

# NUVILEX, INC.

## SG Austria Better Than Advertised; Next Stop \$0.50

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### NUVILEX, INC. (OTC:QB - NVLX - \$0.046)

Price Target: \$0.50

Rating: Speculative Buy

#### COMPANY SNAPSHOT

Nuvilex, Inc. is an innovative biotechnology and natural products company. Nuvilex's leading oncology offerings under development include a late stage treatment for advanced pancreatic cancer and early stage breast cancer treatment using the company's industry-leading live-cell encapsulation technology. The pancreatic cancer treatment is being readied for additional clinical trials and significant advances are in progress with affiliate SG Austria's live-cell encapsulation technology. Current natural products sold via the Web and in outlets across the country include flagship Gluten-Free [Cinnergen™](#) and others to enhance a healthy lifestyle. Future developments are planned for Citroxin™ and Oraphyte™, Nuvilex's antimicrobial and antinematodal agents.

#### KEY STATISTICS

Price as of 9/23/11	\$0.046
52 Wk High – Low	\$0.104 – 0.004
Est. Shares Outstanding	377.0M
Market Capitalization	\$17.3M
3 Mo Avg Vol	255,000
Exchange	OTC:QB

#### COMPANY INFORMATION

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#### INVESTMENT HIGHLIGHTS

In late June 2011, Nuvilex announced that it entered into a definite agreement to acquire all of the assets and technologies of SG Austria Pte. Ltd., the world's leading live-cell-encapsulation company. We believe that management is close to concluding this transaction, which will provide a major confidence boost for investors and a dramatic boost in the share price.

Upon further review, we may have underestimated the value SG Austria brings to Nuvilex. The broad and ground-breaking uses of the technology, existing revenue generation capabilities, and relationships with major pharma firms and development organizations place it in an enviable tier compared to most companies of its size.

The broad applications for the Company's technology include treatment of multiple cancers, enhanced stem cell implementation, and the treatment of life-threatening viral infections. Additional applications under development provide even more shots on goal for this innovative delivery system pioneer.

Nuvilex has captured the attention of the industry. This higher profile will result in greater visibility and a higher valuation as milestones are reached.

Investors should expect to witness major hockey stick-type growth. It is worth noting that both management teams at Nuvilex and SG Austria are collaborating on key R&D projects, similar to the framework of a single entity.

The stock has held up solidly the past few months in the \$0.05 range, but that is a fraction of its true value, in our view. Now that we have had an opportunity to perform due diligence, we believe that Nuvilex is worth \$0.20 just on the oncology, stem cells and anti-viral therapies alone. We now believe that the shares will reach \$0.50 in the next six months, versus our previous timetable of year end and reiterate our Speculative Buy rating.

# **NUVILEX, INC. (OTC:QB - NVLX)**

## **THE SKINNY**

Nuvilex has been transformed from a cult-stock with a quirky history to an emerging, broad-based, multi-functional, therapeutic enhancement platform. Think back to the BASF commercials from the late 1990's. "We don't make....we make everything better." In essence, that is what Nuvilex has with the live-cell encapsulation technology/delivery platform being acquired as part of the SG Austria transaction.

With so many applications possible in biotechnology, stem cell research and applications, cosmetics, environmental uses, etc., finding the capital necessary to execute and reach the maximum potential of the technology's utilization cannot be borne alone. SG Austria has, on its own, and in some cases in joint research projects that provide some revenue, engaged in studies to explore and verify uses of the live cell components and delivery platform. However, for a private company, access to funds to continue R&D on its own, are limited. By allying with a publicly traded entity, access to capital is easier as is the path to meaningful revenue generation and profitability.

As a result, over the years, numerous research organizations and major health care firms have sought out the technology for various studies, applications and trials. In some cases, there are milestone payments associated with these studies. In fact, SG Austria has been paid over \$1.5M in milestone payments due to reaching objectives. Over a longer haul, if successful, these trials can be monetized in the future when the funder of a given study contracts with the Company to provide it with the cells and know-how to utilize the technology for their own purposes. SG Austria is nearing that tipping point of what could be termed as institutional sales and service revenue.

