

ANNUAL REPORT 2018

WELCOME

"Shortly before the new year, I got a card in the mail. It was from a woman named Jessica in California, who has been an ER nurse for a decade, and has two small children. In her note, she wrote: "I contracted *C. diff* after the birth of my daughter. I lost 30 pounds, wasn't able to work or care for my newborn, and [was] on a vicious cycle of antibiotics. Ultimately, I had an FMT after 6 months of suffering."

Jessica isn't alone – about a half a million people contract *C. difficile* infections in the U.S. every year, and 1 in 5 patients find that the infection returns after a round of antibiotics. Each year, 30,000 people die from *C. difficile* infections. For patients who have tried antibiotics unsuccessfully two or more times, the options have been extremely limited. Now, when these infections don't respond to antibiotics, fecal microbiota transplants (or FMT) are standard of care.

Around the time that I received Jessica's card, we sent out our 30,000th FMT preparation to the network of hospitals and clinics that we support to offer this treatment to patients. By the end of the year, we had reached nearly 43,000. Around

the country, clinicians are working to bring this treatment to patients who have run out of options, and for whom an FMT can mean time back with their own loved ones. As Jessica put it, "my children have a healthy and happy mom thanks to you."

We launched in 2013 with two goals: to make sure that patients like Jessica have safe access to FMT, and to accelerate new discoveries on how to improve lives by changing the bacteria that live within us.

Inside each of us is a community of trillions of bacteria and other organisms that comprise the gut microbiome. In describing its significance, clinical researchers often compare the microbiome to a hidden organ – one that, like the brain or the heart, plays an intrinsic role in our bodies and our health. Just as there was urgency to make sure that we could address an immediate need for patients with *C. difficile*, we work with urgency to drive forward the pace of discoveries about how else we can engineer the microbiome to make people well again, or to prevent them from becoming sick in the first place.

I am thrilled to report on the progress we've made towards this vision in 2018, with highlights that include the launch of our research program in severe acute malnutrition, a pilot study of FMT in children for whom nutritional therapy alone is not enough, and the launch of an additional 8 research trials. We also welcomed Lisa Serwin as our new Board Chair, whose own experience as a *C. difficile* survivor and OpenBiome FMT recipient will help guide our mission to meet the needs of the patients we serve each day.

Thank you for engaging with us on this journey of service and discovery.



Carolyn Edelstein



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We are creating a new relationship between microbes and healthcare by exploring how bacteria keep us healthy as well as how they can be engineered to prevent and treat disease.



PATIENT TREATMENT

We believe that every C. difficile patient should have safe access to fecal microbiota transplantation (FMT)

As the incoming Chair of OpenBiome's Board of Directors, Lisa Serwin brings a unique perspective as both a healthcare executive and *C. difficile* survivor.

Over a 25+ year career, Lisa has led start-ups and established organizations in the healthcare, consumer product, and retail sectors. She has served as a CEO, CFO, COO, and is a recognized expert in healthcare technology.

In the summer of 2017, Lisa was diagnosed with *C. difficile*. After enduring three unsuccessful rounds of antibiotics, she received an FMT from OpenBiome that restored her health. The experience inspired her to join the organization. Becoming Board Chair in January 2019, she will help guide our mission: providing safe access to FMT.



BEFORE MY FMT, I WEIGHED 95 POUNDS AND HAD NOT REALLY BEEN ABLE TO EAT SOLID FOOD IN FOUR MONTHS.

THREE DAYS AFTER MY FMT, I WOKE UP AND STARTED TO SOB, TOTALLY OVERWHELMED BY THE SHEER SENSATION OF HUNGER.

MY HUSBAND, WHO HAD BEEN TAKING INCREDIBLE CARE OF ME THROUGHOUT MY ORDEAL, STARTED CRYING ALONG IN RELIEF. I LOOKED AT HIM AND SAID 'WE DON'T HAVE TIME TO CRY! WE NEED TO MAKE ME SOMETHING DELICIOUS TO EAT!'

