniel Roitman
Sheila J. Robbins
Rodin Therapeutics
Edith and Gerald Schaeffer
Finley and Patrick Shaw
Eileen Shields-West
The Shoreland Foundation
Alice Shure
Julie and David Silver
Marilyn and James Simons Charitable Fund
Jill and Sanford Sirulnick
Jean Kennedy Smith
Debbie and Craig Stapleton
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**multi-year pledge*

IN-KIND GIFTS

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Ann Hand LLC
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Darphin
Lab Series
dell'anima
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Feld Entertainment
Fiola Mare da Fabio Trabocchi
Gillies Coffee Company, Brooklyn, NY
Glorious Food
GODIVA Chocolatier
Tim Gunn
Hamilton Farm Golf Club
Brett Heyman
Oscar Heyman Brothers
KARMA by Erwin Gomez
Kendra Scott
Deborah M. Krulewitch
La Piquette
Bonnie E. Lautenberg
Elise Lefkowitz
Philip H. Lovett
Mary's Fish Camp
Monumental Sports Entertainment
Nancy Corzine
Neiman Marcus Mazza Gallerie
New York Nets, LLC
Oscar de la Renta
Rasika West End
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We remember advocates, caregivers, and patients we have lost by continuing to fight for a cure.

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2016 FINANCIAL OVERVIEW

STATEMENT OF FINANCIAL POSITION

ASSETS	2016	2015
Cash and cash equivalents	4,955,417	4,903,074
Investments, at fair value	23,862,266	20,649,664
Contributions receivable	16,433,336	4,962,392
Program related investments	–	536,800
Due from Institute for the Study of Aging	75,712	82,008
Other assets	**52,697**	**25,366**
Total assets	**$ 45,379,428**	**31,159,304**
LIABILITIES AND NET ASSETS		
Liabilities		
Accounts payable and accrued liabilities	7,818	100,536
Grants payable	21,761,264	13,504,012
Deferred revenue	19,350	3,680
Total liabilities	**21,788,432**	**13,608,228**
Total net assets	**23,590,996**	**17,551,076**
Total liabilities and net assets	**$ 45,379,428**	**31,159,304**

STATEMENT OF ACTIVITIES

CHANGE IN NET ASSETS	2016	2015
Support and Revenues		
Support		
Contributions and grants	$ 17,768,167	17,524,509
In-kind services and contributions		
Contributions of services from the Institute for the Study of Aging, Inc.	3,682,032	3,098,678
Contributions of advertising	–	440,200
Contributions of professional services	–	35,000
Proceeds from special events, net of direct expenses	4,038,612	3,590,294
Revenues		
Grant returns, net of payments	471,094	920,018
Conference registration fees and other income	194,269	335,118
Investment income	576,947	4,668
Foreign Currency Exchange (loss)	–	(23,025)
Total support and revenues	**26,731,121**	**25,925,460**
Expenses		
Program services	18,352,961	14,460,393
Fundraising	1,643,278	1,772,890
Management and general	694,962	469,614
Total expenses	**20,691,201**	**16,702,897**
Change in net assets	**6,039,920**	**9,222,563**
Net assets, beginning of year	**17,551,076**	**8,328,513**
Net assets, end of year	**$ 23,590,996**	**17,551,076**

** Preliminary draft of audited financials. Full audited 2016 financials available by request.*

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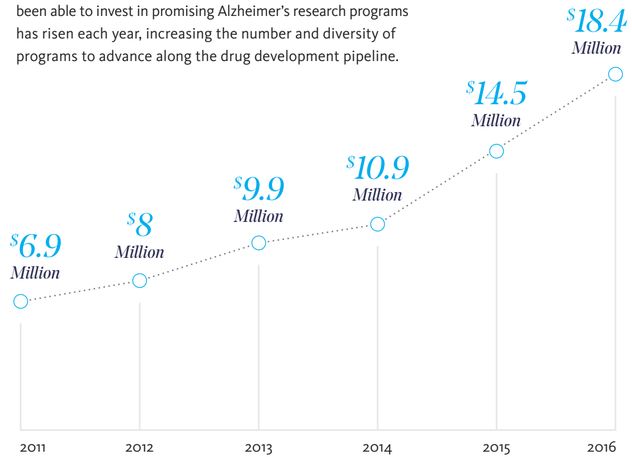

Alzheimer's
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Accelerating the Discovery of Drugs to
Prevent, Treat, and Cure Alzheimer's Disease

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