

Aclaris Therapeutics (ACRS) and the Carbonaro Effect

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October 6, 2015 was a glorious day for investors. The season for the choicest apples for making pie was hitting its stride, and Aclaris Therapeutics went public. Although the underwriters (Jefferies, Citigroup, & William Blair) attempted to price the IPO at \$14-16, 5 million shares were priced at \$11.00 – raising \$55 million. The 10-K states that Aclaris is focused on “significant unmet needs in dermatology”.

Stats:

25 million shares out, 5 million in float (so if you want more, there is likely a lot more stock that will become available)

December 2015, ACRS has \$3.29 per share in cash

The claim to fame: a new treatment for seborrheic keratosis & common warts using hydrogen peroxide (H₂O₂) gel.

What is Seborrheic Keratosis? - These are common *non-malignant* skin tumors. They are unsightly but pose no danger to the patient. Still, you're only as pretty as you feel and dermatologists are happy to remove them. According to the Mayo Clinic “Seborrheic keratosis (SK) are normally painless and require no treatment”. Because the average person would not know what is SK and what is skin cancer, many visits to a dermatologist that sellside analysts/promoters claim are for SK are not. Some people go to the dermatologist out of fear that they might have skin cancer, and it turns out that it is only SK. So if you are promoting a company with a treatment for SK you can say that there are a few bazillion visits to dermatologists each year for SK. Pretty slick.

The current toolkit of the dermatologist for SK: Again from the Mayo Clinic website we have

1. Freezing with liquid nitrogen. I have had this done and it is easy.
2. Scrape/shave the growth away. – Some SK's are so flimsy that you can simply rub them off on your own or the dermatologist will do it and if warranted, send the tissue to be biopsied.
3. Electrocautery – In my opinion not as elegant as using a laser.
4. Laser

For warts, the treatments are essentially the same.

Any dermatologist who graduated medical school within the past 50 years can remove SK's with what is currently in their office and often with 1 attempt of any treatment. The four methods mentioned do not require attending advanced dermatology courses or unusual equipment. With any of the treatments, some short term minor discomfort can occur. We are dealing with inexpensive and EFFECTIVE solutions. One reason is because SK's are surface lesions, spreading horizontally and not in depth. According to the Aclaris mission statement, there must be a “significant unmet need” for treating SK's. My opinion, not so much.

The central patent:

Aclaris bought the rights to a patent originally issued to the late Mickey Miller, set to expire in 2022. In my opinion, the patent reach/claims seem to be absurdly broad. The patent covers just about any H₂O₂ containing solution of any concentration almost regardless of what additional ingredients are added to the mix. Of note and a serious drawback to the story is that the patent itself states “The inventors have discovered that reactive oxygen species such as the superoxide radical, hydrogen peroxide, hydroxyl radical, singlet oxygen and ozone, as well as other oxidants, are effective in eliminating seborrheic keratosis when applied in sufficient concentration **and frequency**. (bold italics mine). The patent explicitly states, “For total removal of the seborrheic keratosis to occur, more than one application of the oxidative composition or compositions to the seborrheic keratosis will sometimes be necessary.” In comparing the effectiveness of H₂O₂ to freezing or other modalities, it is at best counterintuitive to believe that H₂O₂ would remove lesions in fewer visits than currently used methods.

From the patent: “High concentration food grade hydrogen peroxide application results in, surprisingly, the complete removal of seborrheic keratoses, and other unsightly and undesirable skin disorders, without causing scarring, hypopigmentation or hyperpigmentation.” So the inventor is claiming that generic food grade hydrogen peroxide will take care of the problem! Another reference is made to a 35% hydrogen peroxide solution sold by chemical firm FMC Corp. This version called Durox is primarily used for sterilization, but the patent says it works just fine when applied to “the selected seborrheic keratosis”.

Is hydrogen peroxide gel new? Based on how it is discussed by analysts promoting the stock, you would think so. However, hydrogen peroxide gel has been used for years for tooth whitening. Here, on eBay, packs of 2 syringes of 18% concentration are being sold for \$5.00 <http://www.ebay.com/itm/2-18-Hydrogen-Peroxide-GEL-STRONGEST-TEETH-WHITENER-WHITENING-GEL-/380320246326? trksid=p2141725.m3641.l6368>

A 35% concentration is being sold here (10 syringes) for only \$16.03. <http://www.ebay.com/itm/Teeth-Whitening-35-Peroxide-Dental-Bleaching-Tooth-Whitener-Gel-10-Syringes/361396144031? trksid=p2141725.c100337.m3725& trkparms=aid%3D777000%26algo%3DAB A.MBE%26ao%3D1%26asc%3D201412152338%26meid%3Db782f913b726494196a8c50cab3b2f21%26pid%3D100337%26rk%3D1%26rkt%3D1%26sd%3D380320246326>

