Annual Report 2023

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New strategic plan, new dynamic partners

In 2023, GHIT’s 10th anniversary coincided with several milestones: we launched our third strategic plan, welcomed new funders, established new strategic partnerships, and earned our first European Medicines Agency’s positive scientific opinion for a groundbreaking innovation. This report highlights our journey over the past year, underscoring the invaluable role our partners and sponsors play in every part of our progress.

The unveiling of GHIT 3.0, our latest strategic blueprint launched in April, signifies a pivotal step forward in our mission to accelerate global health R&D, ensuring the availability and accessibility of life-saving products worldwide. Built upon three pillars – galvanizing innovation, catalyzing partnerships, and maximizing impact – this plan embodies our commitment to catalyze transformative change. (pages 5-6)

In alignment with our strategic vision, we proudly welcomed three new funders and sponsors – Eiken Chemical, Fujirebio, and Remedy & Company– into our esteemed cohort of long-term supporters, each dedicated to advancing global health outcomes through innovative solutions. Additionally, we forged two strategic alliances, collaborating with the Institut Pasteur de Dakar and the United Nations-backed Medicines Patent Pool, to facilitate technology transfer and foster access-oriented licensing for medical technologies in low- and middle-income countries (LMICs). (page 21)

Pivotal milestone achieved

An exceptional achievement for GHIT came with the EMA’s positive scientific opinion for arpraziquantel, developed by the Pediatric Praziquantel Consortium, to treat schistosomiasis in preschool-aged children. The journey of this innovation truly embodies our institutional mission,
leveraging technology from Japan in partnership with overseas partners to meet a profound global health need, bringing hope to more than 50 million children and their families. (page 11)

This achievement stands out, even among the more than 120 innovative projects that GHIT has supported with over JPY30 billion in the past decade, underscoring the exciting promise and potential of our extensive network of 180 development partners, about 65% of whom are based outside Japan. Each initiative in our portfolio symbolizes a distinctive cross-border collaborative endeavor with the potential to revolutionize health outcomes on a global scale.

Calling ourselves to action

Furthermore, on the cusp of the G7 Health Ministers’ Meeting in Nagasaki in May, we, together with Nagasaki University and Uniting to Combat NTDs, convened global health leaders to call for the prioritization of neglected tropical diseases (NTDs) in the global agenda. This advocacy culminated in the “Nagasaki Outcome Statement” – a call to action for accelerated R&D, access, and delivery for NTDs. As if in response to this call, Japanese Prime Minister Fumio Kishida announced a commitment of USD200 million to the GHIT Fund for R&D over five years during the G7 Hiroshima Summit. (page 6)

As we navigate the future, our role as Japan’s flagship public-private partnership for global health R&D calls us to action every day. We express profound gratitude to our founding partners for their continued support and extend a warm welcome to new allies joining our crusade against neglected diseases. We embrace the opportunities that lie ahead with passion and urgency, consistently inspired by the collective solidarity of our partners.

Osamu Kunii  
CEO & Executive Director

Hiroki Nakatani  
Chair & Representative Director
In April 2023, “GHIT 3.0,” our third five-year strategic plan, took flight, coinciding with GHIT’s 10th anniversary. With a paramount objective to expedite global health R&D and swiftly make essential products available and accessible to those who need them most, this plan reaffirms our role as a global health R&D trailblazer, dedicated to catalyzing global health through Japanese innovation against neglected diseases primarily affecting low and middle-income countries (LMICs). GHIT 3.0 rests upon three fundamental pillars:

1. **Galvanize Innovation**
   - Continuous investment in product development helps fuel innovation at every stage of R&D, from discovery through clinical trials to regulatory approval. We prioritize investments in late-stage product development programs to enable more immediate delivery of drugs, vaccines, and diagnostics to those who need them most. Additionally, we champion product co-creation through innovative technology exploration and foster global, cross-sectoral collaborations addressing diverse challenges like pandemic preparedness and climate change.

2. **Maximize Impact**
   - We are dedicated to accelerating product development for tuberculosis, malaria, and NTDs while strategically optimizing our portfolio and resources to achieve the greatest impact. We are actively exploring diverse funding mechanisms to sustainably support R&D efforts, holding efficiency paramount. Prioritizing institutional development will help us strengthen compliance, risk management, and enhance decision-making transparency.

3. **Catalyze Partnerships**
   - In addition to facilitating unprecedented R&D partnerships with a focus on LICs and LMICs, we work with partners to ensure they have robust launch strategies in place for the clinical candidates we invest in to advance effective access and delivery. Our Uniting Efforts platform, co-created with the Government of Japan and the United Nations Development Programme (UNDP), aligns action across the broader innovation-access-delivery continuum among all global health stakeholders.
R&D: Investments in Product Development

<table>
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<tr>
<th>Objective</th>
<th>R&amp;D milestone</th>
<th>Targeted by March 2027</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leverage innovations from biopharma and academia</td>
<td>Hit-to-lead programs funded</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Preclinical candidates identified</td>
<td>12</td>
</tr>
<tr>
<td>Advance R&amp;D investment pipeline and prioritize late-stage candidates</td>
<td>First-in-human clinical trials conducted</td>
<td>6</td>
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<td></td>
<td>Proof of concept achieved</td>
<td>3</td>
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<td></td>
<td>Approval from a stringent regulatory authority</td>
<td>3</td>
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<tr>
<td></td>
<td>Local program implementation of a product</td>
<td>1</td>
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Replenishment: Major Pledges Pave Path To Success

The GHIT Fund/UNDP replenishment has garnered substantial backing, notably featuring a USD200 million commitment from the Government of Japan announced by Prime Minister Fumio Kishida during the G7 Hiroshima Summit. This, together with recommitments from the Bill & Melinda Gates Foundation, Wellcome, and all founding industry partners, is a powerful testament to the strength and impact of our approach, and the promise of what is to come.

Numerous other critical partners swiftly pledged their support upon GHIT 3.0’s launch, and new funding partners and sponsors have also endorsed GHIT 3.0. Our replenishment continues, with a target goal of USD400 million in the next five years to enhance our operations and investments.

“What started as an investment to test a new R&D financing mechanism has proved its innovativeness and become a pioneering model for others to follow. We’re delighted to continue this relationship over the next three years, with a renewed focus on the impact GHIT can make within the global health landscape.” (May 2023)

Katey Einterz Owen
Director, Neglected Tropical Diseases
Director, Vaccine Development,
Bill & Melinda Gates Foundation
Portfolio

Drugs / Vaccines
- Target Research
- Screening
- Hit-to-Lead

Diagnostics
- Target Research
- Lead Optimization
- Product Design

NTDs
- Chagas disease
- Leishmaniasis
- Onchocerciasis
- Schistosomiasis

Malaria

Tuberculosis

Total Investment
USD 220M

Cumulative investments (in millions)

US dollar amounts represent conversions from Japanese yen at JPY 151.33 = USD1, the exchange rate as of March 31, 2024.
Please visit the GHIT Fund’s website to find out more about each project and partner’s innovations.
https://www.ghitfund.org/investment/portfolio/en

**Investment Overview**

**FY2013-2023**

- **Disease**
  - Malaria: 46.3%
  - Tuberculosis: 9.0%
  - NTDs: 44.7%

- **Intervention**
  - Drugs: 69.3%
  - Vaccines: 22.1%
  - Diagnostics: 8.6%

- **Development Stage**
  - Discovery: 15.7%
  - Preclinical: 52.9%
  - Clinical: 31.4%

**FY2023**

- Total investments: **USD 27 M**
- Invested partnerships: 13
- New Japanese partners: 62
- New non-Japanese partners: 119

As of March 31, 2024
Clinical Candidates — Regulatory Submission

We are one step closer to delivering products to patients in need. 8 programs are underway worldwide, from clinical trials to regulatory submission.