SAFE ACCESS TO FMT

Our material has set the standard in this new field of microbiome-based medicine.

3% of candidates qualify to become stool donors

Potential donors undergo a 200-question clinical evaluation and a battery of laboratory tests to determine that they are healthy enough to donate stool. Active donors are continuously monitored for any changes to their health.

Adherence to Good Manufacturing Practices (GMP)

Stool is processed into FMT treatments in a specialized facility that includes a sterile environment, temperature-mapped freezers, and secure databases.

Adverse event case management

If a patient responds negatively to FMT, we use databases tracking each FMT unit shipped as well as safety samples preserved from each treatment to determine whether our treatments played a role in their illness and how best to follow-up.

Dedicated access to world-renowned leaders in medicine

For patients and clinicians we offer FMT expertise and guidance from in-house gastroenterologists and infectious disease physicians, along with an independent clinical advisory board comprised of international experts on FMT.



To help treat patients with *C. difficile*, we provide stool preparations to a network of physicians across the country.

IN 2018:

We shipped

12,327

stool preparations for FMT.

We partnered with

207

new hospitals and clinics.

SINCE 2013:

We have shipped

42,643

FMT units to a network of

1,192

hospitals.

98%

of Americans live within a 2-hour drive of an OpenBiome FMT provider.



Scott Olesen, PhD
Scientific Director



**THROUGH OUR
RELATIONSHIPS WITH
CLINICAL AND RESEARCH
PARTNERS, OPENBIOME
IS UNIQUELY POSITIONED
TO ADVANCE THE SCIENCE
OF THE MICROBIOME FOR
PUBLIC HEALTH.”**

RESEARCH

*Using FMT to treat *C. difficile* is opening new possibilities for other diseases*

As OpenBiome’s Scientific Director, Scott Olesen will steer our research portfolio to best translate the promise of the microbiome into improved patient care.

