On September 20, 2018, IntelGenx (IGXT) stock raced higher, ending the day more than double the prior day’s share price on news of a signed letter of intent (LOI) to manufacture oral film strips for Tilray (TLRY), currently a hot play in the cannabis sector. With much more attention currently being given to IntelGenx due to the LOI, this article is meant to give a broad overview of the company as of September 2018, and discuss their pipeline beyond the current Tilray letter of intent. As a micro-cap stock, many investors may not have heard of or fully investigated the company, but based on IntelGenx’s pipeline, the company is set up to be much more than a simple cannabis trade.

First, IntelGenx’s founder is Dr. Horst G. Zerbe, who was co-developer of Listerine’s “breath strips” and holds several patents related to oral-films and associated products. Now, his company has put these patents and technology to use in the medical industry. In simple terms, IntelGenx is in the business of taking pre-existing drugs and either putting them in oral-film form (e.g. like Listerine strips) or taking pre-existing drugs and re-purposing them for new treatments. This approach is remarkably low risk because almost all the drugs have already been approved, but with one caveat – they were approved via alternate delivery methods (like pills) or for other purposes. Therefore, most FDA trials of IntelGenx’s products revolve around the safety and efficacy of the new delivery method. Or, in the case of the asthma drug Montelukast, re-purposing the drug for use as an Alzheimer's treatment based on evidence from animal and human subjects.

But, what is the advantage of an oral film over a traditional pill? First, the oral strips dissolve in the mouth, and therefore, limit the chances for upsetting stomachs, which is a problem for some patients. Second, the oral strips dissolve with saliva, and they do not require the patient to drink water, as pills often do, and this could help older patients, infants, or patients who have trouble swallowing. Patients who have trouble with pills may become more compliant when taking their medicine. And last, in many cases, the oral strips are faster acting than pills, and this greatly benefits patients with ailments requiring quick treatment. In fact, IntelGenx has migraine (Rizaport) and erectile dysfunction (Tadalafil) oral films in development. The faster-acting nature of the oral film over pills adds to the attractiveness of oral films as a product. If people want relief of their ailments, the oral films will often deliver the quickest relief. In other areas, like medicinal or recreational marijuana, an individual could get the effects through an oral film very quickly but without the ill-effects of smoke inhalation.

Oral films also present other advantages. For the individual wishing to feel the effects of recreational marijuana, the oral film does not leave the scent of smoke. For the individual out on a date, slipping an oral film into his mouth acts faster and is potentially less likely to ruin a romantic mood than taking a pill and waiting longer. In both situations, the oral film offers the opportunity for more discreet behavior by the consumer. In other words, oral films likely allow consumers to draw less attention to themselves. With oral films, there is no need for a glass of water, or to disguise the scent of smoke, etc.
IntelGenx also recently announced a venture into veterinary medicine. Can’t get your dog or cat to swallow that pill? What if it was in a tasty flavored oral film that you just put on your pet’s tongue? This is another potentially large market.

For those of you wondering how this technology works, this National Institutes of Health (NIH) article discusses the basics of the technology. Simply put, the oral film dissolves on the tongue, and the medicines are absorbed through capillaries in the mouth. Usually, this means that the oral film acts faster and requires less of a dose than might be found in a pill. Due to pills going through the gastrointestinal system and liver, much of their potency is often lost or filtered out before it reaches the bloodstream. In other words, pills have a “hepatic first pass effect” that causes them to lose some of their Active Pharmaceutical Ingredient (API). Therefore, oral films can sometimes be less expensive to produce than pills because less API (the medicinal ingredient) is necessary to have the same effect as a pill would have. Additionally, the lower dosage leads to lower risk of toxicity. For full details, you can always read the NIH report yourself.

While the list below is by no means comprehensive, it details some of the important news, upcoming opportunities, and catalysts for IntelGenx.

