

## PRESS RELEASE: FOR IMMEDIATE RELEASE

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# BIGFOOT BIOMEDICAL ENROLLS FIRST PATIENTS IN CLINICAL TRIAL OF SMARTLOOP™ AUTOMATED INSULIN DELIVERY SYSTEM

## Trial Studies Proprietary Closed Loop Algorithms Utilizing Bigfoot's Cloud-Connected Insulin Delivery System

**Milpitas, CA, July 21, 2016** – Bigfoot Biomedical, Inc., a company founded and led by people affected by and living with Type 1 Diabetes (T1D), has enrolled its first patients in a clinical trial for the Bigfoot smartloop™ automated insulin delivery system.

Bigfoot was founded with the sole purpose of revolutionizing the treatment of Type 1 Diabetes. Its mission is expressed in a system of care to transform the lives of people who depend upon the daily administration of insulin, a life-giving but also dangerous drug.

“Life with T1D using today’s tools is unreasonable...The smartloop™ automated insulin delivery system has the potential to change people’s lives.”

Jeffrey Brewer, Founder & CEO

“Life with T1D using today’s tools is unreasonable,” according to Jeffrey Brewer, founder & chief executive officer of Bigfoot Biomedical. “Therapies are too expensive, too complex, and require intense focus and attention with little support. Also, healthcare providers are overwhelmed, with too many hurdles blocking them from helping their patients. The smartloop™ automated insulin delivery system has the potential to change people’s lives. It is designed to deliver better health with greater ease of use, making life simpler for both the patient and the clinicians who treat them, ultimately lowering cost of treatment.”

Motivated by a desire to improve the lives of their children, Jeffrey Brewer, former CEO of JDRF International, and Bryan Mazlish, the mysterious “Bigfoot” in Dan Hurley’s piece for [Wired Magazine](#), founded Bigfoot Biomedical in November 2014. Moving with unprecedented speed in medical device development, over the past 20 months they’ve assembled a team of 40 people and are driving toward commercialization of a cutting edge approach to improving the lives of people with T1D.

Bigfoot recently received approval by the FDA of its Investigational Device Exemption (IDE) submission for a first clinical study of the smartloop™ automated insulin delivery system. The trial is slated to take place at three sites, each of which is a global leader in closed-loop insulin delivery research. Bigfoot is collaborating with Stanford University School of Medicine in coordination with Lucile Packard Children’s Hospital Stanford and Stanford Children’s Health in Palo Alto, CA, the William Sansum Diabetes Center in Santa Barbara, CA, and the Barbara Davis Center for Diabetes at the University of Colorado School of Medicine in Aurora, CO.

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) has not yet posted this information, but it should be available within the next few days.

## About Bigfoot Biomedical, Inc.

Bigfoot Biomedical was founded by those affected by and living with Type 1 Diabetes (T1D) and is committed to leveraging data, people, and smart technology to create a connected ecosystem of services and solutions that aim to deliver improved outcomes valued by patients, providers, and payers. Learn more at [bigfootbiomedical.com](http://bigfootbiomedical.com). Follow us on Twitter [@BigfootBiomed](https://twitter.com/BigfootBiomed) and [Facebook](https://www.facebook.com/BigfootBiomed).

## About Type 1 Diabetes

Type 1 Diabetes (T1D), once known as Juvenile Diabetes, is an autoimmune disease affecting the cells in the pancreas that produce insulin, a hormone required for converting food into energy. People with T1D must replace this insulin through multiple daily injections or an insulin infusion pump in order to prevent their blood glucose levels from rising too high. An almost entirely self-managed condition, people with T1D must follow a complex dosing regimen and decision process to administer a drug that is potentially fatal when used incorrectly.

## About “Automated Insulin Delivery”

“Automated insulin delivery,” often referred to as “artificial pancreas” or “closed-loop” technology, refers to a wearable system that uses information about glucose (provided by a continuous glucose monitor, or CGM) to automatically adjust the delivery of insulin by an insulin pump to assist in reducing hypoglycemia (low blood sugar) and hyperglycemia (high blood sugar), attempting to increase the time that blood glucose remains in a healthy, target range.

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