**Clinical Candidates**

- **Peru**
  - **SJ733**
    - Malaria / Drug
    - Development Stage: Phase IIb Clinical Trial
    - Country: Peru

- **Colombia**
  - **CpG-D35**
    - Cutaneous leishmaniasis / Drug

- **Brazil**
  - **LepVax**
    - Leprosy / Vaccine

- **Ivory Coast**
  - **apraziquantel**
    - Schistosomiasis / Pediatric Drug

- **AlAQ-FDC**
  - Malaria / Drug
  - Development Stage: Phase III Clinical Trial, Registration
  - Country: Rwanda, Uganda, Angola, Nigeria, Thailand

- **AnAPN1**
  - Malaria / Vaccine
  - Development Stage: Phase I Clinical Trial
  - Country: Gabon

- **Fosravuconazole**
  - Mycetoma / Drug
  - Development Stage: Under Regulatory Submission Preparation
  - Country: Sudan

- **SCH CAA RDT**
  - Schistosomiasis / Diagnostics
  - Development Stage: Product Development
  - Country: Kenya, Philippines

**Additional Notes**

- SJ733: Development Stage: Phase IIb Clinical Trial, Country: Peru
- ALAQ-FDC: Development Stage: Phase III Clinical Trial, Registration, Country: Rwanda, Uganda, Angola, Nigeria, Thailand
- AnAPN1: Development Stage: Phase I Clinical Trial, Country: Gabon
- Fosravuconazole: Development Stage: Under Regulatory Submission Preparation, Country: Sudan
Please refer to the website for details on the clinical trials of each project.
Special Feature

European Medicines Agency recommends arpraziquantel for treatment of schistosomiasis in preschool-aged children

In 2023, arpraziquantel, the pediatric treatment option for preschoolers, developed within the Pediatric Praziquantel Consortium, became the first investigational drug among GHIT’s investments to receive a European Medicines Agency (EMA)’s positive scientific opinion. GHIT has supported the Pediatric Praziquantel Consortium since 2013.

A critical need finally met

Schistosomiasis affects more than 240 million people, about 50 million of whom are preschool-aged children. If left untreated, schistosomiasis can lead to fatal chronic inflammation of vital organs as well as anemia, stunting growth and cognitive impairment— all of which have devastating consequences for the lives of children. The current standard of care treatment for schistosomiasis is praziquantel; it is safe, effective and suitable for school-aged children and adults. However, an appropriate drug for preschool-aged children had been elusive. Until now.

The power of partnership

The Pediatric Praziquantel Consortium was founded in 2012 as the first international, non-profit, public-private partnership in schistosomiasis. It currently consists of 14 partners and collaborators. Astellas Pharma Inc. (Japan), one of the founding members of the Consortium, leveraged its proprietary technology to lead initial formulation development, resulting in water dispersible, climate-stable, child-friendly tablets with improved taste. Founding Consortium member, Merck (Germany), optimized the formulation and, together with Consortium partner, Farmanguinhos (Brazil) manufactured the batches for the clinical development program.

Ensuring access & delivery

A positive scientific opinion from EMA was awarded in December 2023 under the EU-M4all procedure, paving the way for the inclusion of arpraziquantel into the WHO’s lists of prequalified medicines (expected in early Q2 2024) and of Essential Medicines (in 2025). Meanwhile, Farmanguinhos is preparing regulatory submission in Brazil and will manufacture the new pediatric medication for availability in endemic countries. A technology transfer from Merck to Universal Corporation Ltd. in Nairobi (Kenya) will ramp up local production for African countries in the coming years. In parallel, together with Consortium partners, GHIT is supporting the Consortium’s implementation research program (ADOPT), to prepare for the introduction of arpraziquantel in endemic countries in Africa, as well as the definition of a new procurement and funding mechanism to ensure equitable and sustainable access to the new pediatric medication to the patients in need.
Results announced from trial of potential new treatment for mycetoma

Results from the world’s first double-blind, randomized clinical trial of fosravuconazole were announced last year. Fosravuconazole is a potential new oral treatment for the fungal form of mycetoma, a chronic disabling disease. Treatment options currently available for mycetoma are limited, costly, and burdensome, for example, requiring patients to take four tablets every day for 12 months – posing a high risk of disease recurrence due to treatment interruption. GHIT has supported the development of fosravuconazole since 2017. The Drugs for Neglected Diseases initiative (DNDi) coordinated the trial in Sudan, in partnership with the Mycetoma Research Center (MRC) in Khartoum, Erasmus MC in the Netherlands, and the Japanese pharmaceutical company Eisai Co., Ltd. (Eisai). Fosravuconazole, an oral azole antifungal discovered by Eisai, showed potential as a well-tolerated, patient-friendly, and effective treatment for mycetoma, requiring only two pills per week compared to four tablets per day for the currently available treatment. Based on these clinical trial results, the project team is now preparing the registration dossier for Sudanese regulatory authorities.

“Mycetoma disproportionately affects the most vulnerable populations and can cause severe deformities and devastating disability. With GHIT’s support, we have achieved an important milestone by developing fosravuconazole, an effective potential new treatment, which can offer hope to patients.”

A new, rapid diagnostic test for schistosomiasis to support disease monitoring and control

Currently, WHO guidelines for schistosomiasis diagnosis recommend microscopy of stool and/or urine samples. However, this method has poor sensitivity especially when the prevalence and intensity of infection decreases. As such, microscopy requires multiple samples to be taken over multiple days, making it time-consuming and challenging to deploy. To address this, since 2020 GHIT has invested in a partnership between FIND, Leiden University Medical Center, Merck KGaA, and Nagasaki University Institute of Tropical Medicine to develop an affordable, highly sensitive rapid diagnostic test (RDT) for schistosomiasis, which can provide results within 20 minutes. Initial economic analysis indicates that this new RDT, once approved, carries high potential to transform disease mapping and drug distribution. Field evaluations of a new optimized assay is about to start and an open selection process for a manufacturer of the test is under way, garnering significant interest.

“Schistosomiasis is devastating for individuals and communities, but it is treatable and preventable. This new rapid test could transform public health measures by targeting preventive therapy, and ensuring infections are treated early.”
Invested Partnerships in FY2023

**Malaria / Drug**

Fragment and structure-based hit generation platform for new malaria targets

University of Tokyo, University of Oxford, University of Dundee, Medicines for Malaria Venture (MMV)

Fragment-based screening for hit generation has yet to be applied to malaria drug discovery. The goal of the project is to generate high-quality hit compound series against two highly validated malarial targets (Pf DPCK and Pf KRS) by applying, for the first time, the state-of-the-art XChem fragment approach of X-ray structure-accelerated, synthesis-aligned lead discovery. The application of fragment-based screening and optimization to malaria drug discovery is novel. The team will deliver new starting points for drug discovery against high value malaria targets for which there are currently no drug candidates. Development of compounds which can block transmission and be used in chemoprotection/chemoprevention settings, in addition to acute treatment, would be especially valuable to drive the eradication agenda.

