Dendreon's Provenge: Update With The President Of The Large Urology Group Practice Association

January 28, 2013 | 8 comments | about: DNDN

CONTRIBUTOR

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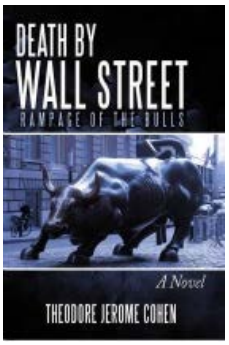

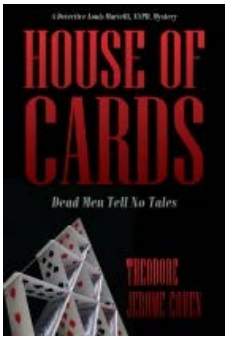

Disclosure: I am long DNDN. **(More...)**

On January 25, 2013, I again interviewed Dr. Deepak A. Kapoor, MD, Chairman and CEO, Integrated Medical Professionals, PLLC, or IMP. Readers will recall our previous exchange almost a year ago, which generated considerable interest among both patients and investors. To say the least, a lot has changed in the intervening months, especially in terms of the treatments available to prostate cancer sufferers. So, it was with great anticipation that I looked forward to learning how Dr. Kapoor and his practice had evolved since we last spoke, especially with respect to the administration of Dendreon's (DNDN) Provenge, Johnson and Johnson's (JNJ) Zytiga, and Medivation's (MDVN) Xtandi.

But first some background. Dr. Kapoor, one of the youngest physicians to have been certified by the American Board of Urology, came to IMP with more than 20 years of clinical and business experience. He received his B.S. magna cum laude from the Pennsylvania State University and his MD from Jefferson Medical College, in the Accelerated Five Year Honors Program. He completed his residency at Geisinger Medical Center, after which he served as Assistant Professor of Urologic Surgery at the University of Minnesota Medical Center. His medical background is diverse, with both laboratory and clinical experience in the academic and private sectors. Dr. Kapoor´s expertise includes basic science research in molecular biology as well as extensive experience in oncologic and reconstructive surgery.

Presently, Dr. Kapoor is President of the Large Urology Group Practice Association, Director and Immediate Past Chairman of Access to Integrated Cancer Care (an informal advocacy group representing the rights of patients to access integrated services of the highest quality), Chairman of SCRUBS RRG (the only national Urology-specific medical malpractice carrier), a member of the Board of Directors of Allied Urological Services (the largest lithotripsy partnership in the United States, where he also functions as Chairman of the Finance Committee), and Founder and Past-President of the Integrated Medical Foundation. Prior to his tenure with IMP, Dr. Kapoor functioned as managing partner of Long Island Urological Associates, during which time LIUA enjoyed double digit growth in each year of his leadership despite declining medical reimbursements nationally.

IMP is a multi-specialty physician group comprising more than 100 physicians operating in the greater New York Metropolitan area. IMP's model is to forward integrate surgical specialists at the point of patient contact with physicians who provide diagnostic and therapeutic services to those patients. IMP's vision is to provide patients with the highest level of care available, as measured by both clinical outcomes and patient satisfaction.

Cohen: It's so nice to talk with you again, Dr. Kapoor. I appreciate your taking a few minutes from your busy schedule.

DNDN VS. ETF ALTERNATIVES

ETFs	TODAY	3 MTHS	1 YR	YTD
DNDN	2.2%	65.8%	-56.4%	20.7%
PRFZ	0.5%	12.0%	14.4%	6.8%
RWK	0.5%	15.4%	14.9%	9.5%
EZM	0.3%	13.6%	14.5%	7.3%
XBI	-0.2%	12.3%	23.8%	9.4%
MDY	-0.2%	12.2%	16.2%	7.3%
XLV	-0.2%	6.1%	19.4%	7.2%
MVV	-0.3%	26.2%	33.8%	15.1%
IRY	-0.8%	6.4%	19.9%	4.9%

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Kapoor: Always a pleasure, Ted. But before we begin, please allow me to say again that I do *not* invest in any companies that produce the drugs we use in our organization. I think it's important for people to know that my decisions regarding the care given to patients are never tainted by conflicts of interest.

