Suneva Medical Poised to Reignite Marketplace Amid Company Transformation

By Jeffrey Frentzen, Executive Editor

Aesthetic manufacturing firm Suneva Medical, Inc. (San Diego, Calif.) has recently returned to the spotlight, thanks to the efforts of the company’s executive team in capturing new markets, leading the industry and building on the resurgence in popularity of Bellafill®, the firm’s long lasting dermal filler.
"Bellafill truly offers some longevity and represents real, lasting improvement in the skin."

Bellafill, which is indicated for the correction of smile lines and moderate to severe atrophic, distensible facial acne scars on the cheek, is also the only dermal filler proven safe and effective for the correction of nasolabial folds up to five years.

Another brand under the Suneva umbrella – the Regenica® skincare line – works to improve the appearance of skin tone, texture and brightness. It also reduces the appearance of fine lines and wrinkles via a powerful dual chamber serum that combines growth factors, cytokines and proteins, with a cocktail of antioxidants, plant-based extracts and other novel ingredients.

“Suneva is a small and nimble organization with renewed determination to partner with customers in order to increase consumer awareness of these strongly differentiated products,” said Preston Romm, the firm’s new CEO.

Regarding the repositioning of Bellafill, Mr. Romm noted, “Longer lasting fillers have been gaining more acceptance in the market. Bellafill’s current RealSelf rating is 93%. Patients are educating themselves. Those who have had dermal fillers for three years or more are looking for something new and longer lasting. Our own consumer survey results and the RealSelf rating are evidence of this growing trend.”

Recent consumer research conducted by Suneva suggests that 82% of patients who have been treated with dermal fillers for three years or more, are very likely to extremely likely to seek a long-term filler, such as Bellafill. Of those surveyed, 71% indicated that they would change physicians if theirs did not carry such a product. Additionally, these patients felt they would now have more money to spend on other aesthetic treatments offered in practice – the top three being all forms of skin rejuvenation, fillers in other areas and body contouring.

According to Anne T. Stubbs, M.D., an aesthetic physician in Columbus, Ohio, physicians have also embraced Bellafill. “It truly offers some longevity and represents real, lasting improvement in the skin,” she noted.

When initially confronted with using a filler that could potentially last for several years, Dr. Stubbs, who has maintained a longstanding business focused on hyaluronic acid (HA)-based fillers, questioned whether this would take away from her current filler practice and repeat patients. “I have not found that to be the case at all,” she said. “I find that patients come back within a year and might want another syringe, or may be looking at another adjunctive procedure that helps. They want something to give them the lift they need and improve their skin at the same time. I keep patients because they are so pleased with the outcomes.”

Originally marketed as ArteFill®, Bellafill consists of bovine collagen gel (80%), which adds immediate volume and lift to wrinkles and scars, for instant results. In
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In addition, polymethyl-methacrylate (PMMA) microspheres (20%) form a scaffold to support endogenous collagen production and tissue matrix formation.

Having been refined over the years, Bellafill boasts an excellent safety profile that surpasses other dermal fillers on the market. In the U.S., Bellafill requires a skin test to identify patients who may be allergic to collagen gel or lidocaine. This skin test is optional in Canada.

As Michael H. Gold, M.D., director of the Gold Skin Care Center in Nashville, Tenn., expressed, Bellafill satisfies the need for an enduring solution and gives superior results for many people, "We have used Bellafill since its FDA approval," he said. "It's great for experienced dermal filler patients who are looking for long-term results. This is also the only filler that has FDA approval for the treatment of acne scars."

Bellafill definitely has a place at the dermal filler table, said William Philip Werschler, M.D., F.A.A.C.S., F.A.A.D., assistant clinical professor in Medicine/Dermatology at the University of Washington in Spokane, Wash. "All filler products have unique indications, and Bellafill is one-of-a-kind with regard to treating acne scars. It is unique, but has its application. Its FDA label is for nasolabial folds and acne scars and it is a good product. Like all products, and pretty much all injectors, I use Bellafill differently for some things than I do for others. I use the cannulas in different areas to volumize the face for asymmetry."