**Malaria / Vaccine**

Towards the clinical development of the new asexual blood-stage malaria vaccine candidate PfRipr5 (PfRipr5-PD)

Sumitomo Pharma Co., Ltd., iBET, European Vaccine Initiative e.V. (EVI e.V.), Ehime University

Malaria remains one of the most significant global public health problems, causing substantial morbidity and mortality. Despite recent advancements in malaria control strategies with the programmatic deployment of the RTS,S/AS01 (Mosquirix™) and R21/Matrix-M vaccines, a more effective second-generation malaria vaccine is urgently needed. This project is advancing the preclinical development of PfRipr5, a new asexual blood-stage malaria vaccine jointly discovered by Ehime University and Sumitomo Pharma Co., Ltd. based on the positive outcomes of a previous GHIT project (T2018-151). PfRipr5 displays a very low level of polymorphism, thus bearing the potential to overcome the shortcomings of other asexual blood-stage malaria antigens. In the future, PfRipr5 is expected to contribute to the development of next-generation multi-stage malaria vaccines, providing greater overall protection and cost-effectiveness than single-stage vaccines.

**Malaria / Drug**

Development of enzyme inhibitors as a SERCAP for relapsing malaria

Mitsubishi Tanabe Pharma Corporation, University of Georgia, Medicines for Malaria Venture (MMV)

Currently, malaria treatment is dominated by artemisinin combination therapies (ACTs). If resistance becomes widespread in Africa (where most deaths occur), a major health crisis is feared. To eradicate the disease, new drugs with novel modes of action which address resistance developing against existing therapeutics are needed. New candidates would ideally be low single dose and have liver and transmission-blocking capability. This project will perform the lead optimization of a novel series of antimalarial compounds which has a unique parasitological profile; high potency against blood, liver and sexual stages as well as exceptional activity against *P. vivax* hypnozoites, the cause of relapsing malaria. The project has the potential to deliver against several target candidate profiles; i) an oral SERCAP for relapsing malaria which does not have the hemolysis liability associated with the standard of care Primaquine, ii) a once-monthly oral chemoprotectant, iii) a three-monthly intramuscular chemoprotectant.

**Malaria / Drug**

Preclinical development of a novel mechanism-of-action in antimalarial compounds

Eisai Co., Ltd., The Scripps Research Institute, The International Centre for Genetic Engineering and Biotechnology (ICGEB)

Existing antimalarial drugs have limitations due to their dosing regimens and side effects, and resistance to frontline therapies is rapidly emerging. There is therefore a critical need for the development of new drugs, antimalarials in particular, with new mechanisms of action (MoA) to combat resistance, and the ability to clear infection with a single dose. In this project, promising, recently generated novel antimalarial compounds will be synthesized and profiled in *in vivo* efficacy studies, exploratory safety studies and multi-species pharmacokinetic studies with the goal of selecting a preclinical development candidate. Then, the safety, pharmacokinetic and efficacy profiles of next-generation PfPheRS-inhibitor antimalarials will be evaluated. The next-generation program is expected to retain the key advantages of that frontrunner program—namely a novel MoA, multi-stage activity and predicted single-dose efficacy—while improving safety profile and treatment cost.
The seasonal malaria chemoprevention is providing prevention to 53 million children in 2023. Although current first-line oral drugs are generally safe and effective, they face challenges such as parasite resistance and incomplete adherence issues. In addition, monthly distribution of oral drugs to every household demands substantial resources and costs in resource-limited settings. Therefore, highly effective long-acting injectables (LAIs) which can cover the whole transmission season by a single injection are needed. The project aims to provide a preclinical candidate for LAI in two years, which covers the entire high transmission season by a single injection with a low risk of resistance, by optimizing a promising lead series which targets the malarial electron transport chain.

lead optimization and candidate selection of novel long-acting injectables which target malarial electron transport chain for malaria chemoprevention and prophylaxis

Dr. Kenji Takaya
Shionogi

Over 6 million people are estimated by the World Health Organization (WHO) to have Chagas disease. For 30 to 40% of people infected, the disease progresses to a late chronic stage, as Chagas disease usually remains asymptomatic for years after infection. Of these, most will suffer cardiac damage, often leading to sudden death or progressive heart failure. Current available treatments are more than 40 years old, and while they show good efficacy in the acute phase, they need to be used in long regimens and cause significant side effects. As a continuation from the Hit-To-Lead development project, this project aims at delivering an optimized lead candidate(s) meeting the DNDi Target Candidate Profile, with the ultimate goal to develop a safe and efficacious new oral treatment for chronic Chagas patients. This project relies on a novel very promising spirocyclic scaffold (Spiro 5) identified in the Hit-to-Lead collaboration and that achieved proof-of-concept of \textit{in vivo} efficacy in acutely and chronically infected pre-clinical models.

lead optimization of a novel chemical series for Chagas disease

Dr. Jean-Robert Ioset
DNDi

Onchocerciasis and Lymphatic Filariasis

Pre-clinical development of the macrofilaricide corallopyronin A (CorA) to treat onchocerciasis and lymphatic filariasis

Eisai Co., Ltd., University Hospital Bonn, Helmholtz Centre for Infection Research

Onchocerciasis (river blindness) and lymphatic filariasis (lymphedema, hydrocele and elephantiasis) are two neglected tropical diseases that afflict 72.4 million people. Current drugs used to control and eliminate these infections mainly kill just the larvae of these worms, hence the need for a drug that can kill adult worms is high. One of the safest ways to kill adult worms, and a curative approach, is to target their essential intracellular bacteria symbionts called \textit{Wolbachia}. This project is developing a new antibiotic, corallopyronin A (CorA), that is effective against \textit{Wolbachia} and rifampicin-resistant bacteria and is safe and nontoxic. The objective of this project is to conduct DMPK and GLP-toxicology in dogs and a PD study in the dog heart worm infection and thus complete the CorA final preclinical development activities to prepare for the first-in-human trial (phase I).

pre-clinical development of the macrofilaricide corallopyronin A (CorA) to treat onchocerciasis and lymphatic filariasis

Prof. Achim Hörauf
University Hospital Bonn

In 2021, the WHO called for a new diagnostic test that could accommodate schistosomiasis control programs, and set the desired performance characteristics as a target product profiles (TPP). This project proposes a sensitive and specific lateral flow immunoassay (LFIA) which will meet the WHO TPP, poised for routine screening of school-aged children. The project team’s experience in LFIA, antigen and antibody production, and biomarker identification will allow it to produce a prototype LFIA in only one year. With no commercial tests able to satisfy the TPP, the Rapid Diagnostic Test (RDT) developed under this project presents a highly practical and cost-effective approach, which could constitute a stand-alone solution and/or could complement other tests currently in development.

A highly sensitive and specific serological rapid diagnostic test to support WHO’s schistosomiasis monitoring and evaluation (M&E) programs

Medical & Biological Laboratories Co., Ltd., Drugs and Diagnostics for Tropical Diseases (DDTD)

Dr. Marco Biamonte
DDTD

In 2021, the WHO called for a new diagnostic test that could accommodate schistosomiasis control programs, and set the desired performance characteristics as a target product profiles (TPP). This project proposes a sensitive and specific lateral flow immunoassay (LFIA) which will meet the WHO TPP, poised for routine screening of school-aged children. The project team’s experience in LFIA, antigen and antibody production, and biomarker identification will allow it to produce a prototype LFIA in only one year. With no commercial tests able to satisfy the TPP, the Rapid Diagnostic Test (RDT) developed under this project presents a highly practical and cost-effective approach, which could constitute a stand-alone solution and/or could complement other tests currently in development.