Cohen: We appreciate your candor. So, let's jump right in with a question about Dendreon's Provenge. Last year you indicated your practice had roughly 2000 patients with advanced prostate cancer and as many as 200 might be candidates for Provenge. How many of those received the treatment?

Kapoor: As I recall, we infused between 60-70 patients.

Cohen: That's not quite as many as you had hoped to treat when we last spoke.

Kapoor: No, it isn't. What I was counting on was our ability to use our EMR [electronic medical records] technology to rapidly screen patients and identify candidates for Provenge. Unfortunately, this was more difficult than we anticipated. More to the point, we were unable to construct an *automated* screening methodology that would allow us to quickly and effectively screen patients with any degree of accuracy.

Cohen: So-

Kapoor: So, we had to go back to reviewing the bone scans, charts, and other data by hand...which is fine, but it takes time.

Cohen: Can you make a prediction as to the number of patients you'll treat with Provenge this year?

Kapoor: It's a little early to do that. The patient landscape is still a little hazy.

Cohen: Hazy in what way?

Kapoor: Well, besides having to screen by hand, there's a variety of misinformation-in some cases, disinformation-out there about the treatment that we occasionally have to address. For example, from time to time we get resistance from a patient when we suggest Provenge, even from someone we believe would benefit from the treatment. It may because of something negative he read on the Internet or heard by word-of-mouth. To the extent Dendreon can educate the consumer-that is, improve the patient's understanding and awareness of their treatment through educational programs or even Direct-to-Consumer [DTC] advertising-I think it will help us and other physicians present the case for administering their product. As well, the patient will be better educated when he comes to the office to discuss his condition and possible treatment pathways.

Cohen: It's my understanding, listening to a presentation by Dendreon's president, John Johnson, at the **31st Annual J.P. Morgan Healthcare** Conference**,** that the company intends to initiate DTC television advertising this spring.

Kapoor: That's certainly welcome news. Anything the company can do to present the advantages in using their product and to correct the misunderstandings some people might have would be a significant 'plus.' It does seem that the new management team has recognized these needs and is making changes to address them.

Cohen: What kind of changes?

Kapoor: Historically, the focus was on the clinical studies and the approval process as well as on educating providers about a novel form of treatment. There was also the issue of dealing with the Medicare NCD [national coverage determination], so the prior group had their hands full with those issues. Now that those hurdles are behind them, there seems to be a redoubled focus on educating the patient, which is of

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great help to us.

Cohen: I raised this subject last year, but I think it's worth discussing again. Is the lack of data on disease progression still an issue when you or a patient raises the possibility of treating him with Provenge?

Kapoor: Still a good question, Ted. And basically, my answer hasn't changed. The men we see still have been conditioned to think in terms of their PSAs. But once they are hormone refractory, PSA is no longer as important. This is the time when we need to talk to them about the overall duration of life and about what's important at their stage of the disease. It takes time to educate the patient, but it's worth it. This is not to say, however, that we wouldn't welcome some means by which to demonstrate Provenge's efficacy.

Cohen: Earlier this month, Geoffrey Porges of Sanford C. Bernstein & Co. stated that when they contacted urologists with significant experience with Provenge, "[T]he busiest urologist Provenge prescribers have been increasing their use, and recruiting colleagues and peers to use the product as well." Would this be a fair representation of what's happening in your practice?

Kapoor: Personally, as the President of the Large Urology Group Practice Association and a director or a chairman of other national urological organizations, I think it would be a conflict of interests [COI] to endorse any particular treatment regimen, or even to give lectures sponsored by pharmaceutical companies, although I certainly respect those physicians that choose to do so. That said, I certainly would give my honest, professional opinion, if asked, on the use of any given treatment or clinical pathway, depending on the case in question. In our practice we manage patients based on prospective clinical guidelines based best practice models developed from evidence-based medicine and national consensus clinical protocols, so this is not really anything I have personal experience with.

