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Berkshire Biomedical with their Cloud-based COPA™ System uses Biometrics to Deliver the exact Drug Dosage to the Intended User



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CEOCFO: *Mr. Mazzocchi, according to your site, "Berkshire Biomedical is providing The Last Mile in patient care." What was the impetus for creating the COPA™ System?*

Mr. Mazzocchi: We define the Last Mile in patient care as virtual care with drug therapy delivered in the most efficient and pragmatic way to provide patient care *where* and *when* patients most need it – the Last Mile. Back in 2016, our primary founder, Tommy Rouse, underwent three consecutive spine surgeries. Despite the fact that the procedures and his post-operative care went very well, his long-term home recovery failed. His pain became unmanageable as he struggled to properly self-administer his medications. He learned quickly that he had no way to really provide accurate adherence information back to his doctor and he became extremely frustrated by the delayed recovery. This became even more of a concern as research about the increasing misuse and abuse of prescription drugs in our society was in the headlines every day. Keep in mind, this occurred during the height of the opioid crisis. As a result, Tommy set out to create a solution. His vision was to create a device and system to remotely support medication delivery to the Intended User with the ability to assess adherence and efficacy and to communicate all of this information back to providers. He and his cofounder, Susan Owen, formulated an idea to develop an easy-to-use, cloud-connected and data-driven medication delivery system to address all these issues. They built a team of trusted and seasoned professionals and an advisory board with members who have executive level backgrounds in healthcare and extensive experience in early stage investing and product development in the medical technology industry.

In developing the COPA System, Berkshire Biomedical identified and partnered with world class engineers, manufacturers, FDA regulatory advisors, and trademark and patent attorneys to support the emerging business. You may have recently seen our press release announcing the issuance of additional U.S. patents surrounding this technology.

From that, the Computerized Oral Prescription Administration (COPA™) System was born! The COPA System is pioneering the use of *Intended User* biometric technology, in a hand-held device and cloud-based, HIPPA compliant, mobile device-enabled DBMS system to effectively and efficiently serve patients.

As the product development processes evolved over four years, we learned and gained a deeper appreciation of the value the COPA System brings to the virtual care market. As our understanding and development advanced, it became clear to us that the value of the System's features was even more important than the original device-oriented benefits. Collectively, the patient data we are aggregating is critically important to physicians, patients and payers alike. For

example, if a hypertension patient calls his or her physician about their medication not working, the physician reacts either by suggesting an increase in their dosage or by prescribing a different medication. Oftentimes, the failure of current medications and dosages are simply because the patient did not adhere to the properly prescribed dosing. With the COPA System, the physician will now know if the patient only took, for example, 1.6 milliliters of medication rather than the required 2.0 milliliters, which resulted in the patient's poor outcomes. These features support medical decisions and actions with real-time usage tracking, data storage and analytic creation and access – all of which is vitally important to all stakeholders involved.

CEO CFO: *How does the COPA System work?*

Mr. Mazzocchi: Our COPA System is a handheld device—that is small enough to fit in the patient's hand. It has an internal chamber where the vial of oral liquid medication is locked into position. The device will be procured from the pharmacist with your prescription and the dosage that is prescribed to the patient comes in standard amber vials. You may get a one month or three-month supply of these vials. A key component of our technology is the Smart Cap which snaps on top of the standard vial to keep all medications secure. It is provided by the pharmacists and that is what interfaces with the device itself. It makes that connection specifically with the particular device, the corresponding patient, and specific medication prescription. Then, when a patient receives the COPA System it is scanned and activated by the pharmacy and corresponds to whom we refer to as the *Intended User*.