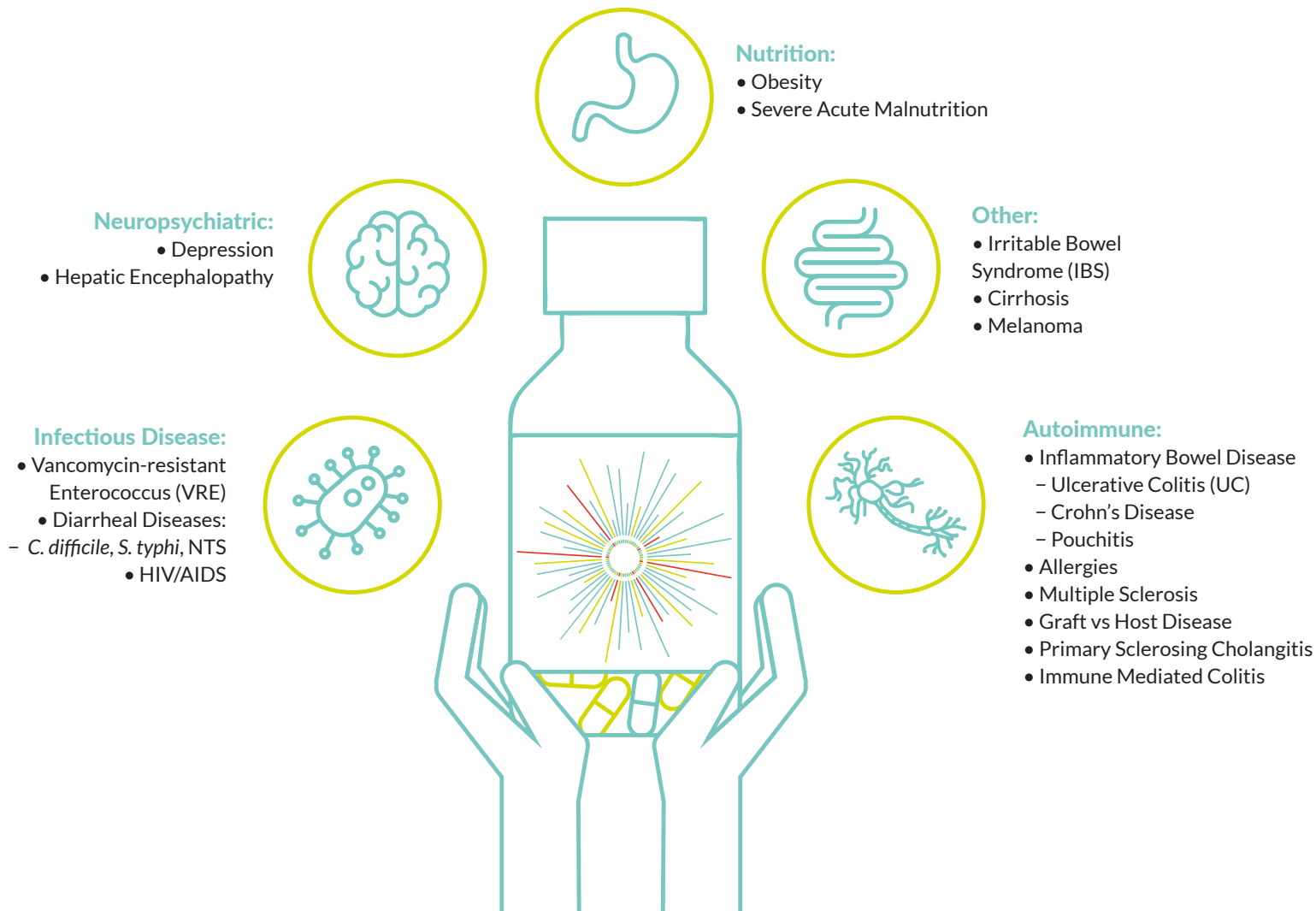
Groundbreaking studies have described links between the microbiome and some of the most difficult-to-treat diseases including depression, multiple sclerosis, diabetes, and autism. Experts in these fields are beginning to explore the therapeutic potential of fecal transplants. Drawing upon our

experience treating *C. difficile*, Scott will help our research partners design clinical trials, analyze data, and create new collaborations with scientists from other academic institutions.

Before coming to OpenBiome, Scott earned his PhD from the MIT Department of Biological Engineering and worked as a Postdoctoral Fellow at the Harvard School of Public Health.



OpenBiome is working with leading academic researchers to explore the therapeutic potential of FMT for the indications shown below:



OpenBiome catalyzes clinical research on the microbiome

30

active clinical trial collaborations or single patient case reports.

9

opened to enrollment or single patient treatment in 2018.

36%

More than 36% of all active and completed FMT studies in the U.S. are associated with OpenBiome.

29

peer-reviewed publications by OpenBiome and our research partners.

7

abstracts presented at scientific conferences including Digestive Disease Week, the annual meeting of the American Gastroenterological Association

RESEARCH SPOTLIGHTS

Highlights from our research portfolio

MAJOR DEPRESSIVE DISORDER

OpenBiome is working with researchers in Switzerland to explore whether FMT can be used to address major depressive disorder (MDD). The incidence of the mood disorder has increased significantly in the United States over the past decade, with the largest jump occurring in teens.

Researchers are hoping to take advantage of the gut-brain axis—a biochemical link, modulated by bacteria, that

connects nerves in the brain and intestines. This connection may underlie nausea that accompanies anxiety (as well as crankiness that rises with hunger).

Although the exact relationship between bacteria and the brain remains an open question, scientists theorize that implanting a healthy microbiome into a depressed patient could help improve mental health.



