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Nuvilex, Inc. – The Road to Phase III Clinical Trials

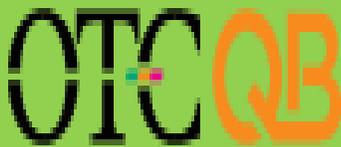
When we first introduced Nuvilex, Inc. (OTCQB: NVLX) back on February 19, 2013, at \$0.0519/share, we did so with an eye to the future, and since then, a great deal has happened at the international biotechnology company that confirms we were right on target with our analysis. This report serves as both a 3rd Quarter update and our first report following Nuvilex on its Road to Phase III clinical trials. In the opinion of Stock Market Media Group, these trials will change this company forever, and could quite possibly make Nuvilex's live-cell encapsulation approach to cancer treatments the same phenomenon that stem cells were in the biotech industry.

Company Overview

Nuvilex is an international biotechnology provider of live, therapeutically valuable, encapsulated cells for research and medicine, presently focusing on developing treatments for cancer, with additional planning underway using the company's natural product knowledge, product base, cell and gene therapy expertise, and live-cell encapsulation technology, in addition to other new products currently under development.

Nuvilex has two, successful independent Phase II clinical trials under its belt for the treatment of advanced, inoperable pancreatic cancer, and in those trials remarkable data was obtained that has it primed to challenge

the likes of Eli Lilly (NYSE: LLY) and potentially replace its multi-billion dollar drug, Gemzar, the current standard single drug for treating patients with advanced pancreatic cancer. Late stage (Phase III) clinical trials will mean everything to the future of Nuvilex, its shareholders and quite possibly the battle against pancreatic and ultimately other cancers. In the trials, Nuvilex's technology could prove it offers the industry a great deal of hope for a new way of dealing with this dreadful disease.

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Company Ticker Symbol	NVLX
Current Price as of 7/31/2013	\$0.157
52-Week High/Low	\$0.22/0.019
Est. Outstanding Shares	509,931,348
Market Capitalization	\$80,059,222

What Is New at Nuvilex, Inc.?

Here are some of the things we've learned since our last report:

- ✚ [**Nuvilex, Inc. Completes Acquisition of Exclusive Worldwide Rights to Pancreatic Cancer Treatment Technology**](#)
- ✚ [**Nuvilex, Inc. Returns 100 Million Shares to Company's Treasury After Completing Acquisition**](#)
- ✚ [**Nuvilex 8-K: Entry into a Material Definitive Agreement, Completion of Acquisition or Disposition of Assets**](#)

As we stated in our first Report on NVLX, in the biotech sector, the money is in companies that are conducting clinical trials that focus on products or therapies for cancer, diabetes or the heart. In the 3rd Quarter, Nuvilex moved one step closer to Phase III clinical trials with its treatment for advanced, inoperable pancreatic cancer that combines live-cell encapsulation with the cancer killing drug ifosfamide.

The latest news out of the corporate offices in Silver Spring, Maryland, is to be applauded. Nuvilex made a blockbuster deal, and we continue to believe it was a steal that could very well provide the company with assets worth far more than the \$1.5 million paid in the acquisition. After completing the \$1.5 million cash acquisition of all of the shares of Bio Blue Bird AG (BBB), the former subsidiary of SG Austria Pte. Ltd., BBB is now Nuvilex's debt-free wholly-owned subsidiary. The huge take-away from this deal is that Nuvilex owns exclusive worldwide licenses associated with the live-cell encapsulation-based pancreatic cancer treatment. These licenses include worldwide rights to utilize the live-cell encapsulation platform technology to develop treatments for any and all cancer types, regardless of the cell type encapsulated.

This means that **any** company, research center, university, etc. that wants to pursue treatments using the live-cell encapsulation technology will have to go through Nuvilex to do so. While that may not seem like a big deal at the moment, if future Phase III clinical trials are successful, and Nuvilex is able to confirm the results seen in the company's two independent Phase II trials using the technology, then there is a very good likelihood that pharmaceutical and biotech companies, cancer research centers and any entity conducting cancer research or involved in cancer treatments will be giving Nuvilex a call.

Shareholders made out in the deal as well when Nuvilex returned 100 million shares of its issued and outstanding common stock that had been held in escrow back to the company's treasury. In the July 16th press release announcing the return of the shares to the treasury, Dr. Robert Ryan, President and CEO at Nuvilex said it best in his statement:

"The modifications made in structuring this transaction resulted in a significant and beneficial event for the Company and its shareholders. We were also able to execute the transaction without transferring to SG Austria the 100 million shares initially held in escrow to complete the acquisition. The advantage to our shareholders is a reversal in what would have been an approximately 20% dilutive event of the total outstanding company stock if we would have acquired the SG Austria assets and personnel, as was originally contemplated.

