Prepared by
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www.oyageninc.com

What OyaGen Is?

- OyaGen is a privately held, biotech company in Rochester, NY with drug discovery technology and research infrastructure that has enabled the development of unique and highly effective treatments for COVID and Ebola as well as a solution for eradicating HIV/AIDS.

- The company is now 20 years old, founded as a Delaware Corp by Dr. Harold Smith, a full professor of Biochemistry at the University of Rochester School of Medicine and Dentistry.

- Since 2003, the company has raised greater than $17MM from investors, licensing deals and federal grants. Approximately 48% of the funds raised have been non-dilutive.

- Industrial, federal, state and VC leaders in the space who have worked with the company acknowledge that OyaGen has advanced novel leads for treating infections by Coronavirus, Ebola and HIV through its high-tech capabilities, ideation and innovation.

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Business Model

- Satisfy the the urgent need for treatments that will address existing and emerging infectious diseases affecting people around the globe by discovering small molecules that inhibit disease processes.

- Validate drug candidates through Investigational New Drug (IND)-enabling preclinical studies for FDA regulatory approval.

- Partner or license IND-enabled drug candidates to governments and/or the pharmaceutical industry for upfront deals, milestones and royalties.

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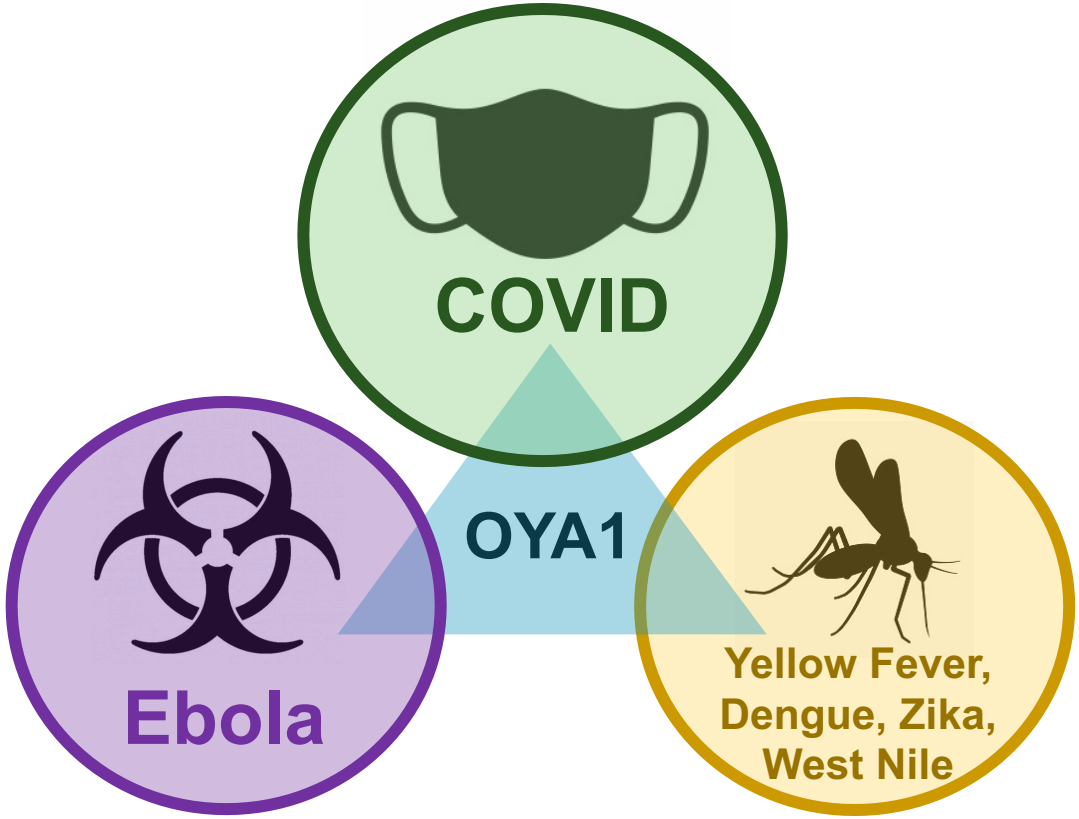
OyaGen's Technology Platform

OyaGen Has Two Advanced Lead Candidates Addressing HIV Rebound as well as COVID and Ebola Outbreaks

HIV/AIDS

SN38 prodrug

OyaGen's oral formulation SN38 prodrug has low nanomolar antiviral activity with extended release, has very low toxicity and acts through host defense factors and HIV TAT to inhibit viral replication and viral rebound even after the drug is removed as a possible functional cure.



OyaGen's broad-spectrum antiviral lead OYA1 has low nanomolar efficacy against COVID, Ebola and Lassa and is predicted to be active against all viruses that use RNA-dependent, RNA polymerases for their replication.

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The OyaGen Team

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OyaGen's Team has Decades of Pharma Industry, Biotech Leadership & Drug Development Experience

Management

Dr. Harold Smith, Founder & CEO
Mr. Thomas Fitzgerald, Ltd, COO
Dr. Ryan Bennett, CSO
Mr. Kevin Phelps, CFO

Board of Directors

Dr. Roscoe Moore
Dr. Richard Ogden
Mr. Kevin Phelps
Dr. Harold C. Smith

Key External Drug Development Advisors

Dr. David Ho (HIV/AIDS basic and clinical science)
Dr. Thomas Chung (medicinal chemistry)
Dr. Viviana Simon (APOBEC/viral resistance)
Dr. Robert Buckheit (drug testing)

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Please see https://oyageninc.com/people for biosketches

An Outstanding Investment and Partnering Opportunity

- OyaGen has identifying drug leads that address treatment and cures for HIV, SARS-CoV-2 and Ebola.
- Market potential for novel drugs for infectious disease that may otherwise escape vaccines or not have an effective vaccine.
- OyaGen technology and knowhow will enable decades of discovery, anticipating and addressing therapeutic needs for infectious diseases.
- Our current drug leads have been validated by third party labs.
- Drug lead synthesis and formulation have been determined.
- Patents cover the drug candidates and their therapeutic indications.
- State-of-the-art research laboratory infrastructure with high-tech knowhow and fee-for-service.