MULTIPLE SCLEROSIS

OpenBiome is collaborating with researchers to enroll a clinical trial testing whether FMT can help treat multiple sclerosis (MS)—an autoimmune disorder that affects 2.3 million people worldwide. For patients, quality of life slowly diminishes as their immune system attacks the central nervous system causing overwhelming fatigue, muscle spasms, and paralysis.

Previous studies have shown that MS patients and healthy individuals have distinct microbiomes but it is not yet known whether altering the population of gut bacteria can improve patient health.





RESEARCH SPOTLIGHTS

The first study to treat food allergies by modifying the microbiome

FOOD ALLERGIES

OpenBiome has partnered with Dr. Rima Rachid, an attending physician at Boston Children's Hospital, to run the first clinical trial that treats food allergies by modifying the microbiome.

Over the past decade, cases of severe allergic reactions to food, most commonly peanuts, have nearly quadrupled. Scientists believe that food allergies may be related to faulty communication between gut bacteria and the immune system and could have the potential to be corrected through FMT.

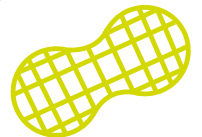
Our Phase-1, open-label study, will treat ten adults with orally administered capsules provided by OpenBiome. Dr. Rachid's team will then track patient safety and response to peanuts over a four-month period. The study is currently enrolling and is expected to be completed in 2019.



Dr. Rima Rachid
Boston Children's Hospital
Allergist and Immunologist



WE HAVE STRONG EVIDENCE THAT CHANGES IN THE GUT MICROBIOTA CAN ACTUALLY LEAD TO ALLERGIC DISEASES.



GLOBAL HEALTH MICROBIOME INITIATIVE

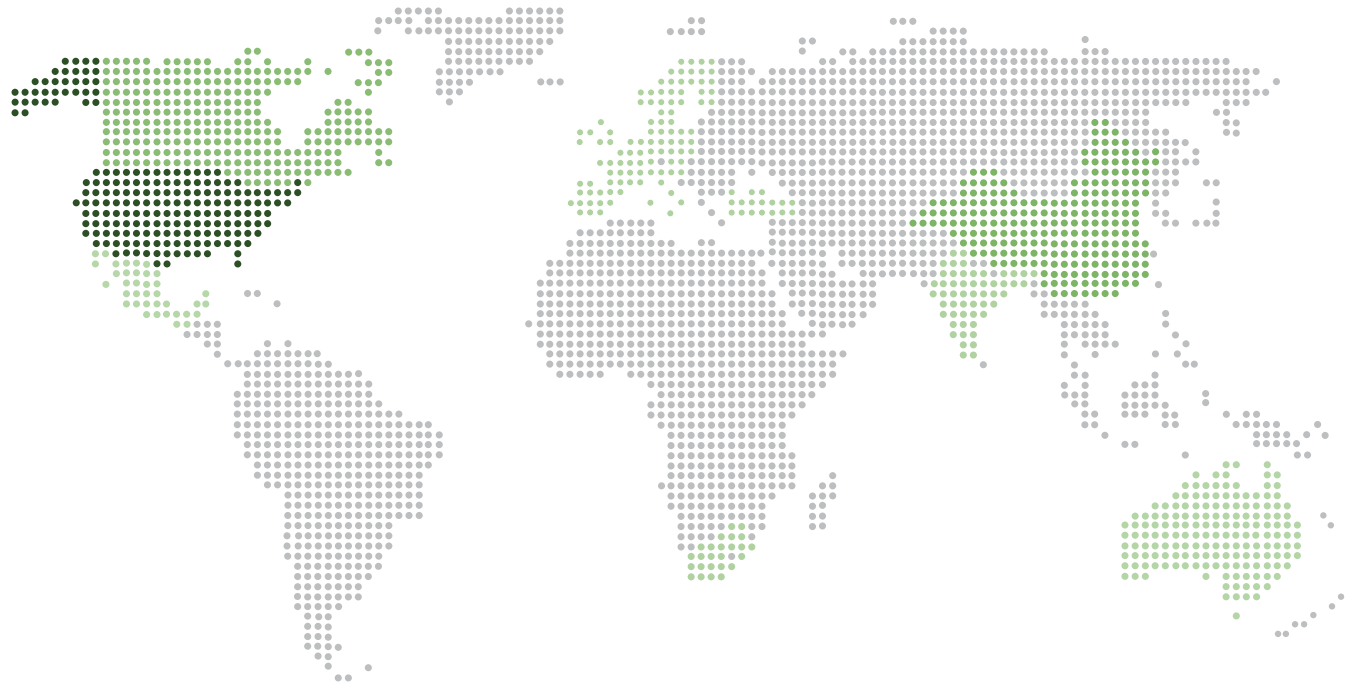
Our Global Health program seeks to generate microbial solutions to microbiome-mediated diseases that primarily affect low- and middle- income countries. This work provides a high impact opportunity to apply the lessons we have learned from treating patients in the United States with recurrent C. difficile. We aim to address some of the greatest global health challenges in underserved patient populations, while also building local capacity for microbiome research.