Cohen: We do know from Dendreon's post hoc analysis of its three pivotal Phase 3 trials and the resulting quartile study that the earlier Dendreon is uploaded, the better. For example, if a patient's PSA is 22.1 or less, the median overall survival is 13 months. However, if the patient's PSA is in the range 22.1 to 50.1, the median overall survival drops to 7 months. Are you screening patients more aggressively these days than you were a year ago to more precisely determine when they first become candidates for Provenge?

Kapoor: Let me preface my response by noting that during 2012, we instituted our proprietary 'Nurse Navigator Program.' All of our patients are entered into this program, the intent of which is to ensure their cases are monitored efficiently and effectively throughout the time they are under our care. Our nurse navigator is responsible for monitoring each patient's clinical pathway, *regardless of their treatment regimen*. Now, if one of our physicians believes a patient *may* be a candidate for Provenge, he will work with the nurse navigator to coordinate the necessary studies in order to determine whether or not the patient qualifies. She'll then work through the insurance authorization process, facilitate the patient's pheresis and treatment, and make sure that clinical follow up is scheduled in a timely fashion. Finally, there is no question, as you noted, that the earlier we can get Provenge to a patient, the better. In fact, it's a pretty good rule of thumb for cancer in general that the earlier we can intervene, the better, regardless of the treatment use.

Cohen: Are sodium fluoride, or NaF, PET scans still your technique of choice?

Kapoor: I do think these are more effective in terms of specificity, but we have real issues related to reimbursement around these studies.

Cohen: Speaking about reimbursement. Any major issues there with Provenge?

Kapoor: Just a few things to mention. First, and surprisingly, we have had patients reluctant to start on Provenge because of cost issues, even some men with very solid coverage. I think that goes back to the issues about patient education and overcoming misinformation that we touched on before, as we don't see patients with other cancers ever really inquire about the cost of therapy. Second, we did run into issues with reimbursement for a few patients last year, even though the drug was pre-authorized by the carrier. Fortunately, we were able to work with Dendreon and the distributor to work through these issues, which have been fully resolved. Other than that, our reimbursements are averaging 14-21 days from Medicare.

Cohen: Last year you said: "At IMP, we are *very* careful about the clinical pathway we use. More specifically, we don't want different patients getting different protocols. Our doctors stick with NCCN Category 1 guidelines." Provenge, of course, has an NCCN 1 rating for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant-hormone refractory-prostate cancer. Given that the FDA recently approved Johnson & Johnson's Zytiga for pre-chemo use, albeit with an NCCN 2A classification in this space, have you changed your protocols to include the prescription of Zytiga in pre-chemo applications? If so, under what conditions would you prescribe it?

Kapoor: We *are* very careful about our patients' clinical pathways. But the fact is, there are a number of guidelines besides those set forth by the National Comprehensive Cancer Network [NCCN]. We have American Urological Association [AUA] guidelines, guidance found in the medical literature, and so forth. So, it's not cut and dried. However, I will say that in our practice, we consider Provenge to be the foundation of care when it comes to the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer [CRPC]. Since the use of steroids is a contraindication to Provenge, we would generally sequence Zytiga in behind Provenge, if its use was indicated based on a specific patient's condition.

Cohen: That's consistent with what the *Journal of Clinical Oncology* had to say on the subject.

Kapoor: Absolutely.

Cohen: What about Medivation's Xtandi? I know that you are enthusiastic about this drug, and, in fact, that IMP is participating in the pre-chemo trial now being conducted by the company.

Kapoor: Other than the patients in the trial, we are *not* prescribing Xtandi for pre-Tax [Taxotere] patients. The simple fact is, Xtandi is not approved by the FDA for pre-Tax use. So, as a matter of practice, we will not prescribe it off-label in that space.

Cohen: Before we wrap this up, Dr. Kapoor, do you have any additional thoughts regarding the treatment of prostate cancer for our readers on Seeking Alpha?

