

# NUVILEX, INC.

**Biotech Valuations 101; NVLX Shares Are Cheap** 

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# NUVILEX, INC. (OTC:QB - NVLX - \$0.1385)

Price Target: \$0.75

#### Rating: Speculative Buy

## COMPANY SNAPSHOT

Silver Spring, Maryland-based Nuvilex, Inc. (OTCQB -NVLX) Nuvilex, Inc. is an international biotechnology firm focused on developing and preparing to commercialize treatments for cancer, diabetes and other diseases based on its live, therapeutically valuable, encapsulated cells platform. In addition, the Company has other initiatives and products under development including cannabinoid-treatments for cancer using the encapsulated cells platform.

## **KEY STATISTICS**

Price as of 8/28/13	\$0.1385
52 Wk High – Low	\$0.22 – 0.019
Est. Shares Outstanding	510M
Market Capitalization	\$70.6M
3 Mo Avg Vol	2,247,000
Exchange	OTC:QB

# **COMPANY INFORMATION**

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# **INVESTMENT HIGHLIGHTS**

Key Takeaways: Nuvilex, Inc. may be the most controversial stock we have covered since 1993. Lost in the battle between the eternal optimists and the eternal pessimists is the true nature of the Company's valuation. When one breaks through the noise, it is clear that the stock offers great potential. Moreover, despite the vagaries associated with speculative biotech stocks, we believe that the risk/reward ratio with these shares is solidly in the investor's favor. In fact, based on a review of the Company' peer group average valuation, we believe the stock could trade in the mid-\$0.20's today. Thus, we reiterate our Speculative Buy rating and our \$0.75 price target.

Biotech stocks that do not have FDA-approved products available for sale are valued based upon the most recently completed phase or phases of clinical trials and the market size of the therapeutic prospects.

The later the completed phase(s), the greater the valuation, as is the case with the size of the market potential and level of unmet need. The more trials, more products, and greater market size, the higher the valuation. If a strategic partner has entered into an investment and development arrangement, the valuation is even higher than others without that benefit.

Biotech stocks trade in ebbs and flows, based upon development news and milestones. When successful milestones are neared or reached, biotech stocks are driven higher. In the absence of substantive news and during periods of relative quiet, these stocks tend to drift lower and naysayers temporarily rule the day. Bad development news crushes these stocks while good news propels them higher.



#### A Candid Nuvilex Primer

In early 2011, a new management team joined the Company with the objective of dramatically shifting the focus of the company from nutraceuticals to biotechnology, along with cleaning up the balance sheet. The new leadership, led by experts with vast experience in bringing products through the FDA process, began the process of righting the ship and began the slow process of acquiring the rights to a novel encapsulation technology platform using live cells and prodrugs that could potentially serve as a delivery platform to treat multiple diseases. The target company (SG Austria) had successfully completed Phase II clinical trials to treat inoperable pancreatic cancer, along with preclinical trials in other oncology areas and diabetes. Results were stellar with a very favorable safety profile which indicated that advanced trials would support the earlier findings.

(For more information on the trials and technology platform, see previous reports and updates.)

As is sometimes the case, the road to closing took a bit longer than expected. Therefore, Nuvilex management was fortunate that the platform was not sold to another Firm. However, due to bad experiences in being previously acquired by a larger entity, and given that the target Firm's principals had a long-standing relationship with the new management team, it made more sense to sell the technology to a "friendly" that had greater experience in proceeding through advanced trials. Moreover, both parties could still maintain tight ties and business relationships.

The final terms of the transaction were more favorable than the initial proposed terms. As a result, NVLX raised \$1.5M at a premium to the market, returned a substantial amount of shares to the Company's treasury, acquired exclusive oncology rights to the platform via the acquisition of a subsidiary, (the other Firm still has rights to everything else excluding diabetes) and took a minority stake in the target company.

Separately, as part of its objective of cleaning up the balance sheet, management successfully reduced debt by \$2.2M and is working to reduce the debt burden further. Based on published data regarding the successful use of cannabinoids in treating certain cancers, management believed that it could be opportunistic and establish a new subsidiary that would perform R&D leveraging the encapsulation technology, and its overall experience in the pharma space to develop medical marijuana-based treatments for cancer. Although in the formative stage of the model and approach toward product research and development, the subsidiary's use of the Nuvilex-owned IP and overall experience should prove to be a unique and valuable commodity in a nascent marketplace that is ever-evolving, with no advanced clinical oncology-based research to date.

Finally, management plans to close on the acquisition of the same technology rights for the treatment of diabetes. This transaction is funded and should close in a couple of months.