NARROWING GLOBAL DISPARITIES IN TRANSLATIONAL MICROBIOME RESEARCH

Research on the microbiome and FMT has been predominantly focused on conditions that impact wealthy countries.

research is concentrated in the United States, China, Canada and European countries. There were no clinical trials in South America and only one in Africa, which is led by OpenBiome.

A systematic review of studies listed on ClinicalTrials.gov revealed that microbiome



THRIVE

The THRIVE Study: A Pilot Investigation of the Microbiome and Malnutrition

An 18-month-old boy has his mid-upper arm circumference measured, as part of a screening program in Kenya identifying children with severe acute malnutrition.

Photo Credits: Russell Watkins/DFID. Reprinted under Creative Commons License.

Our inaugural global health study, **Transfer of Healthy Gut Flora for Restoration of Intestinal Microbiota Via Enema (THRIVE)** is evaluating whether FMT can help treat children with pediatric **Severe Acute Malnutrition (SAM)** who have not responded to standard treatment alone.

- SAM stunts the growth of 20 million children worldwide, primarily from developing countries, and contributes to 1 million deaths each year.
- SAM generally affects children under five years of age.
- SAM is a persistent problem in South Africa with 4.5 new cases of SAM per 1000 children.
- Over 35% of children with SAM do not respond to the standard treatment of nutrient-enhanced foods and antibiotics.

Scientific interest for this work comes from research that confirmed children with SAM have a different microbiome than their healthy counterparts, even after receiving the standard care regimen. Acting on this discovery, THRIVE is exploring whether restoring the microbiome, through FMT, can aid the recovery of children with no alternate treatment options. If safe and successful, we hope to ultimately expand our work in malnutrition through a larger, multicenter trial.

THRIVE is supported by the Bill & Melinda Gates Foundation, Children's Relief International, and the Thrasher Research Fund. Enrollment will take place at our site partners at the University of Cape Town and Red Cross War Memorial Children's Hospital in Cape Town, South Africa.

IN THE NEWS

OpenBiome engages with local, national, and international media.

Our goal is to educate without hyping; to share our excitement around microbiome research with careful consideration of the scientific evidence.

"Becoming a stool donor isn't easy ... The vast majority of applicants are rejected, said Carolyn Edelstein, OpenBiome's executive director. "Only about 3 percent make it through our screening process," she said. "We like to joke with our donors that it's easier to get into Harvard or M.I.T. than be a stool donor."

-Do You Have the Right Stuff to be a Stool Donor?" New York Times June 5, 2018

The
New York
Times

["Drug Companies and Doctors Battle Over the Future of Fecal Transplants"](#)



["What's Living in You? \(Video\)"](#)

NETFLIX

["A User's Guide to Cheating Death: Germs \(Video\)"](#)



OpenBiome executive director, Carolyn Edelstein (far right), speaks with science journalist Ed Yong at a healthcare panel hosted by The Atlantic.