"We believe that the COPA System, with its innovative approach to personalized prescription and drug delivery to the Intended User can be a leading product in this transformation to virtual care." Rudy Mazzocchi

The differentiator between COPA and all other drug delivery vehicles is our unique ability to identify and dispense only to the Intended User. This is driven by our novel use of biometrics. There is a thumb print scanner on the surface which biometrically recognizes the registered patient, or the Intended User. Then, the second biometric element is the mouthpiece itself, which has a dental recognition element that identifies the patient's dental structures and bite profile. Once the patient is confirmed, the device activates the pump mechanism and actually pushes the fluid prescription medication into the mouthpiece. Therefore, even if I were to activate the device myself and hand it to you for dispensing into your mouth, it would not work because it has to recognize the impression of *my* teeth, and only *my* teeth.

The system has a cloud-based database management system that captures all the dosing and usage data regarding the use of COPA in the cloud, where the physician, patient, pharmacist and any other authorized provider, such as a caregiver or the payor, has access to the information. The COPA System also has a notification feature that alerts patients when to take the dosage of medication and it will tell the physician, just as I described in that example, whether or not the patient took their adequate dose. Moreover, it will prohibit them from taking a secondary dose arbitrarily outside of the prescribed dosing regimen. It is very, very smart technology, that virtually supports patients through that Last Mile of the care flow. So you can imagine how important this smart technology is to that patient sitting alone in their home without physicians, nurses or rehab specialists overseeing them. That patient may feel lost and alone, but the COPA System can now empower them in ways not seen before.

CEO CFO: *How easy or how difficult is it to set up and for the patient to become comfortable with a new method of taking pills?*

Mr. Mazzocchi: That is a great question. By design, it's actually very user-friendly. The COPA System is pharmacy ready, meaning it meets standard dispensing workflows and e-prescribing formats. It has an intuitive initial setup. The System and device are active once patient IDs are recorded and stored, which takes only about one minute. New and refill pharmacy-based prescription formats are all based on NCPDP standards, so that part is easy as well. In fact, as part of our regulatory submission with the FDA, we are including the results of a summative study, or the User Study, where we will demonstrate that all of our use instructions, screen shots and tutorials for the COPA System can be easily registered so that patients can abide by and rely on the use instructions of the System.

CEO CFO: *Has anything similar been tried?*

Mr. Mazzocchi: No. There is a lot of smart technology now in healthcare but no one has the ability to identify and dispense medication to the Intended User in a virtual care platform. One example that we have identified is an Australian company called Adherium Limited, and they actually have a smart device for inhalers. However, it is not as sophisticated as the COPA System, and it is not really designed for a specific Intended User. It just provides data on the use of the device. We have taken it further by including biometrics and physician-directed remote medication management capabilities that are specific to the Intended User.

CEO CFO: *How would someone get your COPA System? Would it be at the local pharmacy?*

Mr. Mazzocchi: Under the currently proposed model, yes. The way it would work is that once the physician prescribes the medication with the use of a COPA System, the patient would go to their pharmacist, who will provide registration of the System in accordance with the specific patient. As you will recall, there is a connection between the Smart Cap that is placed on the standard vial and links directly to the COPA device and to its corresponding Intended User. It is actually pretty seamless. Again, we have tutorials that walk you through the processes. As I mentioned, we are collecting that data in the summative study or User Study, which we are filing as part of our 510K submission to the FDA later this month.

CEO CFO: *How does the acceptance of telehealth help?*

Mr. Mazzocchi: Earlier, we talked about the Last Mile in patient care. During this pandemic we have learned so much about the importance of telehealth in the today's marketplace and, with our quarantine and isolation, we began questioning how we can properly manage patient's medications during that Last Mile in a new remote world. Looking at the patient's journey – whether they are on a chronic medication or a medication following a surgery a procedure – procuring, dispensing and reporting progress to the physician is challenging. Today, more than ever, we do not have the ability to freely run to our doctors, the clinic or the pharmacist. It is more about self-management in a "virtual world." Therefore, I think the time is particularly conducive to highlight the need for greater virtual care in drug therapy delivery. The growing acceptance of telehealth, that has been accelerated by recent events, minimizes the amount of education we have to do as a company to inform the public, the physicians, the strategic companies, and the market leaders we are approaching about the value proposition of this device. It has become more intuitive.