AniK Rajani, M.D., a cosmetic surgeon in Portland, Ore., started using Bellafill in 2007 when it was first approved by the FDA. "I realized that patients wanted long lasting solutions and that it was cost-effective for them. They saw the value in this product and liked the idea of having to do fewer injections over time."

Dr. Rajani began injecting fillers in the era of collagen-based products — when treatments would last only a few months. "When Bellafill came along I embraced it," he said. "There is nothing else like it on the market and it is truly the longest lasting product. While some patients are content to receive regularly scheduled maintenance injections every several months, others seek less upkeep."

"There is a niche, especially among men that simply don't want to keep coming in for those injections. They like to have less maintenance," Dr. Rajani reported. "Think about it, with temporary fillers, the face is inflating and deflating over time. With Bellafill, patients look better and the results are maintained."

Although some practitioners have been somewhat cautious about utilizing lasting fillers, Dr. Stubbs regarded Bellafill's safety profile and sophisticated technology, and disregarded any unfounded fears.
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“We were interested in offering our needle fatigued patients a longer lasting filler. With the support of our Sunava sales representative, we were able to quickly bring the product into our practice successfully,” Dr. Stubbs shared.

“Initially, you have to assess the patient to see if they have had HA-based fillers before and determine whether or not they like the volume of certain aspects of their face,” Dr. Stubbs explained. “Since results with Bellafill are long lasting, I make sure that my patients first love their outcomes with other products, then upgrade them to Bellafill.”

In Dr. Rajani’s experience, good candidates have had some cosmetic treatments in the past and are otherwise healthy with no autoimmune disorders. “Just about anyone considering fillers can also consider Bellafill. Men love it and often want to start with Bellafill. Since they typically need more volume, especially if they are fit and active, it is very cost-effective for male clients. Men come in to see us later in life compared with females. They often present in their mid-50s whereas females will come in their 30s.”

When Dr. Stubbs first considered dermal fillers, she was not sure she wanted to inject anything in the face. “I talked to my patients who said they would never get a face-lift, or those that preferred to get little bits of maintenance along the way. I found that they would be willing to come in once or twice a year for touch up work. Those are excellent candidates for Bellafill,” she expressed. “They appreciated getting a little more longevity and continue to come in for other treatments, as well as their touch ups.”

In Dr. Gold’s opinion, Bellafill is safe and effective, and should be injected by well-trained injectors in the appropriate areas. “A lot has been said about potential problems with long lasting fillers, which has not panned out with the product we have on the market now,” he explained. “Precursor products had issues and concerns, which have been virtually resolved with the new Bellafill.”

“Although previous PMMA products have endured something of a checkered past, the end result is that Bellafill is a solid product,” Dr. Werschler maintained. “Injection techniques have changed over the years; to the extent that they have become better and so has Bellafill. It is unique in its application. Today, we also use more cannulas, we are more aware of the complications, and we have expanded the indications of all filler products beyond the FDA labeling. Nonetheless, Bellafill is an excellent and effective product for its FDA label indications of nasolabial folds and acne scars.

“Acne scarring patients benefit greatly from Bellafill treatments,” Dr. Werschler opined. “The scarring itself has a profoundly negative impact on patients, and we’ve found that treatment can be pivotal in preventing devastating psychosocial effects. For these patients, Bellafill’s PMMA-based collagen has been effective with an exceptional safety profile.”
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Dr. Gold also considers the filler’s acne scar treatments to be superior. “This is a great indication for Bellafill. Its efficacy in scars is well documented. We also use it in combination with microneedling procedures, which is a fantastic combination approach to reducing acne scars.”

Patients have been using Bellafill for years, Dr. Rajani advised. “Acne scarring is disfiguring and helping these patients brings amazing satisfaction. Rolling-type scars respond to treatment very well, as do scars with an element of atrophy. The results hold up.”

When asked to discuss the ideal injection techniques with Bellafill, Dr. Gold replied, “Slow and steady. You need to be meticulous. In general, overcorrection should be avoided, and gradual volumization can be achieved across multiple injection sessions. Bellafill is designed to be injected into the deep reticular dermis or dermal-subcutaneous junction. The PMMA microspheres encapsulated by host collagen will persist indefinitely.”

