Farm to Pharm: the Botanical Drug Revolution

HEALTHCARE | BIOTECHNOLOGY

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STOCKHOUSE

A pharmaceutical revolution has commenced. Perhaps one graphic captures the essence of this transition to a new paradigm better than any other.

1. World preview 2014, outlook to 2020; EvaluatePharma, 2014
2. Botanical and Plant-Derived Drugs : Global Markets; Chapter 2, BCC research, BIO022, August 2015

The conventional pharmaceutical industry is presently confronting a number of serious issues. Costs are soaring: current industry estimates are that it takes roughly $2.6 billion to bring a new drug to market. Along with rising costs are extended timelines. It now requires (on average) 12 years to bring a new drug through the pharmaceutical approval process.

This is just the beginning of the problems for Big Pharma. Patent expiration is about to take a huge bite out of the bottom line of these companies. Between now and 2020; **$259 billion** in existing drug sales will lose their patent protection. This rapid decline in R&D productivity combined with a dwindling pipeline of drugs on the market will be an existential threat to some of these corporations.

One of the pharmaceutical companies which is not only focused on the previous graphic but completely understands its implications is **Devonian Health Group Inc** (TSX:V.GSD, Forum). Yes, the market for botanical pharmaceutical products *is* increasing at more than twenty times the growth rate for conventional pharmaceutical products. However, this is because the botanical drugs space is still in its infancy. For investors, this means being able to get in on the ground floor.

This may be putting the cart before the horse. The term "botanical drug" will not be familiar to some readers.

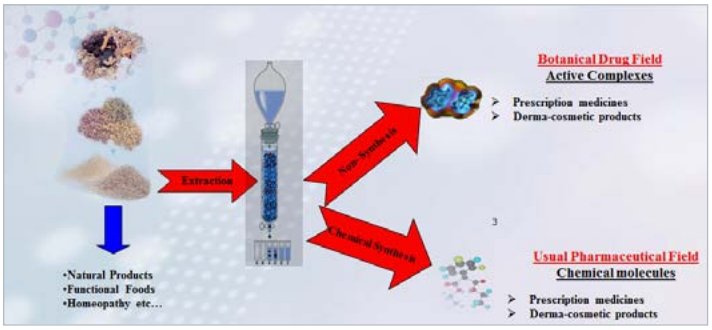
Many pharmaceutical products *begin* from some natural substance template. However, through the (chemical) synthesis process, traditional pharmaceutical products lose their "natural" connection. The final product represents **chemical molecules.**

This is significant in two respects. First, in the eyes of many in the pharmaceutical industry, the synthesis process results in the loss of efficacy. Intrinsic medicinal properties of the original natural substance are lost in the synthesis process.

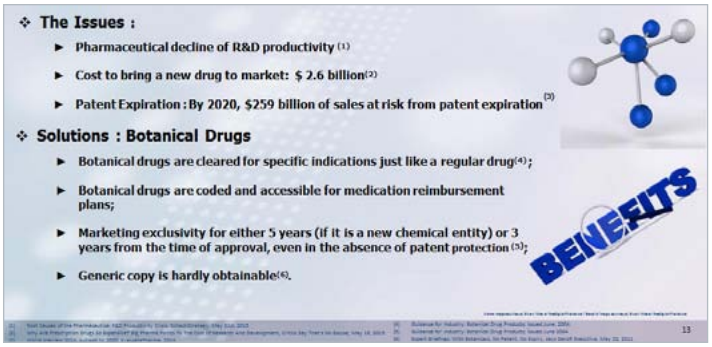
The second complication is the chemical nature of these synthesized drugs. This translates into (often) a long list of side effects. Most readers are familiar with television ads for new chemically-based pharmaceutical drugs. The laundry list of serious, potential side effects makes the "cure" literally sound worse than the disease.

In contrast, botanical drugs avoid this chemical synthesis process. Natural substances are extracted directly from their organic source, and then processed into pharmaceutical products in the form of "active complexes" which preserve all of the efficacious properties of the original natural source.

The result is drug products which exhibit far fewer issues with respect to safety and tolerance. Equally, these more benign substances rarely produce side effects which are in any way comparable to what is typically seen with conventional pharmaceuticals.



Greater safety and tolerance. Fewer side effects. These positive traits associated with botanical drugs also carry over into the drug development and approval process. With fewer safety issues to overcome in the development/approval phase, this translates into both a significantly faster timeline to move through the approval process and a significant savings in costs.

