FROM IDEA TO IMPACT
2016 ANNUAL REPORT
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.

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.

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.”

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PAGE 8

PAGE 9

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.

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

LETTER FROM OUR FOUNDERS
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.

Howie Fillit, MD
Founding Executive Director and Chief Science Officer

INFLAMMATION
Chronic inflammation in the brain can accelerate Alzheimer’s, and may be a danger for the disease too. Fighting and developing drugs that protect against damage while preserving normal inflammatory responses.

NEUROPROTECTION
A 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.

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

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

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).

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

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.

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.

Not every idea advances this far, but more and more of the programs the ADVF 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.
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.

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 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” these 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.

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. 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.
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.

In February, we hosted NEW YORK CITY DRUG DISCOVERY: AN EDUCATIONAL COURSE ON TRANSLATING RESEARCH INTO DRUGS. This one-day seminar introduced the concept of the 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

### VASCULAR

- **Target ID & Validation**
  - Hyung Jin Ahn | The Rockefeller University
  - Narayan Bhat | Medical University of South Carolina
  - Sandra Black | University of Toronto
  - Atticus Hainsworth | St George's University of London
  - Ihab Hajjar | Emory University
  - Olga Meulenbroek | Radboud University Medical Centre
  - Jeffrey L. Cummings | Cleveland Clinic
  - Mauro Costa-Mattioli | Boston University School of Medicine
  - Carmela R. Abraham | Boston University School of Medicine
  - Robert D. Greenberg | UCI School of Medicine

- **Preclinical**
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  - Narayan Bhat | Medical University of South Carolina
  - Sandra Black | University of Toronto
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- **Steering Committee**
  - Robert D. Greenberg | UCI School of Medicine

### TRANSMITTERS

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*Arrows point to stage of funding in 2016; length of arrow not indicative of duration of funding.*
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PORTFOLIO BY PERCENTAGE

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

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

BIOMARKERS:

- **Vascular**: Tools assess the presence of vascular disease.
- **Neurotransmitters**: Assess the presence of neurodegenerative diseases.
- **Neuroprotection**: Tools focus on neuroprotection and repair.
- **Inflammation**: Tools target inflammation-related processes.
- **Misfolded Proteins**: Tools detect misfolded proteins in the brain.
- **Genetics & Epigenetics**: Tools investigate genetic and epigenetic changes.
- **Mitochondria & Metabolic Function**: Tools evaluate mitochondrial function and metabolism.
- **Other**: Includes a diverse set of tools.

**Other**

- **MITOCHONDRIA & METABOLIC FUNCTION**: Includes tools focusing on mitochondrial dysfunction.
- **INFLAMMATION**: Tools assess inflammatory processes.
- **MISFOLDED PROTEINS**: Tools detect and quantify misfolded proteins.
- **GEOGENETICS & EPIGENETICS**: Tools investigate genetic and epigenetic changes.
- **OTHER**: Includes a diverse set of tools.

**Lead Discovery & Validation**

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

**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.

**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.

**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.

**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.

**EVENT HIGHLIGHTS**

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

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

Thomas and Heidi McVilains

Ronald S. Lauder, Laurie Tritsch, Ronald S. Lauder

Jo Carole Lauder, Nancy Goodes, Dr. Howard Fillit, Michelle MacDonald, Melanie Caceres, David Goodes

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

Stephen Toma, Randal Sandler

Gregor Medinger and Gary Lauder

Ronald S. Lauder, horror of New York City, for his discovery and development of novel therapies for Alzheimer’s.
**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.

**multi-year pledge**

OUR SUPPORTERS

20 21

Frances and Nathan Kirsh
Roslyn Goldstein
Caroline Fitzgibbons and
$100,000–$249,999
Carolyn and Malcolm Wiener
Nancy and Melvin R. Goodes

$250,000–$499,000

The Lauder Foundation
Jo Carole and Ronald S. Lauder*
Judy and Leonard A. Lauder*
Anonymous

$500,000 and above

without Alzheimer’s disease.
gives us hope for a future
work in 2016. Your generosity
all those who supported our

We are deeply grateful to

Tad Smith

A.P. Kirby, Jr. Foundation, Inc.
Laurie Dowley and
Joyce Cowin
Blavatnik Family Foundation
Renée and Robert Belfer
Helen and Robert Appel

$50,000–$99,999

Joan Sutton Straus
Charles and Helen Schwab
Lizabeth Furman Sandler and
Lynn Forester de Rothschild
Phoebe and Edwin Rice
Sheila deWitt de Roth de Rothschild
Liz and George Krupp
Karyn and Stephen Khoury
Katie Kamen
Kestenbaum and Bay Foundation, Inc.
Judy and Henry Goldwyn
Emilia and Daniel S. Berenstain
Dina and Robert Salomon

$25,000–$49,999

Beatrice Liu and Philip Lovett
Ann Zimmerli-Haskel and
Patricia B. Sagon
Marilyn and Sam Fox
Cynthia Breen

$5,000–$9,999

Faith Bobrow
Alecia and William Blake
Kathleen Brandt

$100,000–$249,999

Carol Seabrook Boulanger
Randal Sandler
Rothschild and Sir Evelyn de Rothschild

$10,000–$24,999

The Estate Lauder Companies Inc.
The David A. and Mildred H. Morse Charitable Trust
Donors of the Alzheimer’s’ Association
Samuel J. Newhouse Foundation Inc.*
Phoebe and Reid Rice
Lady Lynn Forester de Rothschild and Sir Evelyn de Rothschild
Elizabeth Furman Sandler and Sir Evelyn de Rothschild

$1,000–$4,999

Jo Ann Ackerson
Sue Ann Weinberg
Douglas DiPasquale
Jennie and Richard DeScherer
Bonnie M. Davis, MD and
Kenneth L. Davis, MD

$100–$999

Annie and Joel Ehrenkranz
Colliers International
Carole Cooper and
Bonnie McDonald

$50–$99

Gail and Michael Schlein
Heidi and Martin Schlein

$25–$49

Lorna VanDyke

$10–$24

Wendy Wynn and
Ronald Dickerman

$5–$9

Catherine Fregelius
Trixi Gooden

*multi-year pledge

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The Estee Lauder Charitable Foundation
The Estee Lauder Companies Inc.
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Founding Executive Director and Chief Science Officer

The ADDF is led by two capable Boards who provide strategic vision, expert guidance, and a strong commitment to finding a cure for Alzheimer’s and related dementias.

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2016 FINANCIAL OVERVIEW

STATEMENT OF ACTIVITIES

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

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 16,459,336 6,962,392
Program related investments – 536,800
Due from Institute for the Study of Aging 77,712 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 21,799,432 13,608,228
Total net assets 33,580,996 17,551,076
Total liabilities and net assets $ 45,379,428 31,159,304

$6.9 Million
$8 Million
$9.9 Million
$10.9 Million
$14.5 Million
$18.4 Million

Thanks to the generosity of our supporters, the amount we’ve been able to invest in promising Alzheimer’s research programs has more than doubled each year, increasing the number and diversity of programs to advance along the drug development pipeline.

We’re proud to hold GuideStar’s highest charity rating.

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28
29

* Preliminary draft of audited financials. Full audited 2016 financials available by request.
Accelerating the Discovery of Drugs to Prevent, Treat, and Cure Alzheimer’s Disease

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