Additional tangible value-added characteristics involve is the initial, proprietary use of the technology, whose continued R&D can be executed alone or with another, larger partner on the path to regulatory approval for broad utilization and sale.

### The Technology: View from 10,000 Feet

The patented cell encapsulation technology enables the targeted placement and delivery of any cell type into the body after enclosing the cells inside tiny beads. Depending on the cell type placed into the beads, or encapsulated, these cells enable continuous and/or controlled production and release of targeted therapeutic molecules in an elegant delivery systems that is almost akin to the early concepts of nanotechnology in health care. SG Austria's proprietary offering, *Cell-in-a-Box™*, utilizes beads comprised of a naturally occurring, nontoxic, biocompatible material that protects the encapsulated cells from attack by the body's defense mechanisms. At the same time, the beads provide a microenvironment that enables encapsulated cells to survive for long periods of time.

## **MULTIPLE PATHS TO SUCCESS**

### The Applications

At its core, the basic role of the *Cell-in-a-Box™* technology is a means to protect, isolate, store and transport living cells. However, as noted above, the "BASF" factor means that the technology can be utilized as a targeted delivery system to "make things better." It is difficult to quantify the value and all of potential applications of the technology such as cosmetics, environmental, and the probiotic segments. But by just reviewing the current successes in health care illustrate that in health care alone, it is not a big leap to envision the potential use of *Cell-in-a-Box™* in virtually all critical therapies.

### **Oncology: Pancreatic Cancer and Breast Cancer Treatments**

Prior to the announcement of Nuvilex's intention to buy SG Austria, the Company acquired the rights to the pancreatic cancer treatment technology based largely upon *Cell-in-a-Box™*. Phase II trials using the technology were completed and very favorable.

Despite small sampling (14 patients), these results are game-changing.

- Patients' median survival rate doubled
- The 1-year survival rate was double that of the current gold standard used today, Gemzar
- Patients needed only 1/3 of the chemo dosage
- Quality of life increased substantially
- There was no tumor progression; it slowed in all patients and shrunk in some cases

**Company Report**

These results are not just statistically significant, but major departures from the norm. The keys to note are: substantially higher survival rate, higher quality of life, lower chemo dosage.

How did it work?

The patented technology involves the targeted delivery of encapsulated living cells capable of delivering and converting standard inactive chemotherapeutic cancer drugs (pro-drugs) into active, chemotherapeutic (cancer-fighting) drugs directly to the pancreatic tumor. In addition, this technology allowed for the use of overall lower pro-drug doses, dramatically decreasing the overall body exposure to such toxic agents, yet with greater clinical effect.

Nuvilex recently announced successful results for the treatment of breast cancer from preclinical studies. In recently completed work using the Nuvilex live-cell encapsulation technology and a combination of two anticancer drugs, clear positive results of elimination of breast tumors were achieved in preclinical models.

These results demonstrate that the Nuvilex cell encapsulation technology can be applied to the treatment of breast cancer in order to improve the treatments, effectiveness, toxicity reduction and outcomes for this disease. The studies placed live, encapsulated cells into the tumors and then treated animals with two different anticancer agents. To provide a complete assessment for the ability to use this treatment in humans, this study used two different breast cancer models.

After placement of the encapsulated live cells, when ifosfamide was administered alone to the mice, significant anticancer effects were seen, indicating it had been converted to its cancer-killing form, as was previously observed in the preclinical studies and pancreatic cancer clinical trial. However, when both ifosfamide and 5-fluorocytosine were administered, the combination proved to be superior in cancer-killing ability than ifosfamide alone. The results also indicated encapsulated cells were able to activate both of these very different prodrugs simultaneously. We should also note that this study used two different breast cancer models.

