



HAWAII BIOTECH

Targeting Infectious Disease

**Vaccines and Medical
Countermeasure Drugs**

For A Safer World

Preparedness is now an International goal

- **Pandemics and Epidemics**
 - Naturally occurring or man-made
- **Bioterrorism Attacks**
 - Rogue nations: Iran, North Korea, Syria, Russia.....
 - Independent actors: al Qaeda, Hezbollah, ISIL.....
- **Synthetic Biology**
 - DIY designer drugs and pharmaceutical-based agents

The Growing Pandemic Threat

- **2002-2004 = SARS**
- **2009 = H1N1**
- **2012-2015 = MERS**
- **2014-present = Ebola**
- **2015-2016 = Zika**
- **2019-2021 = COVID-19**
- **2023 = ??**

Our Purpose

To Develop, Supply and Commercialize

- Safe, non-replicating **vaccines to prevent** infections from emerging and re-emerging viruses
- **Small molecule drugs to treat** infectious diseases for which there are no current medical alternatives
- **Adjuvants** to increase the effectiveness of vaccines
- **High-quality purified proteins** to support the research and development of drugs and biologicals by pharmaceutical and biotech companies

Our Vaccine Platform

- Proven, proprietary **S-2 recombinant protein production** platform with special expertise in multiple protein vaccines
- Exploits our deep **experience** and strong **expertise** in the use of recombinant proteins to create non-replicating subunit vaccines
- Proprietary **vaccine development vectors**
- Proprietary **adjuvants** for prophylactic and therapeutic vaccines including mucosal delivery potential
- In-house **cGMP production** capabilities
- Robust and growing **patent estate** – We own all our own technology and intellectual property
- **Efficient infrastructure** facilitates technology transfer to strategic partners and collaborators

Vaccine Pipeline

- **West Nile Virus**
 - Clinical stage prophylactic program supported by NIAID
 - Therapeutic vaccine collaboration with Baylor Medical School
- **SARS-Cov 1&2** – multiple vaccine designs for monovalent, multivalent, prime-boost and thermally stable candidates
- **Ebola Virus** – NIAID funded with University of Hawaii
- **Zika virus** – NIAID funded, clinic-ready vaccine candidate
- **Tick borne Flavivirus** – NIAID funded tetravalent vaccine
- **Other pipeline programs** – Crimean-Congo Hemorrhagic Fever (NIAID), Chikungunya (NIAID)
- **Dengue Fever** – clinical stage program sold to Merck

Competitive Advantages

- Safety of non-replicating recombinant proteins
- Human clinical trial experience with Dengue and West Nile Virus
- Demonstrated speed to IND with Zika
- In-house manufacturing
- Existing network of collaborators critical for correlation of protection
- Phase 1 capability in Australia

Unique Coronavirus Vaccines

Broad development platform for rapid design of subunits and the use of adjuvants that engender balanced Th1/Th2, or Th1 biased responses for

- Individual monovalent Covid-19 vaccine candidate
- Prime-boost with other vaccines to increase durability
- Thermal-stable vaccine candidate
- Multivalent Coronavirus candidate (SARS, MERS, Covid-19, future coronaviruses)

Coronavirus Second Generation Vaccine

- **Combination Vaccine Candidate**
 - Second Generation Cov-1/Cov-2 spike protein combination vaccine candidate
 - Designed for broad coverage by targeting ACE-2 receptor, utilized by SARS family of viruses
 - Expressing ectodomain
 - NIAID funded

Medical Countermeasures (MCM)

- Developing **small molecule drugs** as effective medical countermeasures against bioterrorism threats
- **Civilian** and **military** use
- **Block** both intracellular and extracellular **bacterial toxins**
- Addressing current **threats**
- **Track record of success in Federally funded grants and contracts – DoD and NIH**

MCM Pipeline

- **Anthrax**
 - “Pill in a pocket” oral anti-toxin drug
 - NIAID funded pre-clinical program for therapeutic drug
 - Targeted to file IND by Q3 2021
- **Botulinum**
 - Oral post-exposure Bot A anti-toxin drug
 - In pre-clinical development
 - NIH grant submission April 2021
- **Additional Therapeutic Targets**
 - COVID-19 (SARS-Cov-2)
 - Cholera toxin

HBI Federal Funding

Anthrax Lethal Factor	\$38,526,000	Awarded
Tick-borne flavivirus	2,700,000	Awarded
Ebola vaccine	1,555,000	Awarded
Chikungunya	2,000,000	Awarded
SARS 1-2 (COVID-19)	390,000	Awarded

Patent Estate

<u>Subject</u>	<u>US</u>	<u>Intl</u>
WNV1	Issued	Application pending
Ebola vaccine1	Issued	Application pending
Botulinum anti-toxin drug1	Issued	Application pending
WNV 2		Applications pending
Ebola vaccine 2		Applications pending
Zika vaccine		Applications pending
Botulinum anti-toxin drug 2		Applications pending
Anthrax anti-toxin drug		Applications pending
Coronavirus		Provisional Application Filed

FDA Incentives Available for Additional Value and Exclusivity

Product	Orphan*	Material Threat*	Tropical Disease*	Expedited Clin Dev	Non-patent Exclusivity
Anthrax Anti-toxin Drug	Post-exposure prophylaxis	Yes		Animal Rule EUA	7-year Orphan 5-year NCE
Botulinum Anti-toxin Drug	Prevention of Botulism	Yes		Animal Rule	7-year Orphan 5-year NCE
Ebola&Marburg Vaccines	Yes	Yes	Yes	EUA	7-year Orphan 12-year Ref Prod**
Chikungunya Vaccine			Yes	Animal Rule	7-year Orphan 12-year Ref Prod**
Tick-borne Vaccine				Animal Rule	7-year Orphan 12-year Ref Prod**
West Nile Vaccine	Treatment Only				7-year Orphan 12-year Ref Prod**
Zika Vaccine			Yes	Animal Rule EUA	7-year Orphan 12-year Ref Prod**

* Vouchers ** Reference Product

Past and Current Collaborations

- Baylor College of Medicine
- Centers for Disease Control and Prevention
- Harvard Medical School
- Merck Sharp and Dohme
- National University of Singapore
- Pediatric Dengue Vaccine initiative
- Purdue University
- Southwest Foundation for Medical Research
- USAMRIID
- University of Hawaii School of Medicine
- University of Texas Medical Branch
- University of Queensland
- Walter Reed Army Institute

Forward Looking Statements

To the extent that statements contained in this presentation are not descriptions of historical facts regarding Hawaii Biotech, Inc. (“HBI”), they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as “may”, “will”, “expect”, “anticipate”, “estimate”, “intend”, “believe”, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements involve substantial risks and uncertainties that could cause our development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the conduct of clinical trials, the timing of the clinical trials, enrollment in clinical trials, expectations for regulatory approvals, and other matters that could affect the availability or commercial potential of our product candidates. HBI undertakes no obligation to update or revise any forward-looking statements.



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