
Interview with Bigfoot CEO Jeffrey Brewer: the shift to focus on Unity, its smart pen MDI titration system - June 6, 2019

Executive Highlights

- **Bigfoot Biomedical is now "aggressively" prioritizing Unity, its smart pen MDI titration system, as its first product launch in 2020.** Conversations with payers, HCPs, and competitive dynamics have pushed Unity ahead of its pump-based automated insulin delivery (AID) system, Autonomy. These AID systems were formerly branded Bigfoot "Inject" and "Loop" - we like the rebranding, especially to avoid confusion with the DIY app, Loop.
- **Bigfoot Unity aims to include smart caps for disposable insulin pens, basal and bolus insulin dosing advice that appears on the pen cap screens,** the ability to scan the FreeStyle Libre 2 sensor with a pen cap (!), and a paired Bigfoot smartphone app that can receive alarms from the FreeStyle Libre 2 iCGM ([under FDA review](#)). Bigfoot will charge a single monthly subscription price for the whole bundled system, including FreeStyle Libre 2 but excluding insulin. This will use the dose capture technology originally acquired from Timesulin [in 2017](#). It's unclear if Bigfoot Unity will be a 510(k) or PMA product; we'd guess it would be 510(k)-regulated if FreeStyle Libre 2 gets iCGM status. Bigfoot is not disclosing pivotal trial timing.
- **Launch of Bigfoot Autonomy will now come "after" Unity.** Based on our interview below, a 2020 launch of the hybrid closed loop system seems unlikely - putting Bigfoot Autonomy well behind Tandem's Control-IQ (launch in 4Q19), Medtronic's next-gen 780G (launch by April 2020), and Insulet Horizon (launch in 2H20). Bigfoot is not disclosing pivotal trial plans for Autonomy, which was [most recently](#) expected in 2H19. Relative to the [original ambition](#) to be in a hybrid closed loop pivotal trial in 2016, Bigfoot Autonomy is about four years behind. We dig into those delays below.

In this interview with Bigfoot Biomedical CEO Jeffrey Brewer, we discuss the company's recent decision to prioritize its MDI titration system, Unity. Relative to its [initial founding](#) - to close the loop with a pump - this is a meaningful change! Still, it is a sound strategic move, considering how competitive the insulin pump market is, the major need to help MDI users (majority of insulin users), and the lower-cost and higher simplicity of a smart pen system. Read on for all the details!

Interview with Bigfoot Biomedical

CLOSE CONCERNS: Bigfoot has now decided to prioritize the smart pen MDI titration system, Unity, as its *first* product. What encouraged that change?

JEFFREY BREWER: First, our commitment to Bigfoot Autonomy has not faltered one bit. We've always envisioned that our pen product would come first, actually. We have known that we could get that system to market more quickly, with **fewer regulatory barriers** - reaching more people we could help, sooner. While we are as committed as ever to releasing our pump-based product into the marketplace, **launching this first product (Unity) will allow us to architect the infrastructure that will ultimately support the launch of our closed-loop system.**

Further, **conversations with payers, HCPs, and competitive dynamics have reinforced this decision to launch of Unity ahead of Autonomy. There is a larger commercial opportunity in the connected injection space,** given that only about 8% of the US's 6 million insulin users are on pumps. Support for people using MDI represents

a large unmet need that's going to empower us to create a sustainable business and help more people than our pump product alone.

For med tech companies to succeed where others have failed, they have to be willing to offer more than just advanced insulin pump technologies. They must reimagine the entire service architecture that delivers therapy with payment model innovation, subscription supply management, firmware and over-the-air upgradeability, and rethinking how people are onboarded, trained, and supported on therapies. Payer organizations and health care providers with whom we've spoken are very excited about this particular offering and what it could mean for their populations.

We intend to launch Bigfoot Unity next year (2020), and we're supporting that launch in an aggressive fashion. Bigfoot Autonomy will follow after the 2020 launch of Bigfoot Unity. We're not currently giving details on the exact timing of that launch, but we are confident that Bigfoot Unity will provide a solid platform and proof-of-concept for the entire business model.

Our mission has always been to free people with diabetes to live the lives they choose, regardless of how they take their insulin, as well as offer solutions that could serve a wide variety of healthcare delivery structures, clinicians, and payers.

CLOSE CONCERNS: Skeptics might note that Bigfoot's timelines keep getting pushed back - years later in some cases. What is misunderstood about that?

JEFFREY BREWER: Both the regulatory landscape and the insulin pump market have changed dramatically since our first clinical trial was completed in 2016. We're excited to see FDA leading the way in terms of new classifications for devices and systems in our space and look forward to exploring the ways in which we will fit into that paradigm. We've seen some companies evolve to meet the new challenges and others that have failed to change along with it. We're building a company from the ground up, and we are building in flexibility to respond to the changing landscape while still enabling us to deliver the best solutions for people with diabetes and the overwhelmed health care providers and insurance payers who serve them.

CLOSE CONCERNS Can you share any other product design details on Unity? How is Bigfoot thinking about this new category - closing the loop for injection users?

JEFFREY BREWER: We're handcuffed with sharing too many product details at this point. We need to be mindful of regulatory guidance on making product claims as we are getting closer to submission. However, we can say that our system's workflow is designed to work around the needs of an MDI user. We've done extensive research on the needs of users, their health care providers, and insurance payers about the pain points around today's injection therapies. We are confident that our design will address much of what we've heard. The responses we've gotten to our system design thus far have been highly encouraging, and we can't wait to put this in our community's hands. We're all very excited about setting the bar in this new category.

CLOSE CONCERNS: What will set Unity apart from other smart pen systems (e.g., Companion Medical, Novo Nordisk, Lilly)? What is misunderstood about this category?

JEFFREY BREWER: Many of the systems coming to market are digital dosing logbooks with the intent to provide data for health care providers. We are focused on providing a more robust and delightful user experience for pen users, providing users with a real-time partner in their diabetes self-management, with sensor-augmentation, a supply management auto-fulfillment model, and an intense focus on user experience.

CLOSE CONCERNS: What about the large basal-only type 2 diabetes market? At [Friends for Life last year](#), you shared a whole planned pipeline across the insulin therapy continuum. Is that still the plan?

JEFFREY BREWER: Yes - Bigfoot Unity will initially support MDI therapy, with caps for both long-acting and rapid-acting insulin pens. Bigfoot Unity Basal will come shortly after for those who use only long-acting insulins.

CLOSE CONCERNS: When Unity and Autonomy are both on the market, Bigfoot will have two automated insulin dosing systems - likely with quite different cost profiles. We'd assume the

outcomes will be better with a pump-based system (more ability to finetune dosing); but what will payers be willing to cover? Will the additional outcomes benefit with a pump be worth the incremental cost to the system? How is Bigfoot thinking about this?

JEFFREY BREWER: Our vision is to meet people where they are in their diabetes management regardless of how they take their insulin, but we also know that **payers do not have the data they need today to evaluate real-world benefits of the therapies they cover.** We look forward to working with our payer partners to generate evidence in order to demonstrate the value-add of each solution, but we'll use data to inform decision-making on this front. We're set up to do that.

CLOSE CONCERNS: Thank you, Jeffrey!

JEFFREY BREWER: Thank you for the opportunity to provide an update.

--by Adam Brown and Kelly Close