Photo credit: Kristoffer Triplaar / The Atlantic



ASK US ABOUT THE POWER OF POOP!

people have 10x more microbes than human cells!

from infection, and so much more!

C. diff is a bacteria that causes dangerous gut infections. Each year, 500,000 people contract *C. diff* and 30,000 die.

1 in 5

OpenBiome team members and volunteers run a booth at the Cambridge Science Festival

IN THE COMMUNITY

OpenBiome cultivates appreciation for FMT and microbiome research by participating in community events as well as inviting groups of visitors into our office.

- Invited exhibitor at New York Hall of Science.
- Presented research at Digestive Diseases Week, Infectious Diseases Week, and the American College of Gastroenterology Annual Conferences.
- Invited speaker at The Atlantic Health Summit: People vs. Cancer Panel.
- Hosted international pharmaceutical, medical, undergraduate, and middle school student groups.
- Served as an expert resource to students participating in national science fairs.



ABOUT US



MISSION & HISTORY

OpenBiome's mission is to expand safe access to fecal microbiota transplantation for patients suffering from recurrent *C. difficile* and to catalyze research on the human microbiome.

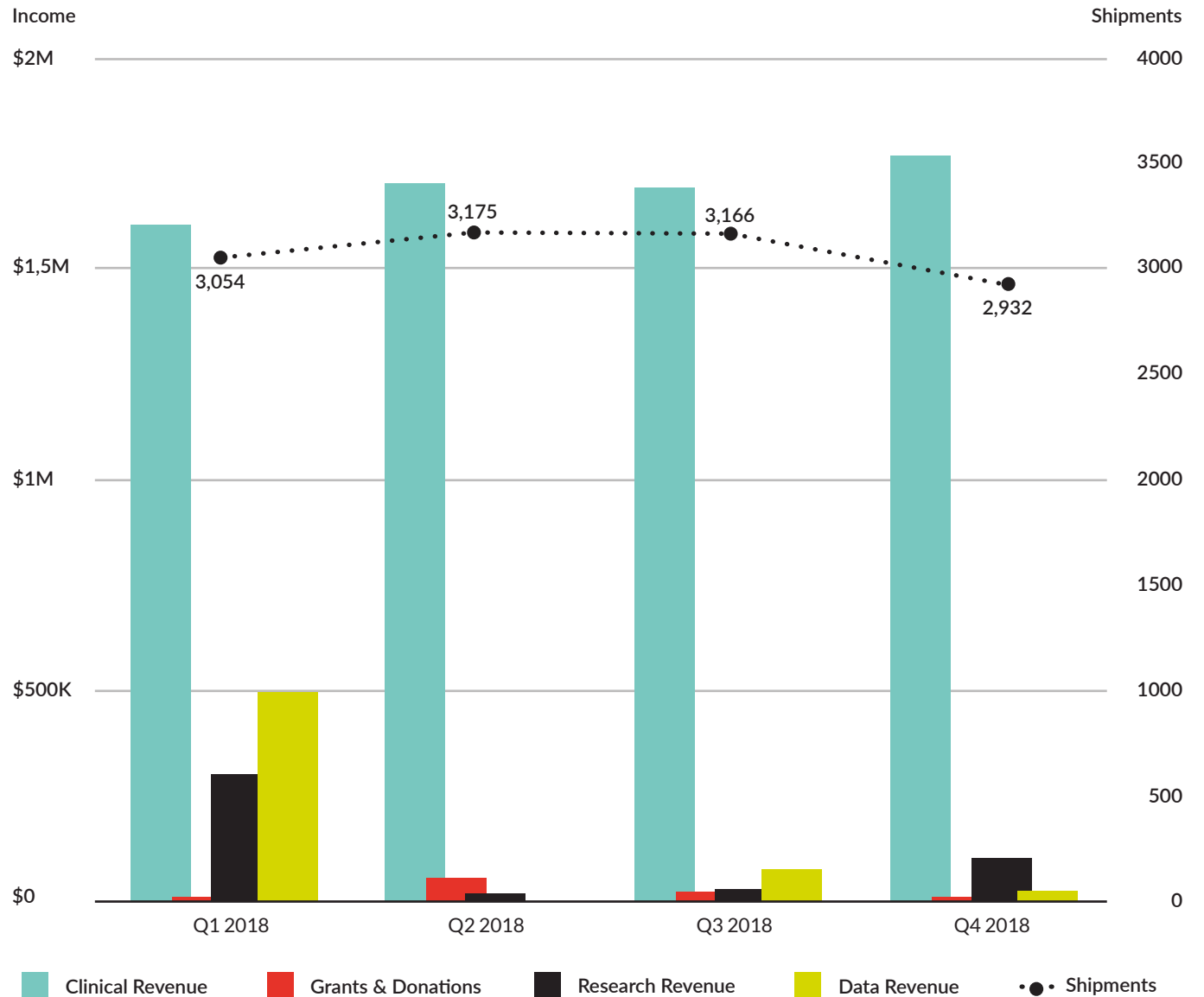
Founded in 2012 in the Alm lab at MIT, OpenBiome aims to reduce the practical barriers to providing FMT and enable translational research investigating new applications of microbiome-based therapies.