A highly sensitive and specific serological rapid diagnostic test to support WHO’s schistosomiasis monitoring and evaluation (M&E) programs

Dr. Marco Biamonte
DDTD
**Onchocerciasis / Diagnostic**

**Supporting WHO onchocerciasis elimination programs: progressing a highly sensitive and ultra-specific rapid diagnostic test to commercialization readiness**

Medical & Biological Laboratories Co., Ltd., Big Eye Diagnostics, Inc. (BEDx), Drugs and Diagnostics for Tropical Diseases (DDTD)

WHO needs new, highly sensitive and ultra-specific rapid diagnostic tests (RDTs) to support its endeavors to eliminate onchocerciasis, a disease also known as river blindness with 21 million active cases and 218 million at-risk individuals. This project proposes a RDT to detect exposure to Onchocerca volvulus, the pathogen responsible for onchocerciasis. Built in a biopsy format, the test detects IgG4 antibodies specific for two *O. volvulus* antigens. WHO has issued two Target Product Profiles (TPPs), and the most stringent TPP criterion is that the test must be extraordinarily specific (≥99.8%). Our RDT was shown by the CDC to have a specificity of ≥99.8%, which will contribute to the eradication of onchocerciasis.

**Malaria / Drug**

**Evaluation and preparation for deployment of an artemether-lumefantrine-amodiaquine fixed-dose combination to counter antimalarial drug resistance in *Plasmodium falciparum* malaria**

Marubeni Corporation, Mahidol Oxford Tropical Medicine Research Unit (MORU), Medicines for Malaria Venture (MMV), Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd. (Fosun Pharma)

*Plasmodium falciparum* malaria remains a leading cause of death in the tropical world, in particular in young children in Sub-Saharan Africa. Currently, artemisinin-based combination therapies (ACTs) are globally the first-line treatments for uncomplicated *Plasmodium falciparum* malaria, and there are no alternatives available. Artemisinin partial resistance (ART-R) is now observed widely, leading to an increase in morbidity and fatality rates. This project will evaluate the safety, tolerability and efficacy of ALAQ-FDC developed and produced by Fosun Pharma compared to the current first-line treatments AL and ASAQ, in areas with different patterns of antimalarial drug resistance. This will be the first time a fixed dose triple ACT is tested and prepared for deployment in malaria endemic countries. From the standpoint of creating new anti-malaria combination therapies, this project represents a pivotal component of the global response to this challenge.

**Leprosy / Vaccine**

**Stronger together: engagement of people affected by leprosy in the LepVax clinical trial**

Sasakawa Health Foundation (SHF), Oswaldo Cruz Institute (IOC/Fiocruz), American Leprosy Missions, Inc. (ALM)

Leprosy is an infectious disease caused by the bacillus *Mycobacterium leprae*, with involvement of the peripheral nervous system. Despite the reduction of global leprosy incidence, leprosy disease remains an important public health concern primarily in endemic regions of India, Brazil, and Indonesia, which made up 78.1% of 174,087 new leprosy cases in 2022. This project is a pivotal phase I/II safety study in a leprosy-endemic region of Brazil to demonstrate safety and immunogenicity of a T-cell directed subunit vaccine, LepVax, in healthy individuals and leprosy patients. LepVax is the first immunotherapeutic to be evaluated for reducing immune related neuropathy in leprosy patients. In particular, the project aims to serve as a model for participatory research, engaging with persons affected by leprosy in clinical trials. Should LepVax prove effective, we could see over 800,000 cases of disability due to leprosy averted, representing over 200,000 disability-adjusted life years (DALYs) by 2040.

**Chagas disease / Drug**

**Screening project**

Nagasaki University, DNDi

**Malaria / Drug**

**Combination of SJ733 with tafenoquine as a possible radical cure for *P. vivax* malaria**

Eisai Co., Ltd., University of Kentucky

SJ733 is a PfATP4 inhibitor that meets criteria for treatment of uncomplicated malaria. Current Phase Ia, Ib, and IIA human data shows an excellent safety profile and tolerability, good oral availability, and moderate drug clearance. In the next phase of the project, the project team will conduct a Phase IIb study examining the potential for radical cure of uncomplicated *P. vivax* malaria in adults with a 1, 2, or 3 day schedule of the SJ733-tafenoquine (TQ) combination. This will set the stage for subsequent pivotal Phase III studies. The overall objective of this project is to examine the clinical safety and efficacy of the combination of SJ733 and TQ for radical cure of *P. vivax* malaria, which is the most prevalent strain worldwide. The purpose is to develop an SJ733-TQ combination drug suitable for treatment of all patients with uncomplicated *P. vivax* malaria.
Kenya/Latin America Visit Report

The GHIT Fund facilitates R&D, with more than 180 product development partners; more than 110 of these partners are based outside of Japan, including 37 based in lower- and middle-income countries (LMICs). In FY2023, GHIT staff members visited some of our partners’ project sites in Kenya, Bolivia, and Brazil, resulting in meaningful personal and institutional connections, helping to strengthen our strategic partnerships with and in LMICs.

Visit Report

Bolivia and Brazil
Development of diagnostic tools for Chagas disease and strengthening global partnerships in Central and South America

In August 2023, Dr. Hayato Urabe, Associate Vice President, Investment Strategy, Portfolio Development & Innovations, visited partner institutions in two South American countries. In Bolivia, he reviewed the development progress of the “Chagas-LAMP” diagnostic tool currently in clinical trial stage and confirmed the local development on the ground. In Brazil, he visited the Oswaldo Cruz Foundation (FIOCRUZ) and the Latin American headquarters of the Drugs for Neglected Diseases initiative (DNDi), a global non-profit organization dedicated to advancing the R&D of treatments for neglected tropical diseases (NTDs).

Chagas disease, a life-threatening illness transmitted by a type of triatomine insect known as the “kissing bug,” infects around 7 million people worldwide and is found primarily in 21 Latin American countries. Due to the lack of diagnostic tools and other factors, there is limited reporting on global infection and prevalence rates. This is also why Chagas is considered a neglected tropical disease. The “Chagas-LAMP” is believed to contribute to improving the efficiency of early diagnosis and treatment of both mothers and newborns, carrying significant implications for future efforts to mitigate the disease’s health impact.

Site visits in Bolivia provided an opportunity to see progress of ongoing development programs firsthand and ensure data compliance on the ground. Visits included discussions with local and municipal stakeholders and healthcare professionals to raise awareness of the importance of early diagnosis and treatment, as well as connection with other local stakeholders to help GHIT better understand local experiences with the disease. Dr. Urabe of GHIT commented “Proactive investment in late-stage product development projects is crucial for accelerating innovation to deliver tools more rapidly to patients in need.”

Our catalytic role in strengthening partnerships

At FIOCRUZ, discussions focused on collaboration to both combat endemic diseases and prepare for future pandemics. At DNDi, Dr. Urabe enjoyed exchanging ideas and information about the status of NTDs in Central and South America.

The GHIT Fund will continue to contribute to R&D in alignment with local perspectives and the needs of countries through strong partnerships with key research institutions in Central and South American nations.
Visit Report

Kenya

Strengthening strategic partnerships with LMICs

As part of our journey towards establishing stronger partnerships in LMICs, GHIT CEO Dr. Osamu Kunii, and Senior Director of Access and Delivery, Investment Strategy, Portfolio Development & Innovations Dr. Isaac Chikwanha, visited Kenya in July 2023. They met with representatives from partner organizations Kenya Medical Research Institute (KEMRI), DNDi, Nagasaki University Collaborative Research Unit in Nyanza province, Universal Corporation Limited (UCL), and the Kenya Ministry of Health (MoH).