Now, because we acquired 100% of the BBB equity, the subsidiary with the technology licenses and assets, and a 14.5% interest in SG Austria, the Company and our shareholders have realized a substantial non-dilutive net gain because the 100,000,000 shares have now been returned to the Company's treasury. Additionally, we have avoided a significant increase in anticipated operating expenses that would have been associated with the original Asset Purchase Agreement, saving critical capital for use in preparing future clinical trials. The funding and subsequent acquisition has created the driving force and capability to **immediately proceed with the preparations for the pancreatic cancer clinical trials.**"

The Road to Phase III for Nuvilex, Inc.

About \$25-million has been invested in two independent Phase II clinical trials in patients with advanced, inoperable pancreatic cancer using the combination of the widely used anti-cancer drug, ifosfamide, together with encapsulated cells capable of converting the ifosfamide into its "cancer-killing" form and in pre-clinical studies of other applications for the technology. In addition, the company has put almost another \$2-million into furthering the development of the technology itself and now an additional \$1.5 million with its latest acquisition.

This is a pretty hefty price tag for bringing the technology to its present stage of development, but with the results that have been seen to date in the two previous clinical trials, the future looks very bright. In those trials, the

results show that Nuvilex's treatment outperforms the current single-agent standard for the treatment of advanced, inoperable pancreatic cancer, Eli Lilly's (NYSE: LLY) Gemzar.

Why is this significant to Nuvilex? It's all about the math and right now. Gemzar – the standard single drug for pancreatic cancer patients – lands Eli Lilly about \$1.4-billion annually. Cancer drugs are big business, and those drugs are even bigger business when they work, and when they extend lives, and so far, Nuvilex's cell encapsulation technology has shown it does work, it does extend lives, and it does so without serious drug-related toxicity occurring.

This, of course, means the small biotech (Nuvilex) is set to square off with the pharmaceutical giant (Eli Lilly). Nuvilex has produced better results when compared to historical data for Gemzar, and now the company is preparing to obtain real time, head-to-head data that, if consistent with the data obtained from previous clinical trials, would prove its treatment is superior to Eli Lilly's. With success, Nuvilex could very well be a household name in the biotech sector, particularly in conversations about the use of live-cell encapsulation as part of treatments for serious diseases like advanced pancreatic cancer.

Live-Cell Encapsulation Technology

Nuvilex's cell encapsulation technology uses living cells, and the company takes a very specific type of cell to address a specific problem a patient suffers from – in this case pancreatic cancer. Virtually any type of cells whether they are drug-activating cells, drug-producing cells, or “beneficial” factor producing cells can be encapsulated with only very minor modifications to the company's process.

Scientists then enclose the cells in unique “capsules” made mainly of cellulose, forming essentially “cotton bags” with live cells inside. The capsules are about the size of the head of a pin. The capsules have “pores” in them that allow nutrients for the cells inside to enter and waste products

and “beneficial” factors produced by the encapsulated cells to leave. Each bundle of encapsulated cells becomes much like a miniature cell factory with the ability to produce whatever is needed.

This basic cell encapsulation process can serve as a “platform” upon which treatments for many serious, debilitating, and even fatal diseases may be built. These diseases include different types of cancer and diabetes.

A glance at the significant results in those two independent Phase II clinical trials in advanced, inoperable pancreatic cancer shows that, with twenty-seven patients included, a substantial response was seen in the use of the live cell encapsulation/ifosfamide combination; in other words, the combination helped patients to a better outcome than that previously reported with standard single-drug (Gemzar) therapy.

Results from these trials showed that the median survival time and one-year survival rate of patients was almost doubled as compared to historical data for Gemzar. The severity of ifosfamide’s side effects was reduced because only one-third of its usual dose was used. No damage to tissues surrounding capsules was seen and cells within the capsules were protected from attack by the patients’ immune systems. Cells inside the capsules were alive and functioning – even after more than two years.

In the company’s future Phase III trials, Nuvilex’s pancreatic cancer treatment will be compared “head to head” with Gemzar and the results could quite possibly be even better than those returned from the Phase II trials. Whereas only two cycles of ifosfamide were used in the Phase II trials, for the Phase III trial, more than two cycles may be given, as is often the case when ifosfamide is used in cancer treatment.

If the results obtained with Nuvilex’s treatment are statistically better than those obtained with Gemzar, the company’s treatment could replace Gemzar as the single-agent “gold standard” for the treatment of this devastating disease.

Success in Phase III Opens Many doors

And, this is only the company's treatment for advanced, inoperable pancreatic cancer which is as severe a disease as it gets – what about using this technology in the development of treatments for other types of cancer? After all, if the company can improve upon the industry's standard single-agent drug for advanced pancreatic cancer which draws over a billion in annual sales, how much could it cut into the market of say – Bristol-Myers Squibb's (NYSE: BMY) Taxol which is used for a variety of cancers? Taxol has netted Bristol-Myers Squibb well over \$11-billion and it too was earning over a billion dollars annually before the generics were allowed to duplicate the drug. Or how about relative cancer "newbies" like Genentech/Roche's Avastin – about \$2.5 billion in sales annually. The list goes on.

Nuvilex's live-cell encapsulation technology could make its mark by improving on the industry standard in one type of cancer after the other, and when you start to think of the billions being made each year in those drugs, that certainly makes the technology well worth the investment to date.

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