1. On September 20th, 2018, IntelGenx announced a Letter of Intent with well-known cannabis firm Tilray. The stock more than doubled on that day, but gave back 1/3 of that gain the next day following criticism from Congressman Matt Gaetz that the U.S. was using Canadian companies (Tilray) instead of U.S. suppliers in our development of cannabis related drugs. As pot becomes legal in Canada on October 17, 2018, IntelGenx will hopefully be producing cannabis-infused films sooner than later. Tilray has also agreed to buy 1,250,000 of Intelgenx’s shares at .80 a share, and has agreed to pay Intelgenx a royalty rate on oral film product sales produced in accordance with the partnership. While the LOI is not a contract, it is the precursor to a contract.

2. IntelGenx has an exclusive license with Eli Lily to produce oral film strips of Tadalafil until the product’s patent runs out. If you don’t know, Tadalafil is commonly marketed under the brand name Cialis, a common erectile dysfunction drug. This is a huge potential market and FDA approval is expected in late 2018 to early 2019. A commercialization partnership for Tadalafil is also expected to be announced in late 2018. If the company executes, it should have at least a year of exclusivity in the production of the faster-acting oral film, even if pill generics may be allowed earlier.

3. Per IntelGenx’s August 10, 2018 conference call, FDA approval of the Rizaport migraine medication oral film is expected in the first half of 2019. As with Tadalafil, a partnership is also expected soon. At one time, Redhill Biopharma was a partner for this drug, but IntelGenx regained the worldwide rights for the drug in 2018 and has entered negotiations with several companies for a potential partnership. Redhill Bio pulled out of the agreement after the FDA responded with a Complete Response Letter (CRL). According to IntelGenx’s press release, the CRL stated that the FDA wanted more information about “third party chemistry, manufacturing and controls, and the packaging and labeling of the product. The FDA raised no questions or deficiencies relating to RIZAPORT®'s safety and bio-equivalence data and did not require additional clinical trials.” Since then, the company has built its own facility in Canada to avoid
problems that might arise through contract manufacturing with third party production. Previously, production had been expected to take place overseas.

4. Commonly called the “Alzheimer’s drug trial” among IntelGenx longs, the Montelukast dosing trial began enrolling patients in September 2018. As mentioned previously, this is a repurposed asthma drug that has shown both animal and human evidence of helping fight the effects of Alzheimer’s and dementia. The evidence for the drug’s effectiveness in humans is especially encouraging with 16 of 17 patients in an early trial demonstrating benefits from treatment. I highly recommend reading the report linked above.

5. IntelGenx is working to receive FDA approval for a Suboxone oral film (a drug that treats opioid addiction). Patent litigation over the drug has been resolved.

6. IntelGenx has a term sheet with Tetra regarding the production of the drug dronabinol, which is based on the pain/anti-nausea agents in marijuana. While Intelgenx’s press release mentions the drug as an anti-nasuea and pain treatment for cancer and chemotherapy patients, a recent Tetra press release mentions that dronabinol is being considered as an anti-opioid treatment and as an AIDS weight-loss treatment.

7. Per the August 2018 conference call, Intelgenx will, along with their partner Chemo, submit an undisclosed drug to the FDA in October 2018 (first-to-file opportunity).

8. As mentioned previous, the company is working on getting into the veterinary medicine market.

9. Three drugs are available for partnering (Loxapine, Monelukast, and Tadalafil). However, eight drugs already have partners. There are at least three undisclosed drugs in the pipeline, and those drugs already have partners. (Source: Pipeline graphic on IntelGenx’s homepage www.intelgenx.com)

10. IntelGenx has a factory in Canada. They own the means of production. The factory has received a GMP compliant inspection from Health Canada and has obtained an amended Drug Establishment License for manufacturing activities.

11. IGXT has never been NASDAQ listed. As has been discussed at prior conference calls, getting onto the NASDAQ will allow some large funds (if they wish) to invest in IGXT and create even greater demand for shares. Right now, many cannot invest in a micro-cap because of fund restrictions. And, generally speaking, getting uplisted should just help the stock price appreciate.