Dr. Rajani employs a combination needle and microcannula when performing Bellafill treatments. “For acne, the best technique involves a 26-gauge needle with an element of undermining the skin and subcision.”

Dr. Stubbs typically injects with a cannula, as well. “The only time I will use a needle is when I am doing an acne treatment, because you need a sharp edge for subcision to get rid of the scar. You want to inject the product very superficially when dealing with acne scarring,” she said. “Bellafill with a cannula has a nice, even spread with very little bruising. Patients find it very comfortable.”

Bellafill also shines in conjunction with other therapies. “I combine treatments more often than not,” Dr. Rajani pointed out. “Resurfacing after Bellafill gives a great look – we’re adding volume and the overlying skin looks better, healthier and younger. Where there is beneficial volume and collagen deposition, the skin responds with a nice appearance that holds over time.”

“If money is a concern for the laser resurfacing patient,” Dr. Rajani continued, “I’ll inject Bellafill and wait several months. Usually, the skin surface will need less aggressive resurfacing. For more immediate results, you can resurface just prior to Bellafill injections. I add PRP and HA-based fillers as needed in certain areas, such as under the eye and chin, where we are looking for better skin and dermal thickening, and where volume is not needed as much.”

Dr. Stubbs shared a similar story. “We use it in combination with the Fraxel laser. After a couple of Fraxel treatments, in order to really get the patient’s own collagen going, we will fill with Bellafill. It is quite remarkable for those really tough scars that don’t seem to be improving with Fraxel.”
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In Dr. Stubbs experience, “Patient satisfaction has been remarkable. I have never had a patient come back and say, ‘I don’t see a difference’,” she said. “Everybody notices a change because that collagen gel gives them a nice lift right away.”

“Patients usually return after four to six months,” Dr. Stubbs indicated. “We can take another picture, because the before and after photos tell a big story. I’m always amazed that once you have improved someone’s appearance, they forget what they looked like to begin with. You have to remind them with the before pictures. We put the photos side by side, and patients are floored when they see the results.”

Dr. Rajani smiles when he brings up the subject of patient satisfaction. “Patients are happy with BellaFill. I tend to be conservative and create an aesthetic look over time. By age 40 most people will have lost at least 10 to 15 mL of volume in the facial region, considering bone and fat loss,” he said. “A good start would then be about 5 mL or roughly five syringes, with a reassessment a few months after that. Each case is different, of course, and the degree of volume loss varies.”

For the practitioner, BellaFill is highly marketable, and can capture an elusive group of prospective patients looking for a durable filler. Dr. Rajani believes, “It differentiates my practice from others, and the return on investment is excellent. Patients understand it is a long-term product and they research the provider. They come in educated about products and procedures, so it saves us time. They typically already have an idea of what they want to accomplish. To top it off, Suneva provides a great partnership with my practice for training, marketing and business development.”

BellaFill has proven to be an effective, safe product occupying a unique niche. Dr. Werschler remarked, “It is the only product with FDA approval – with safety and efficacy data for five years. People are using it, and its growth will be organic.”

Mr. Romm is also upbeat about the potential of BellaFill. “We know there’s a huge untapped market for this product for both acne scars and cosmetic procedures,” he said.

While BellaFill is enjoying renewed interest among physicians, Suneva’s Regenica skincare line synergistically works with injections. Featuring MRCx™ next-generation growth factor technology, Regenica is designed to enhance skin’s natural repair and renewal. It also supplements the growth factors in skin that are lost over time. The Regenica portfolio offers five products targeted to rejuvenate, renew, replenish, recover, repair and revitalize skin. Clinical studies show that when used consistently, these products improve the appearance of fine lines and wrinkles, reduces the appearance of pores and helps even out skin tone appearance to reveal a more radiant complexion.
"The latest clinical trials on Regenica Rejuvenating Dual Serum, showed remarkable results in as early as 14 days. There was a statistically significant improvement in skin brightness, firmness and radiance; and the data improved as time went on."