Is the “invention innovative or non-obvious”? – When you get your teeth whitened in a dentist office, a protective barrier is put in your mouth to protect your gums from the hydrogen peroxide used to bleach your teeth. This is due to the well-known understanding that a decent concentration of hydrogen peroxide will attack the tissue. So, does the idea of applying it to a superficial skin lesion create a strong patent? Coca Cola – (another acidic liquid) will remove paint. So, tomorrow I am applying for a patent to use Coca Cola topically as a SK remover. Then, I will get the same underwriters to take me public.

“You cannot be serious” – John McEnroe vs. Tom Gullikson at Wimbledon in 1981 and David Schneider in reading the central Aclaris patent.

Prior Art - <http://www.google.com/patents/US4826681> L'Oréal

<http://www.google.com/patents/US20040137077> - This patent overlaps patents that Aclaris has. What interests me is that the patent which covers the use of hydrogen peroxide in removing seborrheic keratosis is not owned by Aclaris, but by Physicians Choice of Arizona. PCA

<http://www.thedermreview.com/pca-skin/> sells high end cosmetics internationally. In the patents currently owned by Aclaris, reference is made to PCA suggesting that some PCA products may be used in conjunction with the use of hydrogen peroxide to alleviate potential skin irritation. Essentially, some intellectual property from the Miller estate went to PCA and Aclaris owns other IP. A logical question would be – What would happen in a legal tussle between PCA and Aclaris? Since PCA seems to have the legal right to use the same stuff that Aclaris uses, why don't they? Perhaps the answer is that the conventional methods of removal work just fine, and why bother with hydrogen peroxide. What is also interesting is that their body of patents are method of use patents. All of which in my opinion are not very meaningful.

Google search of “hydrogen peroxide seborrheic keratosis”

This search uncovers additional methods of removal that include apple cider vinegar (also good for toe fungus – sorry, Anacor). The comments of people who have successfully taken care of SK with apple cider vinegar are very interesting. Apple cider vinegar is moderately acidic with a pH of around 4.5, and according to <http://www.h2o2.com/fags/FaqDetail.aspx?fid=26> hydrogen peroxide of a 30% concentration has a pH of 4.7. So, very similar acidity. **Not a coincidence that both do the job.** No doubt that many investors in Aclaris will debunk the apple cider vinegar treatment. Tell that to the people who have used it successfully. Many people have also successfully used tea tree oil at home to eliminate their keratosis.

Regarding people using hydrogen peroxide at home, here <http://www.ag3derm.com/removal-of-seborrheic-keratosis-at-home-with-hydrogen-peroxide/> we see doing it is pretty easy and as the core patent that Aclaris rests upon states – that even decent food grade hydrogen peroxide will do, this does make us scratch our heads more when we realize that investors threw a ton of money at Aclaris.

Insurance Coverage

http://www.aetna.com/cpb/medical/data/600_699/0633.html - Because SK's are considered a cosmetic issue and ordinarily not a medical issue, removing them is generally NOT reimbursed.

And since SK's tend to occur more as we age:

https://www.oxhp.com/secure/policy/derm_procedures_oma_709.html - “

“Removals of certain benign skin lesions that do not pose a threat to health or function are considered cosmetic, and as such, are not covered” ...

For any healthcare plan, if removal of a SK is determined to be medically important, then it would be covered.

The Importance of Language

From the prospectus:

“A study published in the Journal of The American Academy of Dermatology in 2006 estimated that SK affects over 83 million people in the United States. Based on a market survey we commissioned in 2014, we estimate that there are 18.5 million patient visits to dermatologists for SK and dermatologists perform approximately 8.3 million procedures to remove SK lesions annually in the United States. We estimate that the cost of these procedures to third-party payors **and** patients is more than \$1.2 billion annually.”

The critical word in the above paragraph is bolded. Given that insurers are not interested in covering cosmetic procedures, **why include the word “and”?** For the minority of portfolio managers who bother to read a 10-K, my point of reimbursement is verified. Pg. 30 – “We do not expect third-party payors to cover and reimburse customers who use A-101 or A-102 on patients for the treatment of SK”.

Additionally, when a dermatologist wants insurance to pay, he or she can remove the lesion with a procedure that will spare the lesion tissue by scraping or other method in order to send it to a lab to be biopsied. It is a way for the doctor to get paid more (happened to me). If you use a method which alters the lesion, it may alter the biopsy analysis. Obvious conclusion – If you want to make more money, don't put acid on the lesion.