Facilitating collaborative networks and consortia within LMICs

Several activities support our key objectives of strengthening GHIT’s strategic partnerships with LMICs, the first being forming collaborative networks and consortia that bring together research institutions in LMICs, Japan, and other countries.

Such networks enable the exchange of expertise, sharing of resources, and joint research initiatives to address common health challenges. A good example is the work that the Pediatric Praziquantel Consortium has done in developing arpraziquantel, a potential new treatment option for schistosomiasis in preschool-aged children. “The impact of KEMRI and the Kenyan MoH’s contribution to arzipraziquantel’s development and eventual distribution will transform the lives of tens of millions of children. This could bend the schistosomiasis burden curve and inform national and WHO guidelines. The significance of this work cannot be overstated, and the fact that such work was achieved in a simple laboratory like Homabay, which studies schistosomiasis in Kenya, is commendable. The Homabay team should be proud,” Dr. Kunii reflected.

Encouraging knowledge sharing and technology transfer between research institutions in LMICs and Japan

Our second key activity is facilitating the sharing and transfer of knowledge and technology with LMIC-based research institutions, which helps promote open access to research findings, facilitates technology licensing agreements, and fosters joint R&D and access and delivery collaborations, including regulatory.

Guiding GHIT Fund R&D investments towards a needs-driven approach

Our third activity focuses on maximizing the impact of our diverse investments on the ground. To achieve this, GHIT engages more proactively with research institutions in LMICs, where the neglected infectious diseases are most prevalent, to identify gaps in research, and needs relevant to local contexts. This, in turn, informs GHIT’s investment prioritization process. Fruitful discussions with partners in Kenya demonstrated the value of these connections in helping inform GHIT’s investment approach.
The GHIT Fund convened 120 key stakeholders for its 10th Anniversary Dinner at a hotel in Tokyo on October 20th, 2023 to thank its supporters and share its third five-year strategic plan, “GHIT 3.0.”

Dr. Hiroki Nakatani, GHIT Chair & Representative Director, opened the event with a statement of profound gratitude to all the partners who have supported our global health efforts over the past 10 years, and a request for continued partnership over the next decade.

Mr. Seiji Kihara, Acting Secretary-General of the Liberal Democratic Party and Member of the House of Representatives, offered a congratulatory toast, expressed his appreciation for the GHIT Fund’s past contributions and his expectations regarding future developments in global health. This was followed by a “Kagami Biraki,” a traditional sake barrel opening ceremony, where our Council members formally welcomed GHIT’s new phase and offered blessings for its productive future.

Among our esteemed guests was global health luminary Honorable Professor Keizo Takemi, Member of the House of Councillors in Japan’s National Diet and Minister of Health, Labour and Welfare, who played a pivotal role in GHIT’s establishment. His congratulatory remarks emphasized the impact of collaboration over the past decade and expressed hopes for continued growth and impact.

“I believe that the past 10 years of collaboration between industry, academia, government and the private sector, connecting Japanese and overseas institutions and promoting global open innovation, have not only contributed to people in developing countries, but have also made a significant contribution to strengthening drug discovery in Japan. I sincerely hope that the GHIT Fund will continue to grow in this major role and further promote activities to improve the health of people in the global community, especially in low- and middle-income countries.”

Following Hon. Prof. Takemi, Dr. Osamu Kunii, CEO of the GHIT Fund, delivered a presentation titled “GHIT 3.0 – Towards the Next 5 Years,” reiterating our commitment to work alongside partners in Japan and overseas to enhance the efficiency and acceleration of research and development efforts, ensuring products reach patients in need as quickly as possible.

Later in the evening, we were delighted to welcome musician Ryota Fujimaki as a special guest. His connection with Dr. Kunii in Africa and his involvement in various GHIT activities added a poignant touch to the event. Together, they reflected on the importance of addressing neglected health issues. Mr. Fujimaki’s impassioned musical performance further enriched the gathering.

Dr. Kunii closed the event with a call to fortify collaboration and continue our collective advancement in the fight against infectious diseases, in partnership. He reiterated deep gratitude to all the stakeholders who have supported the GHIT Fund over the past decade and appealed for continued backing as we embark on the next phase of our journey.
In FY2023, GHIT welcomed three new partners to the fold. Fujirebio Holdings Inc. and Remedy & Company Corporation have joined the GHIT Fund as associated partners, while EIKEN CHEMICAL CO., LTD. has become a sponsor.

We anticipate that Fujirebio’s expertise and experience in clinical diagnostics, Remedy’s experience in clinical trials in developing countries harnessing the latest technologies and technological innovations, and EIKEN’s expertise and knowledge in diagnostic reagents will help to advance product development. With the launch of GHIT 3.0, many important partners have expressed their continued support, strongly demonstrating the expectation placed in the GHIT Fund to have a positive impact on global health.

In October 2023, the GHIT Fund has signed a Memorandum of Understanding (MOU) with the Institut Pasteur de Dakar (IPD), a Senegalese non-profit foundation, to advance research and development in the field of infectious diseases in low- and middle-income countries (LMICs). IPD focuses on advancing healthcare access in Africa through innovative biomedical research and the manufacturing of essential vaccines and diagnostics, and engages in public health activities including in surveillance and diagnostics through its Syndromic Sentinel Surveillance in Senegal (4S Network), supporting over 22 African countries in epidemic outbreak detection and management. Through this new partnership, the two institutions will accelerate product development for neglected diseases in LMICs in the areas of therapeutics, vaccine and diagnostic research and development, and strengthen collaboration to support low-cost vaccine and diagnostics manufacturing in LMICs through technology transfer and know-how sharing with Japanese pharmaceutical companies and academia.

In the same month, the GHIT fund also signed a MOU with the Medicines Patent Pool (MPP), a United Nations-backed public health organization, to strengthen their collaboration in the improvement of access to medicines. MPP is working to increase equitable access to innovative medicines and other health technologies through public health-oriented voluntary licensing and technology transfer. Through this partnership, the GHIT Fund and MPP will share knowledge and perspectives on access-oriented licensing and other issues relating to the affordable access to medical technologies in LMICs and will identify opportunities for further collaboration.
In October 2023, the GHIT Fund invited Willo Block, Executive Vice President of External Relations, FIND and Ayushi Agnihotri, Deputy Director of Resource Mobilization, FIND for a joint seminar to explain FIND’s strategy for global health. FIND is an international non-profit organization dedicated to driving progress towards global health through innovative diagnostics. FIND seeks to ensure equitable access to quality diagnostics around the world and is focused on connecting countries, communities, funders, decision-makers, healthcare providers and developers to spur diagnostics innovation and make testing an integral part of sustainable and resilient healthcare systems. Japan is a global leader that can shape healthcare and health systems in emerging markets, and its long-standing partnership with the GHIT Fund has enabled POCT tuberculosis diagnostics and the targeted mass drug administration for schistosomiasis. FIND and the GHIT Fund will contribute to the diagnostic innovation through their partnerships.

As a member of the World NTD Day Japan Preparatory Committee, the GHIT Fund held a special webinar event on January 30, 2024, for “World NTD Day” to raise understanding and interest in neglected tropical diseases (NTDs). The webinar featured a “Tell us Kunii-sensei!” section moderated by Osamu Kunii, CEO of the GHIT Fund. The speakers explained the current issues regarding NTDs from their perspectives as researchers and businesspeople, answering questions about the nature of NTDs and whether NTDs exist in Japan.