BOARD OF DIRECTORS

- Jim Burnham – Chairman of the Board
- James Burgess – President
- Eric Alm, PhD
- Jim Bildner, JD
- Neil Rasmussen
- Lisa Serwin
- Mark Smith, PhD
- Jane Williams, MD MPH

2018 FINANCIAL STATEMENTS

QUARTERLY GROWTH



BALANCE SHEET

ASSETS

Current Assets	
Cash	\$2,317,825
Accounts Receivable	\$1,129,543
Inventory	\$188,080
Prepaid Expenses	\$72,534
Total Current Assets	\$3,707,982
Non-Current Assets	
Property and Equipment, net	\$313,069
Security Deposits	\$68,182
Total Assets	\$4,089,233

LIABILITIES AND NET ASSETS

Current Liabilities	
Accounts Payable	\$34,435
Net Accounts Payable - Related Party	\$708,624
Accrued Expenses	\$458,779
Current Portion of Note Payable	\$ -
Current Portion of Capital Lease Payable	\$ -
Total Current Liabilities	\$1,201,838
Non-Current Liabilities	
Capital Lease Payable	\$ -
Total Liabilities	\$1,201,838
Net Assets	
Unrestricted	\$2,887,395
Temporarily Restricted	\$ -
Total Net Assets	\$2,887,395
Total Liabilities and Net Assets	\$4,089,233

INCOME STATEMENT

Unrestricted Operating Revenues and Support	
Sales of Product (Net of Discounts)	\$6,008,840
Research Sales	
General Research	\$460,721
Government Contracts	\$33,565
Private Grants	\$51,000
Shipping and Handling Fees	\$759,600
Less Cost of Clinical Program Sales	(\$3,688,014)
Gross Profit on Sales	\$3,625,712
Data Licenses and Royalties	\$595,000
Other Income	\$19,070
Major Donations	\$ -
Other Donations	\$3,085
Net Assets Released from Restrictions	\$ -
Total Unrestricted Operating Revenues and Support	\$4,242,867
Operating Expenses	
Program	
Clinical	\$840,270
Research	\$2,474,766
Total Program Expenses	\$3,315,036
General and Administrative	\$697,509
Fundraising	\$104,733
Total Operating Expenses	\$4,117,278
Change in Net Assets	\$125,589
Net Assets, beginning of the year	\$2,761,806
Net Assets, end of the year	\$2,887,395



OPENBIOME



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