Regenica Rejuvenating Dual Serum is a revolutionary breakthrough in skincare. The twin chambers deliver both a 95% concentration of patented MRCx, and a powerful formula of over ten skin essential ingredients, including advanced copper peptides, amino acids, anti-oxidants and plant-based extracts.

According to Gail K. Naughton, Ph.D., CEO and chairman of the board at Histogen, Inc. (San Diego, Calif.), which developed the proprietary MRCx technology, "We wanted to focus on binding aesthetic and therapeutic uses to our unique growth factor material. Adding the patented manufacturing process – which does not utilize bovine serum or potential irritants or additives – induces newborn skin cells to become multipotent stem cells."

"The mixture of growth factors these cells make is very important for stimulating stem cells in your own body to make new collagen, and basically rejuvenate the skin," Dr. Naughton stated. "The latest clinical trials on Regenica Rejuvenating Dual Serum, showed remarkable results in as early as 14 days," she added. "There was a statistically significant improvement in skin brightness, firmness and radiance; and the data improved as time went on. At the end of the 90 day trials, we had a significant value of p001 for all end points; including brightness, firmness, evenness, improvement in fine lines, more even pigmentation, a decrease in photodamage and overall skin appearance."

"In the same clinical study, 97% of patients were very satisfied by day 30, and 100% saw notable difference and were very satisfied at day 90," Dr. Naughton reported. "This product repairs the intrinsic and extrinsic skin damage and environmental factors that age skin over time. In addition, it is very potent. We found out that if you put Regenica growth factors on an injection site right away, it very quickly heals and helps prevent the bruising that normally occurs."

"The symbiotic relationship between Bellafill treatments and follow-up Regenica therapy is just one more example of Sunnea's forward thinking product strategy," noted Dr. Stubbs. "The company's doing a great job putting together the right products for its customers, and supporting practices with education and training. Sunnea is also good at connecting physicians, so the opportunity to network with colleagues is huge. I have not seen this kind of dedication from some of the other companies."

As noted by Mr. Romm, Sunnea has increased its customer support and partnership in practice development as part of the company's rebuilding effort. "As previously mentioned, the findings from our recently conducted consumer research of 300 aesthetic patients revealed that the vast majority of respondents were extremely or very interested in a five-year filler and that most would change physicians for such a product. This is a powerful statement. Add to that the large proportion who indicated that they would obtain other aesthetic services if they did not need to spend money regularly on dermal filler treatments and it is clear that by
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offering physicians an opportunity to fully engage and retain their patients, Bellafill is a real practice builder.”

“We have evaluated the historical support programs and taken steps to enhance these programs in the creation of a true partnership with our customers,” Mr. Romm added. “I think there’s a lot of headway on the aesthetic side. We have created a comprehensive partnership program called ‘Suneva Premier Partnership,’ which launches in the second quarter of 2017. This program is designed to support and help grow Bellafill and Regenica brand awareness through staff training on product knowledge as well as other key business enhancing programs to support the success and growth of our customers and our products.”

“We are proud of the solid science backing our products, and will dedicate time to properly educating the physician and consumer markets,” Mr. Romm emphasized. “We will continue to fund and support significant ongoing research for our products.”

“Suneva has also been sending signals to acquire or launch additional products. “I have a great vision for the future of Suneva with additional products and business partnerships,” Mr. Romm noted.

According to Dr. Werschler, the company is poised for another breakthrough as one of the top suppliers of aesthetic solutions. “Suneva is reinvigorating itself in the marketplace,” he said. “They brought in a new CEO and others to reposition the company in a strategic direction, and I say let them exercise their tactic. They have fresh ideas, and their marketing efforts are raising the profile of Bellafill and Regenica among physicians.”

A renewed interest in Bellafill has been the real catalyst, though. “It is recognized by those in the industry who are open minded, who believe in the science and read the articles,” stated Dr. Werschler. “It is a product that has proven itself to be safe and effective for intended uses, and like all injectable fillers, its range of use has expanded in innovative ways among the aesthetic injector community.”

Manufacturer’s note: The statements and opinions expressed in this article are those of the physicians interviewed, and do not reflect the official position of Suneva Medical.