In addition, the awards ceremony was held for the first-ever Neglected Tropical Diseases Student Contest held in Japan, organized by the NTDs Youth Organization to coincide with World NTD Day, with GHIT sponsoring the contest. The contest received 35 entries from students ranging from junior high to graduate school. The goal was to raise students’ understanding and interest in NTDs.

The GHIT Award went to four first-year nursing students from Makuhari Sogo High School in Chiba Prefecture. Their winning submission highlighted the need for solving problems through partnerships.
In May 2023, on the eve of the G7 Health Ministers’ Meeting, global health leaders from around the world convened in Nagasaki to call for the prioritization of neglected tropical diseases (NTDs). Gathered at the Symposium for G7 Health Ministers’ Meeting in Nagasaki, “Accelerating Research, Development, Access, and Delivery for Neglected Tropical Diseases” hosted by the GHIT Fund, Nagasaki University and Uniting to Combat NTDs (Uniting), leaders in global health jointly developed the Nagasaki Outcome Statement which calls for the acceleration of R&D, access, and delivery for NTDs.

The Statement builds on and reaffirms the “Kigali Declaration on NTDs,” a high-level political declaration that is mobilizing political will, community commitment, resources and action, and securing commitments needed to end suffering caused by NTDs. The Statement outlines how tackling NTDs is critical to achieving G7’s ambitions on universal health coverage and pandemic preparedness.

In addition to six asks to G7 Leaders to support investments in R&D, access and delivery, the Statement recognizes that the global NTD community must play a key role. Seven call-to-actions are outlined for the NTD community including the development of innovative funding mechanisms to mobilize substantial funding for NTD elimination.

Signed by approximately 20 organizations and individuals including Uniting to Combat NTDs, Nagasaki University and GHIT Fund, the Nagasaki Outcome Statement commends G7 Leaders for including NTDs in the G7 Leaders’ communiqué, and for prioritizing universal health coverage and pandemic preparedness. It urges Leaders to continue to support investments in R&D for vaccines, new drugs and diagnostics for NTDs, as well as financing to ensure access of these innovations and technologies to the most vulnerable populations affected by NTDs.

For the full Nagasaki Outcome Statement, please refer to the website on the right.

NIKKEI FT Communicable Diseases Conference / UN High-Level Meeting side event

The NIKKEI FT Communicable Diseases Conference, organized by the Nikkei, took place in Tokyo in October and GHIT was a sponsor as in previous years, with discussions moderated by Osamu Kunii, CEO of the GHIT Fund. The conference was preceded by a side event at the UN General Assembly High-Level Meeting in September entitled ‘Ongoing pandemic TB response and future pandemic preparedness - how to make synergy’ in New York, USA, jointly organized by the Nikkei, the Government of Japan and the Stop TB Partnership, which featured discussions with renowned experts from around the world on how Japan can contribute to the fight against infectious diseases.
In November 2023, the GHIT Fund held a meeting of the Expert Panel of the Hit to Lead Program (HTLP), which targets the discovery of lead compounds in the early stages of research and development. The HTLP Expert Panel consists of members from three Product Development Partnerships (PDPs), the TB Alliance, the Medicines for Malaria Venture (MMV), and the Drugs for Neglected Diseases Initiative (DNDi), as well as the Bill & Melinda Gates Foundation. Each member has extensive knowledge and experience in drug development.

Together with Mitsubishi Tanabe Pharma Corporation, Eisai Co., Ltd., and Daiichi Sankyo Company, Ltd., collaborators of PDPs on screening and HTLP projects, the Expert Panel discussed the progress of the projects, the acceleration of product development, and new collaboration opportunities with Japanese pharmaceutical companies. The Panel also visited to the Japan Agency for Medical Research and Development (AMED), and participants exchanged views on future collaboration and outlook on drug development.

We leverage Japanese innovation and fight neglected diseases through partnerships.
The GHIT Fund is an international organization that supports the product development of drugs, vaccines, and diagnostics for malaria, tuberculosis and neglected tropical diseases (NTDs).

Diseases "neglected" by the world

Despite the many people suffering from various infectious diseases, such as malaria, tuberculosis, and neglected tropical diseases (NTDs) in low- and middle-income countries, they have been "neglected" due to the lack of safe, approved products for treatment and prevention.

- **Malaria**
  - Deaths in 2022: 610,000

- **Tuberculosis**
  - Deaths in 2022: 1.3M

- **NTDs**
  - Cases in 2021: 1.6B

By comparison:
- Deaths from lung cancer in Japan in 2021: 76,000

Source: *1 WHO  *2 National Cancer Center Japan

Why developing new drugs for neglected diseases is so difficult

- **High cost** (over USD 500M)
- **Time consuming** (over 10 years)
- **Lack of financial profit**
- **High barriers to entry**
- **Poverty**
- **Lack of progress in R&D**
- **Sickness and stigma prevent make study and work impossible**
- **Few or no treatment options**

This makes it difficult for companies to participate in product development.

Patients are caught in a vicious cycle.

The GHIT Fund tackles these challenges head-on.

25
Our approach

The GHIT Fund is an international non-profit organization that supports product development of drugs, vaccines, and diagnostics for malaria, tuberculosis, and NTDs that are difficult for companies to invest in alone. We fundraise through global public-private partnerships.

GHIT by the numbers

- **Total Investment**: Over USD300M
- **Total Invested Programs**: Over 120
- **Total Product Development Partners**: Over 170
- **Clinical Trials**: Over 10 projects
- **Registration**: 1 project

As of December 31, 2023

Goals to be achieved by 2027

Delivering new drugs, vaccines, and diagnostics to patients who suffer

- Galvanize Innovation
- To the patients
- Catalyze Partnerships
- Maximize investment impact

Tackling neglected infectious diseases through global partnerships

The GHIT Fund serves as a networking hub to accelerate product development by connecting Japanese and global institutions, including governments, private companies, foundations, NGO/NPOs, and UN agencies.

- Over 60 Japanese organizations
- Over 100 non-Japanese organizations

GHIT 3.0

Our third five-year plan
A Decade of History and Diverse Approaches to Work

GHIT Fund (GHIT) celebrated its 10th anniversary since the launch of its operations in April 2013. One aspect that has supported the growth of our organization is our unique GHIT Culture, which embraces and respects the diverse backgrounds of our people, their values, and varied approaches to work. We sat down to talk about the appeal of working at GHIT, while looking back on the past decade.

From left to right: Hayato Urabe (Associate Vice President, Investment Strategy, Portfolio Development & Innovations), Eriko Koyama (Senior Manager, Investment Strategy, Business Development), Hiroki Shibata (Manager, External Affairs & Corporate Development)

A desire to support low- and middle-income countries and contribute to global health

Urabe: This year marks the 8th year since I joined GHIT in April 2016. Having experienced the 10th anniversary of GHIT, I now feel that we have grown both as an organization and as a team.

The investment strategy team that I oversee is responsible for evaluating product development projects, which stand at the core of GHIT, searching for new innovations, supporting investment decisions, managing progress and developing access and implementation strategies.

Koyama: I work in the investment strategy and business development department, which involves supporting the early stages of R&D, forming new partnerships, and inviting organizations to become new product development partners. Our department’s role is to connect partners and communicate with various stakeholders.

Shibata: I recently joined GHIT in September 2023. Currently, as the person in charge of external affairs and corporate development, I am responsible for fund-raising and managing board meetings, among other duties.