So, in matter of months, management will have closed two technology platform acquisitions representing billions in market size with funds raised from accredited investors. In addition, the Company has reduced debt by \$2.2M, streamlined operations, and begun the formation of a separate subsidiary's model to develop cannabinoid-based treatments for cancer that could be used in combination with those developed using the very platform it acquired, with nutraceuticals in the far background, as they have been since 2011.



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#### **Biotech Valuations**

Biotech companies are typically founded by scientists with no operating experience whatsoever but considerable experience in R&D. A scientist or group of scientists may own patents on a given drug, molecule, or therapeutic platform and have spent a few years performing tests in the lab along with animal modeling, before striking out on their own. Funds are typically raised privately along the way in order to fund research and development that lead to a Phase I human clinical trial. In some cases in order to help defray expenses, the Firm will engage in other businesses such as contract services or the sale of disparate products in order to aid in cash flow generation.

With each step along the path, a valuation is assessed the Company. As the biotech firm successfully achieves a milestone development, an imaginary box is checked and the valuation rises, since the firm is making slow but forward strides leading to the next stage of development, and ultimately approval. If the size of the market is large, the valuation is higher than one that has a narrow market. If it is a crowded treatment market, it may not be valued very highly either. During this time, biotechs are what some of my former colleagues in the trade would call loss-making companies. Since all they did was R&D, did not produce products and went through money like water, it makes sense to use that moniker.

At times along the development path, the Company requires additional funds and may opt to go public. Here again, based on prospects, the value of the IP, current test, study, and trial results to date represent the factors used to assess valuation. The burn rate may also play a role, as too large of a burn rate is a red flag. Once a firm is public, its valuation is also compared to a peer group which represents the therapeutic treatment arena and the similar stage of development. Higher valuations are afforded those with greater IP, stronger results, a partnership with a bigger player, etc. Anything in the Company's history that is unrelated to the R&D cycle and milestones is considered irrelevant and not used in the valuation process. One exception would be if management either had a colossal success or a colossal failure in a previous firm.

Since the product development cycle can be as long as 15 years, and news regarding development is occasional, biotech stocks are subject to wild swings in either direction. Moreover, the very nature of the model breeds significant shorting of stocks, especially in the period from Phase II through the filing of a NDA (New Drug Application).

As with any other stock, biotechs have their fans and detractors. Since there can be no resolution until the FDA process is either halted or completed, investors can choose to believe in the validity and potential or not. Hence, the speculative nature of these stocks for bulls and bears. It is not uncommon for the shorts to rule the day for a while only to cover in a panic later when the company achieves a milestone event.

In general, unless hit with a failed trial or inability to raise funds for the next phase, valuations generally rise for biotechs based upon their milestone achievements, and we expect that will be the case with Nuvilex.



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#### **Nuvilex Milestones**

There are a series of milestones ahead which will drive Nuvilex's stock higher.

- Closing of diabetes technology platform rights acquisition
- Establishment of GMP facility for full-scale production of live cells to be used in future trials
- Development and submission of next stage pancreatic trial protocol
- Roadmap for diabetes treatment R&D
- Roadmap for breast cancer treatment R&D
- Commencement of full-scale R&D of medical marijuana research division
- Initiation of advanced clinical trials for pancreatic cancer
- Potential pharma partner

Clearly, to accomplish the next few stages will require funds, as they do for all biotechs. However much like with the SG Austria deal, look for NVLX to raise the appropriate funds at the appropriate time, in conjunction with the successful achievement of key objectives, as most other biotechs do.

#### Nuvilex Valuation

As with any biotech, the proper measure for Nuvilex's valuation is a comparison to a peer group of other midlate stage biotechs, with essentially zero contribution from the nutraceutical business and a to-be-determined bonus assigned to the medical marijuana initiative. There are no direct peers for Nuvilex. However, if we draw from a handful of firms either in Phase II/III, in oncology, or have a somewhat similar therapeutic platform, we find market caps that range from \$50M to \$400M. These include (the smallest) Rexahn (NYSEAMEX – RNN) to (the largest) Merrimack (NASDAQ – MACK). The average market cap of these firms is around \$170M. This compares with Nuvilex's current market value of Nuvilex's shares is \$70M. As a result, even if we took a 30% haircut to the average market cap of \$170, Nuvilex should be trading in the mid-upper \$0.20's today. As milestones occur, the stock should move closer to our \$0.75 target price.

With major milestones already achieved in just a few months, and a 500% increase in the stock price from its lows, what more could an investor ask for?

We continue to rate these shares Speculative Buy with a \$0.75 price target.



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**COMPANY UPDATE** 

# NUVILEX, INC. (OTC:QB NVLX)

# **Recent Trading History For NVLX**

(Source: Stockta.com)





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#### Senior Analyst: Robert Goldman

Rob Goldman founded Goldman Small Cap Research in 2009 and 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

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