

Novel Non-Toxic Hypochlorous Acid Eye Care Product Avenova® Shown to be Useful in Managing Blepharitis, Dry Eye, Pre- and Post-Eye Surgeries; Company Expects Continued Double-Digit Sale Growth in 2017



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Interview with:
Mark Sieczkarek
Chairman and CEO

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- Mark Sieczkarek

Interview conducted by: Bud Wayne, Editorial Executive CEOCFO Magazine

CEOCFO: *Mr. Sieczkarek, you have served as interim CEO of NovaBay Pharmaceuticals since November 2015 and then named as CEO the following year in addition to continuing your role as Chairman. What accomplishments or changes can you point to that have occurred over that time?*

Mr. Sieczkarek: I recognized an exciting opportunity to commercialize a unique product, Avenova® lid and lash hygiene, in a large, untapped U.S. market that we estimate at 41 million Americans. Avenova is the only eye care product formulated with our proprietary, stable and pure form of hypochlorous acid that has shown potent antimicrobial action yet is non-toxic to mammalian cells and neutralizes bacterial toxins. This novel, patented formulation makes it ideal for tackling chronic conditions such as blepharitis and dry eye, as well as for pre- and post-use in eye surgeries.

As Chairman I saw the market potential for Avenova and was instrumental in developing a go-to-market strategy. I assumed the interim CEO position in November 2015 to leverage my experience with prior successful medical product launches, including several in the ophthalmic market, to help NovaBay grow revenues and ultimately reach and sustain profitability.

In November 2015, I refocused our entire organization solely on Avenova commercialization. This entailed substantially reducing our R&D and clinical activities to direct more resources to our commercial priorities. In early 2016, we made a significant change in our commercial focus. Our early launch strategy was aimed at optometrists to carry and sell Avenova from their offices. We switched this strategy toward Avenova sales through the ophthalmic channel in which patients fill their prescriptions through pharmacies. This allowed us to capitalize on

insurance reimbursement already in place. In fact more than 90% of Avenova sales through this channel are reimbursed at meaningfully higher prices than we received through our former strategy. This has the desired impact of significantly increasing revenue and gross margin. We raised \$20 million of capital last year to support growth through friendly transactions mainly with previous investors. I also made a significant investment of my own funds as a demonstration of my conviction toward NovaBay and Avenova. In June 2016, I accepted the position as permanent CEO.

Our approach and strategy are paying off. For the fourth quarter of 2016, Avenova sales grew 146% over the prior year period. It is notable that two-thirds of those sales came from the higher-margin prescription ophthalmology channel, up from 30% in the prior year period. And, we ended 2016 with \$9.5 million in cash, our highest cash balance in two years.

CEOCFO: *NovaBay has two technologies - Neutrox® and Auriclosene®. Would you tell us about them and the indications you are targeting?*

Mr. Siczek: We have two highly novel and distinct compounds, Neutrox and Auriclosene, both aimed at harnessing the power of white blood cell chemistry to address global, topical anti-infective markets without giving rise to antibiotic resistance. Our efforts have been focused on chemically modifying these compounds to impart qualities that allow them to be developed as therapeutic products.

Neutrox is FDA-cleared as a medical device and is a proprietary, stable and pure form of hypochlorous acid. Neutrox has proven in laboratory testing to have broad antimicrobial properties and is used in the formulation of several commercial products. Our clinical-stage Auriclosene is a patented, synthetic molecule with a broad spectrum of activity against bacteria, viruses and fungi. In fact, Auriclosene has been designated as a new chemical entity and granted composition of matter patent protection to 2028 by the U.S. Patent Office. Our first-in-class Aganocide compounds, developed from our Auriclosene technology, have proven to be fast acting with broad spectrum of activity, as well as effective against multi-drug resistant bacteria and biofilm, all with a good safety profile.

CEOCFO: *You have three Neutrox-based products - Avenova®, NeutroPhase® and CelleRx®. Please tell us about the products, the markets they are in and what differentiates them from other products currently on the market?*

Mr. Siczek: Avenova is the only eye care product formulated with Neutrox. It removes debris from the skin on eyelids and lashes of those suffering from blepharitis without burning or stinging the eye. Eye care specialists have historically prescribed warm eye compresses and baby shampoo, which often have minimal results. Additionally, steroids and antibiotics can be prescribed for short time spans. We have heard from numerous ophthalmologists and optometrists that patients return time and again for relief of the crustiness, itchiness and inflammation around the eye due to blepharitis. Avenova, with continuous use, has the proven ability to address the symptoms in as little as two weeks. Blepharitis is a chronic condition and we have heard the patients need to use Avenova twice-daily to ensure continuous relief.