Kapoor: I would only add that this is a very exciting time for us in the field of urology in general and prostate cancer care in particular. The drugs approved in the last several years, coupled with those now under development, portend great progress on the treatment front. This only can work to the benefit of our patients. We're looking forward to the results of studies on combination and sequencing of the newer prostate cancer agents, and of course, will modify our protocols to reflect the best available data. I truly believe we are on the cusp of a new age in the treatment of prostate cancer.

Cohen: Thank you, Dr. Kapoor, for a most illuminating exchange.

Kapoor: You're welcome, Ted. Always a pleasure talking with you.

Technical Analysis (1 pm ET, Monday, January 28, 2013)

The daily chart for Dendreon, courtesy *StockChart.com,* shows the stock 'backing and filling' as it corrects an Overbought condition. While the price is still holding above the 200-day moving average, the MACD now has turned neutral.

The weekly chart for Dendreon shows the Relative Strength rising, with the stock challenging the 50-week moving average (a resistance level). A move above $6.90, now, would signal the beginning of a new uptrend. The MACD is still positive (but barely).

Additional disclosure: I am long DNDN and the May 2013 $3 PUTs. I am not a registered investment advisor and do not provide specific investment advice. The information contained herein is for informational purposes only. Nothing in this article should be taken as a solicitation to purchase or sell securities. Before buying or selling any stock you should do your own research and reach your own conclusion. It is up to investors to make the correct decision after necessary research. Investing includes risks, including loss of principal. I am long DNDN and will not alter my position within 72 hours of the time of publication of this article. I am not a registered investment advisor and do not provide specific investment advice. The information contained herein is for informational purposes only. Nothing in this article should be taken as a solicitation to purchase or sell securities. Before buying or selling any stock you should do your own research and reach your own conclusion. It is up to investors to make the correct decision after necessary research. Investing includes risks, including loss of principal.

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Comments (8)

Giancarlo Nicoli Comments (91)

Ted,
well done!
Thank you.

Theodore Cohen Comments (1488)

Author's Reply Hi, Giancarlo!

I was just thinking of you! Happy New Year. Hope you and the family are well.

And thanks. Dr. Kapoor was very gracious and gave me more time than I expected.

Be well.

Ted

portosanta95 Comments (151)

Great article Ted, thank you!
Very interesting is this:
"However, I will say that in our practice, we consider Provenge to be the foundation of care when it comes to the treatment of asymptomatic or minimally

symptomatic metastatic castrate resistant prostate cancer [CRPC]. Since the use of steroids is a contraindication to Provenge, we would generally sequence Zytiga in behind Provenge, if its use was indicated based on a specific patient's condition."
Seems that DNDN is on track to succes.

bioimmuno Comments (65)

Your interviews are far more informative than the typical Wall Street sell side analyst reports. Well done! How has this interview/information altered your investment thesis and plans regarding DNDN and other related stocks in the space?

Theodore Cohen Comments (1488)

Author's Reply Thanks.

It really hasn't had much impact on my position. As I noted, I'm long, but hedged with May $3 puts...just in case Medivation suprises (or something else takes the markets down in the near term, given the 'frothiness' in some of the major biotechs).

I believe John Johnson and his troops have a good plan in place to turn the company around. Closing the NJ plant together with the institution of automated processes throughout the operation should bring the COGS down to the 30-40% range by the end of the year. Even at the current revenue stream, then, on a gross margin basis, the company should be worth in the mid- to high teens to an acquirer.

http://bit.ly/Vh6hBu

Ted

Theodore Cohen Comments (1488)

Author's Reply I have to admit...I was a bit surprised to hear him use the term 'foundation.' Had not heard that from anyone in quite a while.

It seems clear that in his practice, at the least, they are extremely careful (cautious?) about the clinical pathway used, and the guideline(s) employed, for any given patient.

Ted

IT153 Comments (113)

Thank you Ted for more update.

Theodore Cohen Comments (1488)

Author's Reply You're welcome. Happy to provide.

Ted

Guest

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