**Conclusion:**

If the pancreatic cancer therapy were to win approval, this technology could be worth at least \$200 - \$300M a year in revenue to Nuvilex just for pancreatic cancer treatment. We arrive at this figure by assessing an expected price of \$40,000 - 50,000 per patient dosage times the estimated 43,000 new pancreatic cancer patients in the U.S. each year. That represents a \$2 billion annual market opportunity in the U.S. alone. If Nuvilex were to capture only 10-15% market share, our \$200M - \$300M revenue figure would be on the money.

The Nuvilex – SG Austria teams are working diligently to move on to the next phase of trials, which would assuredly have a larger sampling size. A number of steps must be undertaken prior to the filing of a clinical trial protocol, including the preparation of large quantities of the cells needed in the beads. We expect that during 1H12, Nuvilex will be engrossed in the next trial's implementation. This is management's top priority.

Breast cancer is the second-leading cause of death in women. The American Cancer Society estimates that over 200,000 new cases are diagnosed in the U.S. alone each year. Breast cancer is often treated with single cancer-killing drugs or with various combinations of such drugs. As a result of the need for multiple drugs in treating most cancers, substantial toxicities are typically the most problematic aspects of cancer treatment.

Management plans to take this therapy to human trials as quickly as possible. Given the huge number of women afflicted with this condition, the Nuvilex therapy could have a major impact on quality of life, survival, and market penetration and revenue.

If indications continue to demonstrate greater efficacy and lower toxicity using the Nuvilex therapy, we would not be surprised to see favorable preclinical results for other forms of cancer as well, which would only increase the therapy's value.

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## **Stem Cells:**

Following its pancreatic cancer clinical trial, SG Austria engaged in preclinical research employing human stem cells. The research confirmed that the live-cell encapsulation technology addresses some of the pitfalls associated with existing stem cell utilization. These include:

- keeping stem cells alive for significant periods of time
- rejection and destruction by the recipient's immune system
- migration of the stem cells to unwanted sites

Cells encapsulated in SG Austria's porous cotton-based beads remain alive for long periods of time in humans, surviving intact for at least two years. Once encapsulated, cells are protected from the body's immune system. Furthermore, encapsulated cells remain within the beads and do not migrate out of the beads to other sites in the body.

## **Conclusion:**

Clearly, the Company's *Cell-in-a-Box™* approach could significantly advance the implementation and utilization of stem cells for a host of debilitating diseases and conditions, thus making Nuvilex a major force in the stem cell arena, which is slated to grow from \$21.5 billion to well over \$60 billion in 2015. We believe that by partnering with leading players in the field, Nuvilex could find that companies with deep pockets would be happy to collaborate or license the delivery system and engage in further research which could result in meaningful development and licensing revenue.

## **Anti-Viral:**

In animal studies, the Nuvilex therapy demonstrated that it has the potential to treat moderate to life-threatening human and animal viral diseases even after the disease has already been established. The tests even showed that encapsulated cells were capable of producing antibodies against the West Nile Virus. Interestingly, this research, paves the way for a novel, live-cell, antibody-based, immunotherapy to treat a variety of simple to severe viral and non-viral diseases. Use of the *Cell in a Box™* platform may render antibody-based treatments cost-effective, avoid side effects associated with use of large antibody doses, and reduce unwanted responses to the therapy. As a result, these findings represent a substantial market opportunity for Nuvilex as it offers a critical opportunity to serve unmet needs of patients.

## **Conclusion:**

Some more work needs to be done here, but again, we believe that other players will seek out Nuvilex for joint development in this vast segment.

## **THE NEXT STEPS**

Investors should expect that Nuvilex will raise the requisite \$2.5 million to close this critical acquisition. The Company has already provided funding to SG Austria as part of the purchase agreement. According to the recently filed 10-Q, interested parties have been assisting Nuvilex with these commitments. It was initially expected that the transaction would close in late August, following the completion of due diligence. We believe that the story is deeper than what we envisioned, extending the due diligence timetable. Plus, since the market has been in a slump, we expect that the deal will close sometime on October 2011.

