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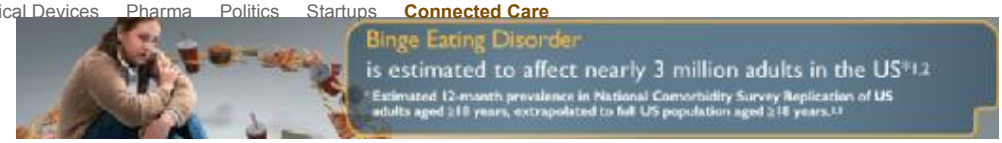

Opioid dependence treatment from BDSI aims to challenge RB's Suboxone

April 12, 2012 12:28 pm by Frank Vinluan | 2 Comments

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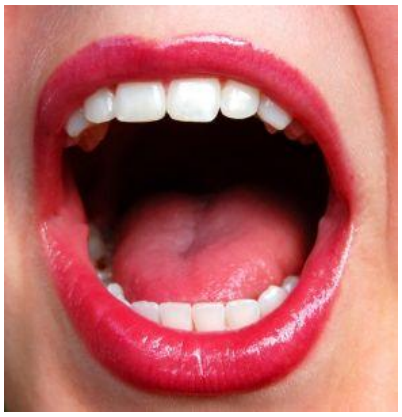

As drug abuse grows and drug addiction specialists seek new ways to treat opioid dependence, BioDelivery Sciences International (NASDAQ:BDSI) is positioning itself to enter that market as early as next year.

BDSI plans to file a new drug application for its opioid dependence treatment BEMA Buprenorphine in the first half of 2013. Like current market leader Suboxone, sold by Reckitt Benckiser (LSE:RB), BEMA Buprenorphine would be administered via a small piece of film that dissolves in the mouth. But BDSI believes differences in its drug delivery technology would give it the edge over Suboxone. BDSI will need an advantage to take on RB's blockbuster drug, which generated more than $1.2 billion in 2011 sales.

BEMA Buprenorphine could become the second transmucosal product on the market to treat opioid dependence and it has the potential to reach sales of $300 million, CEO Mark Sirgo told a New York audience of investors and analysts during a presentation on Wednesday. He was joined by two addiction medicine specialists, Dr. Gregory Sullivan, medical director at Parkway Medical Center in Birmingham, Alabama, and Dr. Aafaque Akhter of Norton Healthcare in Norton, Massachusetts.

Opioid dependence has long been treated by methadone. But buprenorphine's 2002 entrance into the market offered an

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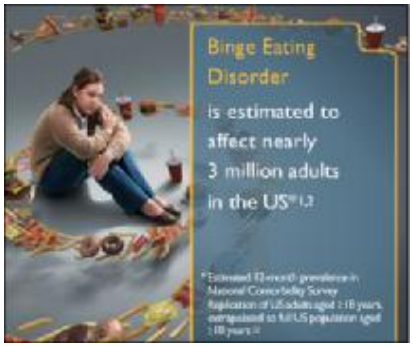

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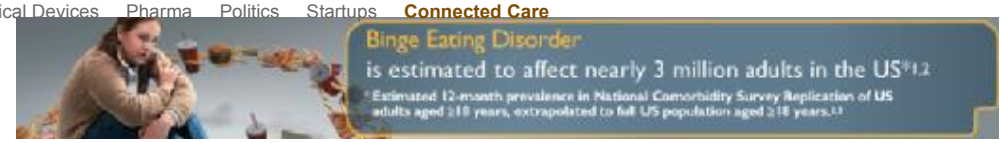

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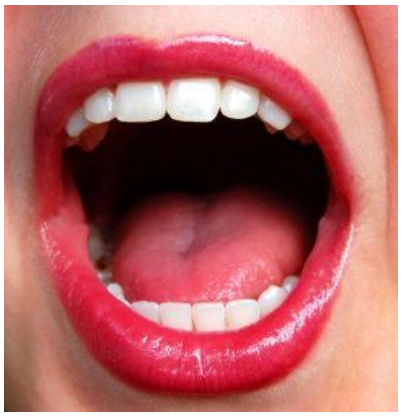

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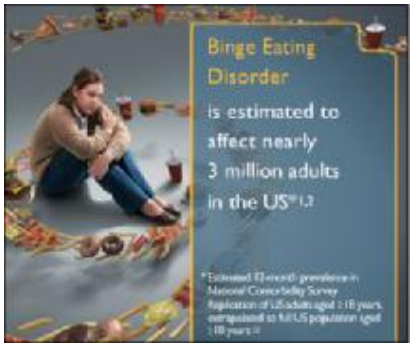

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alternative. Buprenorphine reduces drug cravings and, unlike methadone, can be used on an outpatient basis, Sullivan said. Also, unlike methadone, it does not give drug addicts any highs. Sullivan calls buprenorphine a “miracle drug.”

Akhter said that heroin is no longer the opiate of choice. Most opiate addiction is associated with pain killers. His typical patient is someone who was prescribed opiates for surgical pain and got hooked. Buprenorphine led to a surge in treatment for those patients, he said.

RB’s Suboxone combines buprenorphine with naloxone, another drug that deters drug abuse. Suboxone was first developed as a tablet placed under the tongue. RB later developed a dissolvable film version, also placed under the tongue. The product’s sale grew as buprenorphine continues to grow as an opioid dependence treatment option. The Suboxone film is the only transmucosal product available. But Suboxone’s drawback has been an unpleasant taste. Sullivan said nearly all of his patients complain about the taste, but they have had no alternative.

“We need more options and this is definitely one,” Sullivan said.

Suboxone also presents another issue for patients and prescribers. Because the product is placed under the tongue, it causes the mouth to produce a lot of saliva. Andrew Finn, BDSI’s executive vice president for product development, said that the saliva production leads to much of the active drug being swallowed rather than absorbed into the bloodstream. BDSI’s technology delivers medication through a piece of film placed on the inside of the cheek. Finn said that a second layer on the film prevents the buprenorphine from coming out and mixing with the saliva and then being swallowed. That means BDSI’s product needs to administer less medication than Suboxone to have an effect.

Like Suboxone, BEMA Buprenorphine combines buprenorphine and naloxone in a single transmucosal product. BDSI is developing BEMA Buprenorphine through the U.S. Food and Drug Administration’s 505(b)(2) pathway, which allows the company to seek approval by showing its product is bioequivalent to the already-approved Suboxone. A series of studies requested by the FDA are ongoing or on track to start in 2012. The last study, a safety study in opioid dependent patients, is expected to produce data in the first quarter of next year. BDSI expects it will be in position to file a new drug application shortly after.

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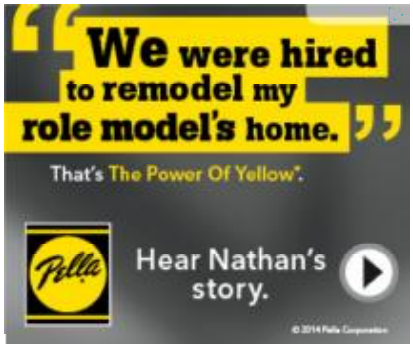

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By Frank Vinluan
Frank Vinluan is the North Carolina Bureau Chief for MedCity News.
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