12. Intelgenx also deals in tablets, not just oral films, and offers several other services.

In summary, IntelGenx is not a "one-trick pony". The Tilray letter of intent that caused the stock to double on 9/20/2018 was an unexpected bonus for most IntelGenx investors. Due to company statements in conference calls and presentations, most knew that cannabis deals and discussions
were underway, but those were actually secondary considerations compared to the upcoming Tadalafil news and other events.

Risks and Problems:

In regards to problems and risks, there is the potential for competitive pressure, that products might not be approved or would be delayed, and other traditional risks associated with doing business. So far, the biggest frustration for IntelGenx investors has been delays. Whether the FDA requests for more information (as with Rizaport), delays in the start of clinical trials (as with Monelukast), or building a factory, investors have seen several delays over the past two years. The added presence of non-disclosure agreements with some partners also adds to investor frustrations as details about some partner negotiations and drug progress cannot be publicly discussed.

However, many catalysts seem primed to explode in the next 6 to 24 months. The pipeline is robust – far beyond just a cannabis deal with Tilray – and most of the drugs have already been approved by the FDA, but in other forms of administration or for other purposes. Therefore, the risk is, to some degree, less than if the company were developing “new” drugs. And the migraine, erectile dysfunction, and Alzheimer’s drug markets are huge, not counting the numerous other opportunities, even if the cannabis market were to collapse.

In regards to the IntelGenx's financials, there is a small revenue stream, and the company does have debt. Most recently, the company ran at a loss, and during the August 2018 conference call, CFO Andre Godin stated that there is enough cash on hand for about six months to a year of operation, although a full year would be "pushing it". And, per the call, numerous revenue sources are expected within that window ($2 million in warrant executions, an interest free loan from Canada, upfront partner or milestone payments, as well as sales revenue). Additionally, since then, Tilray announced the intention to buy 1,250,000 shares of IntelGenx.

Still, a September 24, 2018 SEC filing for a potential offering of up to $100,000,000 in new shares does present the risk of dilution. Again, the company has stated there are no plans for an offering unless deemed necessary, but a prudent investor should be aware of this possibility. Since three drugs are unpartnered, and drug trials are expensive, the company could decide to raise capital by issuing some of these shares instead of relying on a partnership.

Furthermore, oral film technology is what marketers might call a “new-to-the-world” product or “discontinuous innovation”. That is, if oral film medicines become popularized, they could have an industry-changing effect. For example, could medicinal oral films eventually replace most pills? Perhaps, but being early to market with a new technology often comes with added marketing expenses. Consumers need to know that medicinal oral films exist as well as why they are superior to pills. Otherwise, IntelGenx may find itself facing slow growth or low sales due to the sluggish acceptance of oral films by consumers. If IntelGenx is to succeed, the superiority of oral films over pills must be clear to consumers. Thus, depending on how well the public accepts the initial round of product launches, marketing expenditures could be a source of additional costs for IntelGenx.
And, some risks are common to micro-cap stocks in general. In the over-the-counter market, dilution, as mentioned above, is often a risk, volatility and/or low trading volume can be problematic, and illegal, naked shorting takes place. Indeed, IntelGenx stock has already demonstrated some of these traits. Over the seven-day period starting on September 18, IntelGenx stock swung from $0.76 to $1.83 and back down to $0.96. The volatility was high. Then, the September 24 SEC filing brought up the potential of dilution.

In conclusion, if you are new to IntelGenx or looking for a current summary of the company’s status, this article is by no means complete, but it should give you a fairly good status report on the company as of September 2018.

As always, the information here is only one investor’s opinion and interpretation of the company's current status and opportunities. As such, there is room for error, and all investors should perform their own research and verification before making any investment decisions.

Full disclosure: I am a long-term shareholder in IGXT. This article does not fully discuss Intelgenx’s sales figures, financial statements, and activities outside of North America. While, in my opinion, the company is in satisfactory financial shape and has a potentially bright future, it is, in my opinion a speculative play based on the future product pipeline.