Looking back on the past decade and challenges

Urabe: At the time of its establishment, it was important for GHIT, a Japan-based international public-private partnership, to achieve recognition. Success could be measured by sound investment or grant-related decisions leading to the advancement of R&D projects. However, by the 8th and 9th year, we had made steady progress in the product development stage. We thus transitioned to a stage where we are not only making investments, but also seamlessly promoting the projects we have invested in through clinical trials and regulatory approvals, and concentrated on how to deliver the products to patients in need. We increased the size of the team in charge of access and delivery and both my team and the organization have grown significantly over the past 10 years.

Koyama: I feel a sense of accomplishment when I see past investments finally lead to results. At GHIT, one of the requirements to apply to our investment program is that Japanese partners and non-Japanese partners jointly conduct R&D. We set this condition because we want to combine the strengths of Japanese and overseas organizations to develop drugs, diagnostics, and vaccines (products) through open innovation. Of course, Japanese researchers may hit a wall if they want to apply for GHIT’s investment program but cannot find a suitable overseas partner.

My job is to connect Japanese and non-Japanese organizations. Partners may
take two to three years to apply to GHIT, and researchers sometimes reapply multiple times with new partnerships. I find my work most rewarding when these projects are finally selected by GHIT.

Shibata: I have only been with GHIT for a short time, and the board meeting and GHIT 10th anniversary dinner were held soon after my joining. This was my first time managing a GHIT conference or event, so I prepared carefully alongside my more experienced team members. I believe that the board meeting went smoothly because of our careful attention to details during the preparations. The 10th anniversary dinner was another major event attended by important stakeholders. I experienced a great sense of accomplishment after its successful conclusion and felt humbled by the support of our many stakeholders.

A culture supportive of diverse approaches to work

Urabe: GHIT is still only in its 10th year and is operating with a small team of highly skilled employees. At the time of its founding, none of GHIT’s employees were parents. As GHIT grew in size and recruited staffs with children, achieving a balance between work and family has sometimes proved difficult. On these occasions, it was important to concentrate and increase productivity to make the most of one’s limited time, build a relationship of trust with supervisors, and get both supervisors and teammates to understand one’s personal work style. Many of my teammates have children and we share our situations and help each other to ensure the job gets done, and I think this can be only accomplished with an established culture of trust.

Koyama: I gave birth two years ago and returned to work after taking maternity and childcare leave. Since my husband is busy with work, it is my role to drop off and pick up my child, so I was unsure whether I would be able to work full time. Luckily I was encouraged by other “mothers” returning and being able to work full-time, thanks to our organization understanding flexible working styles.

Urabe: GHIT has a full flextime system in place to allow employees to work flexibly. For example, remote meetings with Europe often take place in the evening, and in those cases, we sometimes leave work an hour earlier than usual.

Shibata: My wife also works full time, so I often take our children to and from daycare. I have to finish work at 5pm to pick up my children so I work under the full flextime system with no core time. If my children have a fever and require care, I may work from home, and it’s reassuring to know that my supervisor and teammates understand.

Urabe: We also have several foreign nationals working at GHIT. This results in a culture of diverse values conducive to the emergence of new ideas. We work in diverse and flexible environments in terms of work locations and time differences, so we share information by staying in close contact.

Koyama: The personal time system is also very helpful. During their first year at daycare, my child often had a fever, so I had to use a lot of paid vacation time. This system can also be used for regular hospital visits.

*Personal time: Employees are allowed to take up to three hours off a week for personal time during working hours.

Urabe: These systems are predicated on responsibility and performance. It’s important for employees to manage themselves so they can reliably produce the expected results. Needless to say, we must use our limited time efficiently while building a relationship of trust and communicating with teammates and supervisors.

Career vision at GHIT

Shibata: I am still passionate about the aviation industry I worked in before. GHIT’s vision is to eliminate neglected infectious diseases that affect over a billion people with the aim of achieving health equity. By carrying out my current duties, I will support the achievement of this vision and help more people stay healthy and safe, enabling them to use airports to travel to their favorite places and meet their loved ones. I hope to be able to contribute to the actualization of such a world, even modestly.

Koyama: The degree of awareness around “neglected diseases” still remains low. In order to reach researchers and many other people who don’t know about GHIT, I would like to start with organizing in-person meetings and sharing the greatness of Japanese technology with the world.

Urabe: I have set my own personal principles based on three pillars: “Connecting laboratory to society,” “Connecting Japan and Overseas,” and “Connecting LICs/LMICs and HICs.” I hope to be able to create paths for Japan to contribute significantly. I am fortunate that my current responsibilities encompass these three pillars, and I wish to always think outside the box, discover new technologies and explore new approaches.

From a management standpoint, I want GHIT employees to enjoy an experience that ultimately brings them as close to their career vision as possible. My goal is to support my fellow teammates in their acquisition of the skills necessary to achieve their dreams for the future. Part of my vision is to support their visions.
## Finances

### FY2023 Financial Summary

<table>
<thead>
<tr>
<th>Balance Sheet</th>
<th>JPY</th>
<th>USD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
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<td></td>
</tr>
<tr>
<td>Current Assets</td>
<td>51.2</td>
<td>0.3</td>
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<tr>
<td>Fixed Assets</td>
<td>8,723.7</td>
<td>57.6</td>
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<tr>
<td><strong>Total Assets</strong></td>
<td>8,774.9</td>
<td>57.9</td>
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<tr>
<td><strong>Liabilities</strong></td>
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<tr>
<td>Current Liabilities</td>
<td>110.8</td>
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<tr>
<td>Non-current Liabilities</td>
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<td><strong>Total Liabilities</strong></td>
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<td><strong>Net Assets</strong></td>
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<td>Designated Net Assets</td>
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<tr>
<td>General Net Assets</td>
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<td>-</td>
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<tr>
<td><strong>Total Net Assets</strong></td>
<td>8,658.6</td>
<td>57.2</td>
</tr>
<tr>
<td><strong>Total Liabilities and Net Assets</strong></td>
<td>8,774.9</td>
<td>57.9</td>
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*The US dollar amounts in this section represent translations of Japanese yen, solely for the reader’s convenience, at JPY151.33 = USD1, the exchange rate as of March 31, 2024.*

*This financial summary is an excerpt from the GHIT Fund’s audited financial statements, which are audited by Ernst & Young ShinNihon LLC. The GHIT Fund is a Public Interest Incorporated Association and is registered in Japan.*

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### Our Funding Partners & Sponsors

#### Full Partners

- MOFA Japan
- Ministry of Health, Labour and Welfare
- UNDP

#### Public

- Bill & Melinda Gates Foundation
- Wellcome Trust
# Net Assets Variation Statement

## Change in General Net Assets (in millions)

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<tr>
<th>Ordinary Income</th>
<th>JPY</th>
<th>USD</th>
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<tbody>
<tr>
<td>Grants Received</td>
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<tr>
<td>Contribution Received</td>
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<td>Foreign Exchange Gains</td>
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<tr>
<td>Misc. Income</td>
<td>8.9</td>
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<tr>
<td><strong>Total Ordinary Income</strong></td>
<td><strong>3,747.8</strong></td>
<td><strong>24.7</strong></td>
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</table>