CEO CFO: *What has changed in your strategy for bringing the COPA System to market? What are you finding and how are you adapting with the pandemic and COVID-19?*

Mr. Mazzocchi: Another interesting question. Actually, our strategy hasn't changed. Four years ago, when our founders were developing the COPA System, they knew there was a growing need for a virtual care medication delivery system and we had defined and fixed our strategy prior to the onset of this pandemic. That said, there is no way they could have predicted the COVID-19 outbreak or how it would underscore the urgent need for the COPA System. So, you might say that our timing is somewhat serendipitous as this current crisis has demonstrated the relevance of telehealth and it has created an opening to modernize the care delivery system. We are now seeing an increased focus on digital health platforms, particular digital therapeutics as they deliver evidence-based therapeutic interventions that prevent, manage or treat these disorders, diseases or trauma. Increasingly, we are seeing the integration of device, data acquisition and technology, more and more every single day in healthcare; it helps drive the adoption of virtual care models. We believe that the COPA System, with its innovative approach to personalized prescription and drug delivery to the Intended User can be a leading product in this transformation to virtual care.

Another area that the COVID-19 pandemic has put a spotlight on... is clinical trials. This is another area where we saw the COPA System as being a value-add. Now as we are talking to potential strategic partners, and the quarantine has put a hold on a number of their clinical studies, they are scrambling to figure out how to meet the challenges of managing the at-home delivery of drugs within the confines of a trial. In discussing the COPA System, it really sparked an interest from both big and small drug developers as they saw that it could provide the assurance of proper dosing and adherence, along with the all-important data collection required in these controlled FDA-sanctioned studies. In fact, it greatly surpasses the current data collection conventionally captured in written surveys. So, this is an area where the pandemic

has created a greater potential for the COPA System in a new application that we originally did not contemplate. Again, I think our timing is excellent.

CEO CFO: *With your long history in the industry I am guessing you have a great many opportunities. Why Berkshire Biomedical and what surprised you when you actually came on board?*

Mr. Mazzocchi: You are right. Throughout my career I have been involved in the build out of many medical technologies and biotech companies. However, at the heart of it, I am really a medical device guy. It is a specialty I developed early on in my career, ranging from active implantable devices to, what I call, procedural-enabling surgical disposables. I was drawn to the COPA System because it is an all-encompassing device and system that can have a huge impact in what I like to call our "brave new virtual world." When I was approached to join the team, you are right, I did do my due diligence. I found that the COPA System truly addresses what we describe now as The Last Mile in providing safe and smart handheld technology that not only is physician-driven, but assists the patient with the proper management for their life-altering medications. I had that "aha" moment when I recognized how this cutting-edge technology was converging with a great market need. With the COPA System, I saw it as a completely new and unique system -- a true game-changer.

What we do for patients is so critical, particularly when you consider today's virtual environment and the ongoing need for surveillance of medications as highlighted by the opioid crisis. The COPA System fulfills a number of key unmet medical needs in our current medication delivery system. First, we provide a critical level of safety that is activated via the patient's own biometrics with medication dispensed only to the Intended User. *This the primary differentiator and one that no other system can claim.* In addition, the system provides a record of adherence and the ability to provide real-time data delivery that I have never seen before--a game-changer for both patients and physicians. Importantly, we believe the data management features of this device are critical for physicians and payers in establishing important prescription dosing information to analyze the pharmacoeconomics of medication protocols, clinical outcomes and more. It is a multibillion-dollar problem today that is only growing with the increasing demand for information and evidence-based medicine.

I have been in this industry for a long time and have seen the evolution of healthcare markets and how they adopt to new technologies. Given the current need for safer medication delivery and the call for real-time data, the COPA System will play a meaningful role in virtual drug therapy delivery. I am very excited to be a part of the team that will bring this cutting-edge technology to the market.