In addition, despite subpar financials reported in the recent 10-Q, we have a high degree of confidence that the Company will obtain favorable funding terms, as it is clear that Nuvilex will be playing in a different sandbox. With that in mind, we believe that the stock will leap ahead once news of the closing is issued. Thus, investors would be wise to look ahead relative to Nuvilex's appropriate forward valuation and prospects, rather than the financials in the rear view mirror, or risk missing out on the evolution of a ground-breaking, targeted, multi-therapy enhancement delivery platform.

Following the execution of the acquisition, we believe that we will learn more on the development side in the health care space as well as other segments. A major catalyst will occur when management submits its protocol for the next stage pancreatic cancer trial and we would not be surprised to see the stock break through our \$0.50 on the news.

## VALUATION: THE SUM OF THE PARTS

There is more that meets the eye with Nuvilex, Inc. Under Nuvilex "proper", the Company owns:

- Valuable natural product brands
- Two potentially blockbuster natural products (*Citroxin™* and *Oraphyte™*) primed for partnerships with major consumer or industry-specific companies
- A preclinical anti-cancer agent, *Alternia™*
- The critical pancreatic cancer treatment

With SG Austria, Nuvilex can leverage the flagship technology to further develop:

- Its breast cancer treatment that completed preclinicals
- The stem cell studies
- Migrate studies of the anti-viral therapies to human trials
- Explore other oncology, neurology and cardiovascular therapies
- Uses of the technology in probiotics (given the storage feature of the system)
- Explore environmental and cosmetics applications

In addition to the favorable clinical and preclinical studies, the Company has been cited in many key well-regarded industry publications, their peers, and conference organizers, as leaders in the space. While the live-cell encapsulation technology may not be the holy grail of targeted therapy approaches, the fact that it appears to be replicable in different environments and for so many conditions, that its agnostic characteristics are a major intangible asset.

The combined firms have leveraged their technologies to execute a total of at least five of clinical and preclinical trials. Given their current stages, we preliminarily assign the following present values, pending closing of the acquisition and further development.

**Pancreatic cancer therapy: \$30M  
Stem Cells: \$20M  
*Alternia™ & other preclinicals: \$20M  
Nat prods, SG dev revs, other segments: \$20M***

This brings our estimated current value for Nuvilex to roughly \$0.25 per share, which reflects slightly lower valuations for these segments industry-wide, over the past few months. For example, typical biotech company valuations for those in the Phase II stage of development for oncology treatment tend to fall in the \$25-35M range, and thus we have used the average of \$30M for Nuvilex's pancreatic cancer therapy. We maintain that the stock will reach \$0.50 and break through in 1H12. We should note that since we underestimated the value of what SG Austria brings to Nuvilex, we believe that ultimately, the ceiling is much greater than at first glance. We continue to rate these shares Speculative Buy with a \$0.50 near term price target.

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Recent Trading History For NVLX  
(Source: Barchart.com)

NVLX - Nuvilex Inc (PINKSHEETS) - Daily OHLC Chart



**Company Report****Analyst: Robert Goldman**

Rob Goldman has over 20 years of investment and company research experience as a senior research analyst and as a portfolio and mutual fund manager. During his tenure as a sell-side analyst, Rob was a senior member of Piper Jaffray's Technology and Communications teams. Prior to joining Piper, Rob led Josephthal & Co.'s Washington-based Emerging Growth Research Group. In addition to his sell-side experience Rob served as Chief Investment Officer of a boutique investment management firm and Blue and White Investment Management, where he managed Small Cap Growth portfolios and *The Blue and White Fund*.

**Analyst Certification**

I, Robert Goldman, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report.

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