Is the Horse Dead Yet?

Being an animal lover, the last thing I would want to be accused of is beating a dead horse. However, I may enjoy kicking it a few timesjust to be sure, so what Aclaris wants to do is:

- Take a chemical whose properties have been well characterized since 1894 and sell it to dermatologists to use in non-reimbursed procedures when they have other excellent methods that they are quite comfortable in using. But Aclaris needs to prove that hydrogen peroxide works, so they are spending money on clinical trials. Hint – Of course it works, but so does apple cider vinegar (same pH), liquid nitrogen, etc. End game – Who cares?

Will Dermatologists use it?

Of course, some will. But changing physicians behavior when they have treatments that work well already - that are easy to do, is not easy. And how much would a dermatologist pay for what is a very inexpensive chemical? Upping the annual number of removals that Aclaris claims of 8.3 million to 10 million is a good start. Doing that will remove the issue of bulls claiming that I am attempting to slant the argument. So, at 100% market share we have 10 million x \$2.00 doctors cost = \$20 million annual

revenue. Of course, they will use clinical trial validation in order to charge an absurd amount. (Don't forget the special applicator.) But nitrogen is also the most common element in our atmosphere so liquid nitrogen will never be in short supply. And if a doctor somehow falls in love with the acidic answer, there is always buying it by the gallon from a local chemical company. And a q-tip which is very cheap can make a fine applicator. Nevertheless, Jefferies in their initiation of coverage states that Aclaris hydrogen peroxide could become a \$500 million per year....drug. Hint to Marty McFly – It isn't even a drug. The misinformation in the Jefferies reports are so absurd – similar to their promotion of Anacor - ANAC (same analysts) which I disassembled in a sell recommendation on Seeking Alpha and Sumzero that it is tough to know where to begin. Worth noting is that if all goes well in the clinical trials, Aclaris would begin selling their product in 2018. Jefferies has the firm going profitable in 2019 with revenue of \$44.5 million ramping to \$156 million in 2020. That is a bit higher than the \$20 million I came up with giving them 100% market share. Ahh, but I forgot about selling the applicator. Sloppy work on my part.

The Carbonaro Effect (<http://www.trutv.com/shows/the-carbonaro-effect/index.html>)

In “Conjurers’ Psychological Secrets”, <http://www.amazon.com/Conjurers-Psychological-Secrets-S-Sharpe/dp/0921298145> Sam Sharpe says that misdirection is sometimes defined “as the intentional deflection of attention for the purpose of disguise.” As such, it would encompass anything that prevents you from noticing the secret method (i.e., the technique used to bring about the observed effect). Please note that the following conversation did NOT occur between the management of Aclaris and the investment bankers for the deal.

Aclaris – “We want to raise money for an obvious method to take care of these skin lesions that are not pretty. You know how vain people are. If we raise enough money for this, maybe we can use the money and buy something that actually could make money”.

Investment Bankers – “Our people can get it done. The calendar has been a bit dry lately and our salesforce is hungry and eager. We’ve got analysts who will support your stock”

Act 2 – Janus kinase inhibitors. JAK inhibitors are being developed for inflammatory and immune oriented disease such as psoriasis, rheumatoid arthritis, alopecia. They have the interesting potential of restoring hair growth. There are many JAK inhibitors with numerous biotech firms working in the area. These include: Abbvie, Lilly, Incyte, Pfizer, and others. The interest of Aclaris is dermatology. Prior to the IPO, Aclaris licensed two inhibitors from Rigel Pharmaceuticals (RIGL) to be developed for hair loss. On March 28, 2016 Aclaris bought Vixen Pharmaceuticals, a company founded by a woman with great hair http://www.eurekalert.org/pub_releases/2015-10/cumc-bei102015.php Much has been written about the potential for JAK inhibitors to restore hair growth by altering the dormancy of hair follicles. Clearly, baldness is a potential major win for whatever companies come out with effective treatments, and there are several causes of baldness so what will work for one type of baldness may not necessarily work for another. There is great data using stem cells to restore hair growth so I would expect stem cell therapy to become more discussed among the dermatology community. Because the market potential dwarfs

that of using hydrogen peroxide for SK removal, this in my opinion is what the company really cares about. Aclaris got Mickey Miller's peroxide patent for only \$7 million plus a single digit royalty but the Rigel JAK deal cost them \$8 million up front, with \$90 million more on the way if they develop a product plus royalties....so we know what is at the end of the rainbow. But with a bear market in biotech, the SK treatment *in theory* was the nearer term revenue driver and gave the company the money to spend on the follicular dream. Thank you, Michael Carbonaro.

Price Target? - "You cannot be serious."