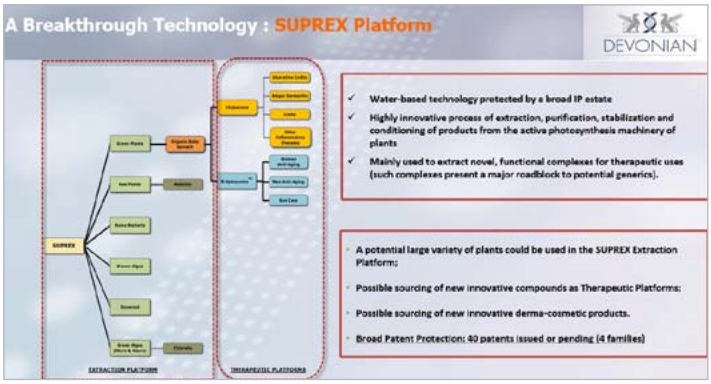


But where to invest to take advantage of this pharmaceutical revolution?

Farm to pharm™. This is more than Devonian's trademark and more than just some corporate slogan. The Company lives and breathes this mantra, and it translates directly into GSD's operations. In terms of the process for developing and producing botanical pharmaceuticals, Devonian's quality control standard is simple: seed to pill.

CEO Boulet is adamant. GSD must be able to monitor *every* aspect of the production process from (literally) the seeds to be used in the growth of these natural substances to the final botanical drug itself. The goal of such rigorous control is higher quality pharmaceutical products with greater efficacy.

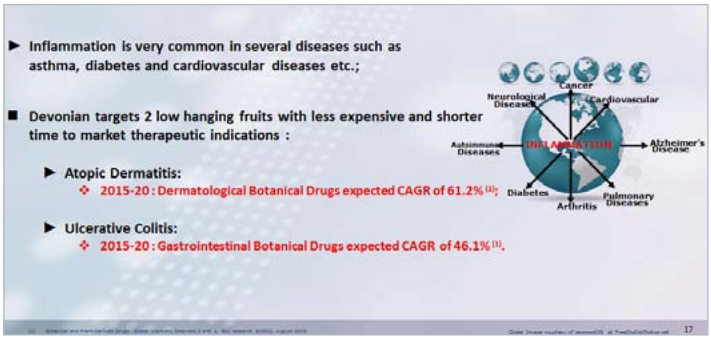
However, Devonian is not merely a story about meticulous quality control in the development and production of its proprietary botanicals. The essence of superior botanical pharmaceutical products means capturing the essence of these natural substances. This makes the **extraction process** of critical importance with respect to the quality of the final botanical product.



This extraction process is a closely-guarded Company secret. GSD's proprietary name for this process is "Suprex". Among the strengths of the Suprex extraction platform is that it can be applied to *a wide array* of plant products which are considered to possess superior medicinal properties.

Not surprisingly, Devonian has already fielded numerous inquiries from other companies with respect to Suprex. These inquiries range from other pharmaceutical companies looking to produce their own botanical drugs to cannabis companies seeking this technology to help unlock the medicinal properties of cannabinoids. But GSD is keeping its industrial secret in-house.

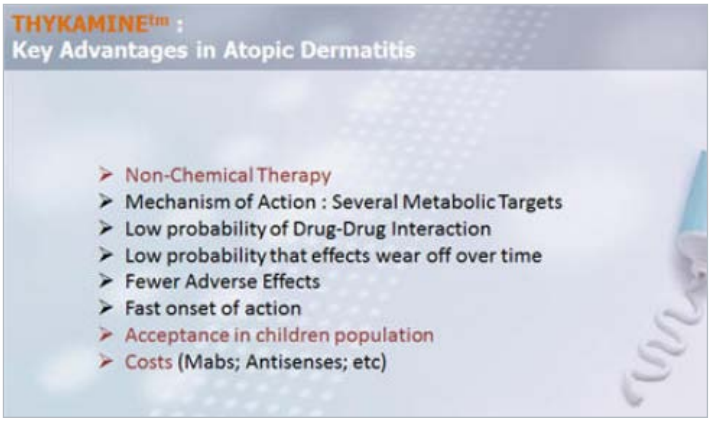
The first natural substance to be exploited by Devonian in the production of these proprietary botanicals is organic spinach. The nutritional properties of spinach are already well-known and acclaimed. However, Devonian has identified important medicinal properties associated with this super-food.