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Contact Information

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Current and Future Lead Development, Testing and Funding Needs

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OyaGen's Development Plan and Initial Need for $8 MM USD

- **HIV $35.5 MM as a tranched investment (first tranche)**
  - **Milestone 1**: $5 MM to complete antiviral efficacy studies with the oral SN38 prodrug in humanized mice +/- antiretrovirals to determine the optimal criteria to prevent HIV rebound
  - Synthesis cGMP chemistry, oral formulation and conduct stability studies
  - Conduct pharmacokinetics with oral dosing of formulated drug
  - Complete IND-enabling studies and schedule an FDA pre-IND meeting to discuss human safety data, mechanistic studies and the proposed clinical study.
  - Apply for an IND
  - **Milestone 2**: Raise $3.5 MM for a Phase I clinical trial
  - **Milestone 3**: Raise $27 MM to conduct a Phase II clinical trial
  - **Milestone 4:** Partner with Pharma for follow on Phase II clinical trials
- **COVID/Ebola $18.1 MM as a tranched investment (first tranche)**
  - **Milestone 1:** Raise $3 MM to complete antiviral efficacy studies on OYA1 in the hamster lung model
    - Reengage the FDA with the completed data package they requested
    - Apply for an IND
  - **Milestone 2:** Raise $5.5 MM for a Phase I clinical trial using cGMP OYA1 on hand
  - Partner for the Phase II clinical trial and additional OYA1 cGMP synthesis
  - **Milestone 3:** Raise $4.3 MM to develop an oral formulation for OYA1
    - conduct oral dosing/pharmacokinetics in two species
    - conduct *in vivo* antiviral efficacy studies
    - apply for an IND
  - **Milestone 4:** Raise $5.3 MM to prepared cGMP oral formulation of OYA1 and conduct Phase I clinical trial
  - **Milestone 5:** Partner for the Phase II clinical trials

Take Home

- OyaGen is filling a need for a rapid response to viral pandemics with novel therapeutics.
- Globally, broad-spectrum antivirals such as OYA1 are highly desirable.
- OyaGen lead compounds in development will fill a need for treatments for diseases where there are no vaccines (HIV), where vaccines are infective (Ebola) or where people cannot or will not take a vaccine (COVID).
- Through OyaGen's collaboration with the University of S. Australia, the company will produce leads that are formulated to be orally available, slow release and may be used for prevention and functional cure strategies.
- The company and its platform for drug discovery have had multiple millions of dollars in federal government support through grants and in-kind services.
- The company not only has deep technological expertise in the biological and drug discovery sciences but also has a track record of successful grant and patent applications and publishing manuscripts.
- OyaGen has a track record of successfully working with Contract Research Organizations (CROs), academic collaborators, and providing fee-for-service drug discovery.
- The company is developing drug discovery platforms for other viral diseases and for cancer treatments.

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OyaGen's Asset Pipeline
SN38

- OyaGen has patented and published camptothecin derivatives as first-in-class HIV therapeutics.
- The mechanism of action is to prevent HIV Vif-dependent degradation of APOBEC host-defense mechanism along with inhibition of HIV Tat.
- OyaGen has shown in collaboration with the University of South Australia that nanoparticle, oral formulation of SN38 prodrug:
  - enables extended release of SN38 over 48 hours while maintaining drug levels at the IC_{90} for HIV inhibition
  - enables durable HIV remission with undetectable HIV levels in a subset of treated animals three weeks after dosing has stopped
  - significantly reduces toxicity associated with SN38 or Irinotecan alone
- The University of South Australia plans to evaluate the SN38 prodrug formulation in clinical trials for rectal cancer and from these studies, human safety data will be available to complement an IND application for clinical trials or HIV rebound and a functional cure.

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OyaGen's Asset Pipeline
OYA1

- OyaGen holds two patents for the use of OYA1 as broadly neutralizing antiviral against Ebola and Coronaviruses. Our published data demonstrated that OYA1 is effective alone or in combination therapy at low nanomolar IC_{90} and with low off target effects.
- OYA1 is dual acting on Ebola, inhibiting viral replication through the RNA-dependent, RNA polymerase (RdRp) and prevents viral particle assembly and release.
- OYA1 inhibits Coronavirus replication through the viral RdRp. The company therefore proposes that OYA1 will be effective against all viruses that require RdRp for their replication such as Lassa, Yellow Fever, Dengue and Zika.
- OYA1 is well tolerated in human subjects as shown through historical cancer clinical trials which used OYA1 at a range of doses and dose frequencies that were 10-times more than the effective dose predicted to stop COVID and Ebola.
- Our studies have been confirmed by third parties, peer reviewed and published in three papers and received two NIH grants. 134 grams of cGMP OYA1 has been prepared and stability tested. Animal PK and tox that have been recommended by the FDA in a preIND meeting have been performed.

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