CEO CFO: *Is COPA strictly liquid at the moment? Might pills be in the future?*

Mr. Mazzocchi: That is a great question. It is currently designed for liquid oral medications, even though we know that the majority of prescriptions are pill based. As we speak to pharmaceutical companies, they are confirming what we knew--that there are actually advantages of oral liquid medications over pill or capsule formulations. We believe the introduction of the COPA System may even alter design and development programs of big pharma longer-term. Now that the COPA system offers a very tightly controlled system for an Intended User, they can actually look at developing or even converting some current pill formulations to liquid oral medications. That said, we've also learned that big pharma has many pipeline development programs under way with therapeutics that are strictly oral liquid medications.

We believe there could be enormous opportunity in taking this foundational technology and adapting it for other applications. I previously mentioned smart inhalers. This would be ideal. There are many other ways we can expand the reach of this technology in a variety of markets. For example, we have talked to ophthalmology companies that are looking at how to deliver controlled liquid medication, in the form of eye drops, to the surface of the eye to treat macular degeneration. In addition, we are already exploring expansion into other formulations that meet direct to mouth dispensing and which would require modest modifications but not complete retooling. In terms of transitioning the COPA System to use pill or capsule formulations, I am not sure we would want to focus on this now as it would take time and additional investment to conduct the reengineering needed to make that conversion. What we could see happening in the nearer term is the transition of therapeutic developments moving from pill or capsule formulations to liquid oral medications. As mentioned earlier, we see this trend is already happening today.

CEOCFO: *What are some of the key events or milestones we should look for at Berkshire Biomedical in the next six to twelve months?*

Mr. Mazzocchi: We have an exciting year ahead as we expect to file our submission to the FDA this Fall and anticipate receipt of FDA market clearance for the COPA System sometime around the end of the year. In the meantime, we are working to identify and execute an appropriate partnership with one or more strategic partners within 6-9 months. We've already initiated outreach to potential partners prior to our planned FDA submission.

In tandem, we are making plans for full commercialization in Q3 of next year and continue to work on scaling commercial manufacturing and assessing different strategic marketing plans to support the COPA System launch. Ideally, it would be with strategic partners who want to fund co-development of additional clinical studies to support claims related to their drugs in combination with the COPA System. In addition, we would partner with them on their strategy for the marketing plans to bring it to the global market. For now, we are submitting the COPA System with broad device claims, but we may pursue studies that demonstrate, both in the near term and longer term, that the device helps with adherence and reduces drug misuse and abuse.

We are pleased with the response from our early outreach, and we have generated considerable initial interest in the COPA System among these potential partners. It is particularly encouraging when you consider that we have only recently come out of our 'stealth mode' with the announcement of our additional U.S. patents last week. So far, it has been a great process and we are making traction toward our goals to identify and establish multiple strategic alliances. While there had been some challenges with connecting to the right people during quarantine, we are now finding that the increased interest in virtual care highlighted by the pandemic has helped spur interest in the COPA System.

This is going to be a very exciting year ahead and we are looking so forward to seeing this technology in the hands of patients and their providers, so the time is now!

CEOCFO: *What, if anything, might people miss or misunderstand about Berkshire Biomedical and the COPA System when they first look?*

Mr. Mazzocchi: One of the biggest misconceptions about the COPA System on first introduction is that people think this is just a medication dispenser. It isn't until you actually sit down with someone and describe the complete multi-faceted features of the COPA system and how they allow for true virtual drug therapy delivery that the light bulb goes off! I have seen this multiple times. When talking with senior executives at big pharma about the device, the data that it collects, the safety parameters for the Intended User, the potential benefits it could offer in clinical studies and the value it can bring to their franchise with multiple different drugs, we are getting those "aha" moments and are generating interest in partnerships. We are very bullish on the variety of opportunities to partner with these companies and look forward to advancing our goal to establish such alliances in the coming 6-9 months.



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