## bigfoot

## BIGFOOT BIOMEDICAL PRESENTS DATA FROM CLINICAL RESEARCH CENTER TRIAL AND SIMULATION MODELING AT DIABETES TECHNOLOGY MEETING

## Agreement Between Predicted Simulations and Actual Trial Results Supports Use of Modeling for Device and Trial Development

**Milpitas, Calif. – November 3, 2017** – Bigfoot Biomedical, Inc., a medical device company harnessing the power of artificial intelligence to automatically and continuously optimize insulin delivery for people with insulin-requiring diabetes, will present data from a clinical trial at the 17th Annual Diabetes Technology Meeting in Bethesda, Maryland.

The trial provided validation for Bigfoot's groundbreaking in-silico metabolic simulation engine. Prior to initiation of the trial, Bigfoot conducted extensive modeling and prospective simulations to refine the algorithms and anticipate system performance during the trial. This simulation environment proved highly predictive of how Bigfoot's investigational automated insulin delivery system would perform when tested in a highly heterogeneous group of subjects, coming from different therapy types (injection and infusion pump) and of different ages, body types, and duration of disease. During the trial, the system performed as anticipated when evaluated under tests designed to challenge glycemic control.

"Bigfoot is heralding the future of artificial intelligence to accelerate the development and testing of drug delivery therapies," said Jeffrey Brewer, the company's president and chief executive officer. "Our ability to model the physiology of insulin-requiring diabetes allows us to simulate months-long clinical trials consisting of thousands of subjects in mere minutes for a fraction of the cost."

"Our ability to model the physiology of insulin-requiring diabetes allows us to simulate months-long clinical trials consisting of thousands of subjects in mere minutes for a fraction of the cost. "People with insulin-requiring diabetes must constantly monitor their blood glucose levels, what and when they eat, and when and how they exercise in order to make calculations and decisions about using insulin," said Lane Desborough, Bigfoot's chief engineer. "Algorithms for automating insulin delivery must be safe and effective for a diverse group of people and account for significant variations in meals, stress, exercise, and illness. Our innovative virtual clinic provides critical insights into how our technology is anticipated to function in these real-world situations. The agreement between our predicted results and our study data validates and supports our use of modeling and simulation to hone our algorithms and predict clinical outcomes."

Bigfoot's aim is to develop highly personalized, safe, and secure insulin delivery systems for people with insulin-requiring diabetes. The ability to run algorithms through a timely, robust, and cost-effective simulation engine speeds the ability to iterate development, testing, and trialing, moving the company more quickly toward the achievement of its mission to diminish the burdens associated with managing insulin-requiring diabetes.

Jeffrey Brewer, CEO

Bigfoot completed this feasibility trial of its investigational automated insulin delivery system in late 2016 and anticipates a pivotal trial of the system will begin in 2018 at clinical sites across the United States.

## About Bigfoot Biomedical, Inc.

Bigfoot Biomedical was founded by a team of people with a personal connection to type 1 diabetes and, with its Loop and Inject services, seeks to change the paradigm of care for insulin-requiring diabetes by leveraging data, connectivity, automation, and machine learning to reduce the burden on people with insulin-requiring diabetes and maximize the leverage of health care providers. Learn more at <u>bigfootbiomedical.com</u>. Follow us on Twitter <u>@BigfootBiomed</u> and <u>Facebook</u>.

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