## Ordinary Expenses

<table>
<thead>
<tr>
<th>Ordinary Expenses</th>
<th>JPY</th>
<th>USD</th>
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<tbody>
<tr>
<td>Operating Expenses</td>
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<td>23.6</td>
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<tr>
<td>Management Expenses</td>
<td>171.4</td>
<td>1.1</td>
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<tr>
<td><strong>Total Ordinary Expenses</strong></td>
<td><strong>3,747.8</strong></td>
<td><strong>24.7</strong></td>
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## Extraordinary Loss

<table>
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<tr>
<th>Extraordinary Loss</th>
<th>JPY</th>
<th>USD</th>
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<tr>
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<td><strong>0.0</strong></td>
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<tr>
<td><strong>Total Extraordinary Loss</strong></td>
<td><strong>0.0</strong></td>
<td><strong>0.0</strong></td>
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## Change in Designated Net Assets (in millions)

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<tr>
<th>Grants Received and Others</th>
<th>JPY</th>
<th>USD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Governments, NGOs, Multilateral Organizations</td>
<td>3,618.6</td>
<td>23.9</td>
</tr>
<tr>
<td>Foundations</td>
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<td>9.0</td>
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<tr>
<td>Contributions Received</td>
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<td>10.6</td>
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<tr>
<td><strong>Total Grants and Contributions Received</strong></td>
<td><strong>6,585.0</strong></td>
<td><strong>43.5</strong></td>
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Leadership

Council

Composed of representatives of the Japanese government, global foundations and private companies which contribute funding, GHIT’s Council votes on important affairs, such as the election and dismissal of governors, amendments to the articles of incorporation, and the approval of financial statements.

Takeshi Akahori
Ambassador, Assistant Minister, Director-General for Global Issues Ministry of Foreign Affairs

Eiji Hinoshita, MD, PhD, MSc.
Assistant Minister for Global Health and Welfare Ministry of Health, Labour and Welfare

Trevor Mundel, MD, PhD
President, Global Health Bill & Melinda Gates Foundation

Cheryl Moore
Chief Research Programmes Officer Wellcome

Astellas Pharma Inc.
Kenji Yasukawa
Representative Director, Chairman of the Board

Chugai Pharmaceutical Co., Ltd.
Osamu Okuda, PhD
Representative Director, President & CEO

Daiichi Sankyo Company, Limited
Sunao Manabe, PhD
Representative Director, Executive Chairperson & CEO

Eisai Co., Ltd.
Haruo Naito
Representative Corporate Officer and CEO

Shionogi & Co., Ltd.
Isao Teshirogi, PhD
Representative Director, President and CEO

Takeda Pharmaceutical Company Limited
Christophe Weber
Representative Director President and CEO

Board of Directors

Composed of global health and management experts, GHIT’s Board of Directors oversees the work of the leadership team and votes on important affairs related to business management, such as the approval of important regulations, mid-term strategies, annual plans, budgets, and investment opportunities.

Chair & Representative Director
Hiroki Nakatani, MD, PhD, MHPEd
Visiting Professor Keio University School of Medicine

Vice Chair
Peter Piot, MD, PhD
Professor of Global Health, London School of Hygiene & Tropical Medicine Special Advisor to the President of the European Commission on European & Global Health Security

Executive Director
Osamu Kunii, MD, PhD, MPH CEO, GHIT Fund

Mahima Datla
Managing Director Biological E. Limited

Satoshi Ezoe, MD, MPH, MPA, PhD
Director, Global Health Strategy Division International Cooperation Bureau Ministry of Foreign Affairs

Tetsuya Itani

Daikichi Momma
Vice Chairman Institute for International Economic Studies

Ann M. Veneman, JD
Former Executive Director, UNICEF Former Secretary United States Department of Agriculture

Supervisory Board Member
Hikaru Ishiguro, LLM
Statutory Auditor INSPIRE Corporation

Saori Nakamura
Attorney at Law Hiryama Nagareya Shirai Law Office

Ko-Yung Tung, JD
Former Senior Vice President and General Counsel, World Bank Former Lecturer on Law, Harvard and Yale Law Schools International lawyer

Ex-Officio
Ko-Yung Tung, JD
Director, Neglected Tropical Diseases

Richard Seabrook, PhD, MBA
Independent Senior Advisor, Wellcome CEO, 360Biomedical Ltd Sector Specialist - Expert in Residence University of Bristol

Ex-Officio
Katey Einterz Owen, PhD
Director, Vaccines Development Bill & Melinda Gates Foundation
Selection Committee

Composed of domestic and foreign experts with a wealth of knowledge and experience in R&D of therapeutic agents, vaccines, and diagnostic agents, the Selection Committee (SC) examines and evaluates applications and progress reports from program applicants and recommends investment opportunities to the Board of Directors. To avoid any conflict of interest between our backers and development partners, the SC does not include private sector representatives.

Chair
Ann Mills-Duggan, PhD
Independent Consultant

Timothy Jinks, PhD
Head, Infectious Diseases Interventions
Wellcome

Paul Jorgensen, BS
Independent Consultant

Osamu Kunii, MD, PhD, MPH
CEO

Ken Duncan, PhD
Deputy Director
Discovery & Translational Sciences
Bill & Melinda Gates Foundation

Ken Ishii, MD, PhD
Professor, Institute of Medical Science
University of Tokyo

Hiroo Koyama, PhD
Platform Unit Leader
Drug Discovery Chemistry Platform Unit
RIKEN Center for Sustainable Resource Science

Karen L. Menge, PhD
Independent Consultant

Naoto Uemura, MD, PhD
Professor, Department of Clinical Pharmacology and Therapeutics
Oita University Faculty of Medicine

*Retired on March 22, 2024

Rieko Yajima, PhD
Director, Drug Discovery Innovation
SPARK Program in Translational Research
Stanford University School of Medicine

Ann Mills-Duggan, PhD
Independent Consultant
Chair

Kazue Seki
Director, External Affairs & Corporate Development

Eriko Mugitani
Associate Director, Brand Communications

Shin Sakai
Associate Vice President, Corporate Operations

Naoto Uemura, MD, PhD
Professor, Department of Clinical Pharmacology and Therapeutics
Oita University Faculty of Medicine

The leadership team facilitates the development of business, investment, and organizational growth strategies, executes strategies based on the approval of the Board of Directors, and implements administrative tasks.

Leadership Team

Osamu Kunii, MD, PhD, MPH
CEO

Karen L. Menge, PhD
Independent Consultant

Hayato Urabe, PhD, MPIA
Associate Vice President, Investment Strategy
Portfolio Development & Innovations

Ken Ishii, MD, PhD
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As of March 31, 2024
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Support from our generous funding partners and sponsors helps GHIT’s investments and operations advance and create meaningful impact. We would like to express our deepest gratitude for their generous support.

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As of March 31, 2024
## Overview

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<thead>
<tr>
<th>Name</th>
<th>Global Health Innovative Technology Fund (GHIT Fund)</th>
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<tbody>
<tr>
<td>Address</td>
<td>Ark Hills Sengokuyama Mori Tower 25F, 1-9-10 Roppongi, Minato-ku, Tokyo 106-0032</td>
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</tbody>
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| | TEL: +81-36441-2032 /
| | FAX: +81-36441-2031 |
| Launched | November 6, 2012 (Operations started in April 2013) |
| Chair & Representative Director | Hiroki Nakatani |
| CEO & Executive Director | Osamu Kunii |
| Activities | 1. Facilitation of global R&D partnerships for the discovery and development of new health technologies for the developing world |
| | 2. Investment in these global R&D partnerships through a grant-making mechanism |
| | 3. Advancement of Japan’s contribution to global health |
| Website | https://www.ghitfund.org/en |