We have developed additional commercial products with Neutrox. Our NeutroPhase® Skin and Wound Cleanser for wound care has been cleared for cleansing and removal of foreign material, including microorganisms and debris, from wounds. NeutroPhase has also been identified as a successful cleanser for microorganism removal and toxin neutralization associated with the devastating disease necrotizing fasciitis also known as “Flesh Eating Disease.” We have partnerships for NeutroPhase in the U.S. as well as select overseas markets, most notably China. CelleRx® has been developed with Neutrox as a gentle cleanser for various skin and cosmetic procedures.

CEOCFO: *I noticed from a few press releases that there are a number of ophthalmologists who are using and commenting on the results of NovaBay’s Avenova lid and lash hygiene. How do these relationships develop and has this helped in building confidence in the medical community?*

Mr. Sieczkarek: We understand the essential nature of gaining support from the eye care community to introduce a novel product such as Avenova. Early in commercializing Avenova, we approached leaders in the ophthalmic and optometric communities to form world-class advisory boards. We have without a doubt benefitted from this approach. Our key opinion leaders are providing significant support at ophthalmic conferences and events informing other eye care specialists about the use of Avenova in providing relief to patients suffering from chronic conditions such as blepharitis. Many of our advisors have issued their own press releases featuring observations from Avenova use by their patients. And, in fact a highly respected ophthalmologist Dr. Richard Lindstrom, who himself is a chronic sufferer of blepharitis, is featured in one of our print advertisements.

CEOCFO: *In September of last year NovaBay released the Phase 2b study results where your Auriclosene® demonstrated statistically significant and clinically meaningful results for the prevention of urinary catheter blockage and encrustation. Would you tell us about this?*

Mr. Sieczkarek: We were highly pleased with the data from our Phase 2b clinical study with Auriclosene Irrigating Solution (AIS). AIS demonstrated statistically significant and clinically meaningful results in the prevention of urinary catheter blockage and encrustation in subjects with chronic indwelling urinary catheters who have repeat history of blockage. With completion of this study, we believe that AIS is ready for a pivotal Phase 3 registration trial. About 100,000 of patients with indwelling catheters in the U.S. chronically suffer from blockage and encrustation. We estimate the healthcare costs to manage these patients in the \$1.5 billion range. The results of this clinical study show the potential of AIS to prevent urinary catheter blockage and encrustation in this patient population, which could provide millions of dollars in cost savings for the healthcare system and significantly improve the quality of life for these patients. We estimate the market for AIS in this indication at more than \$700 million and we believe AIS represents a substantial commercial opportunity. We are actively pursuing partnering, licensing or joint venture deal structures to monetize this non-core program and advance it through pivotal trials to commercialization.

CEOCFO: *What is the marketing and growth strategy for NovaBay? How will you expand your product reach?*

Mr. Sieczkarek: Our primary focus will be on Avenova commercialization having barely scratched the surface of the U.S.

market of 41 million Americans. Our plan is to continue to execute on a strategy that has produced significant revenue growth and margin expansion. We will look for opportunities to expand our commercial operations along the way; however, we remain committed to reaching and sustaining profitability.

We are highly excited by the clinical results from Aganocide in treating patients with urinary catheter blockage and encrustation and we have other products that we are keen to partner. Our plan is to use fees from licensing and other transactions to further support Avenova commercialization.

CEOCFO: *Do you have funding in place for continued growth?*

Mr. Sieczkarek: As we announced in our January 9, 2017 release, we completed 2016 with a strong balance sheet with approximately \$9.5 million in cash and equivalents. This represents the highest cash balance we've reported in more than two years.

CEOCFO: *With a new President and administration in place in the US, how will that affect healthcare and pharma companies in general, and will it have any specific effect on NovaBay in the coming year?*

Mr. Sieczkarek: It's too soon to predict what the new administration will do in the healthcare arena, but I'm cautiously optimistic. President Trump has given signals that he wants to open up Medicare to a more rational pharmacoeconomic based bidding process. Since the use of Avenova often reduces the patient's need for multiple office visits and repeated use of various antibiotics and steroids, I believe the cost savings potential Avenova offers could do very well in this environment.

CEOCFO: *In closing, please address our readers, many of which are in the business, investment and healthcare communities? What is special about NovaBay and why should they continue to follow you over 2017?*

Mr. Sieczkarek: We are highly excited by our prospects in 2017. We have a proven track record of increasing Avenova sales and our strategy this year is to continue double-digit revenue growth, particularly from the high-margin ophthalmology channel as we focus on sustained profitability. We are seeking opportunities to license or partner our other products to provide additional revenue to support Avenova commercialization. We have tight expense controls and a strong balance sheet to fund operations.