A key element with respect to the medicinal importance of spinach is its anti-inflammatory properties. Inflammation is one of the most

common (and troublesome) health disorders, and is a symptom of numerous health conditions.

The Company has extracted and produced an anti-inflammatory derivative from organic spinach which it calls Thykamine™. While GSD expects Thykamine™ to have potential medicinal applications with respect to a number of medical conditions, Devonian's initial focus is on the treatment of two diseases: ulcerative colitis and atopic dermatitis (better known as eczema).

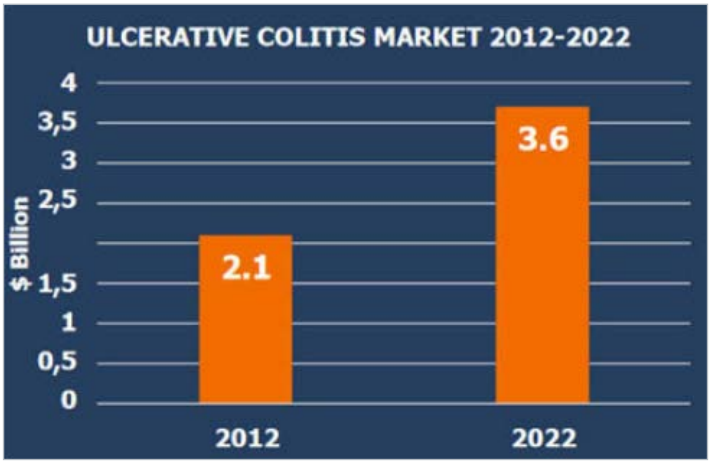


There were several reasons why the Company chose these two medical conditions as the initial focal points for its drug pipeline.

1. Large and growing markets
2. Poor outcomes with existing therapies
3. The need for ongoing, symptomatic relief

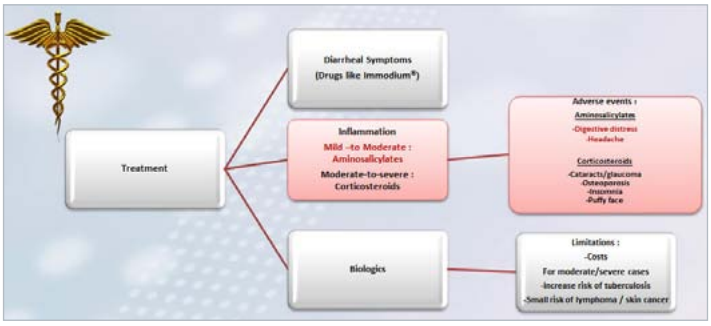
Ulcerative colitis

The treatment of this medical condition is already a multi-billion dollar market, projected to continue to grow. Of equal importance are the poor patient outcomes, given existing treatments on the market.



The Ulcerative Colitis Drug Market Will Increase From $2.1 Billion in 2012 to $3.6 Billion in 2022, Decision Resources Group Company, Christopher Comfort

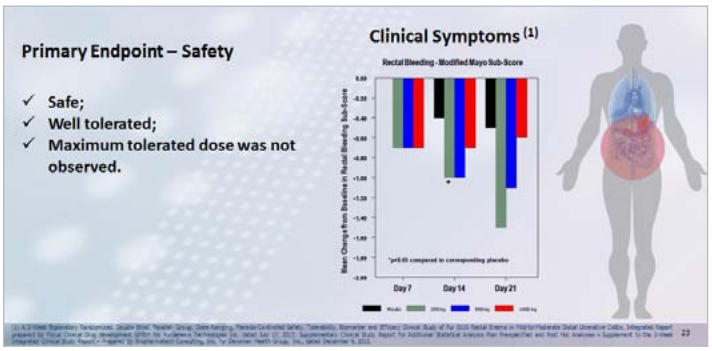
The poor outcome for patients begins with the fact that this is an incurable condition. Current therapies (at best) provide symptomatic relief. Worsening the outlook for patients is that these therapeutic options are accompanied by complications from regular usage, as well as (in the case of biologics) the sky-high cost of treatment.



In the most recent (U.S.) Phase IIa clinical trials for Thykamine™, this botanical therapy has shown superior therapeutic potential in numerous areas:

- Rapid onset of relief
- Non-chemical therapy
- Expected Shorter duration of treatment (Flare)
- Fewer adverse effects
- Healing?

The Company's clinical trials have met all expectations to date. However, in one respect the results have exceeded expectations.



In the clinical trial, the duration of treatment was 14 days. However, additional improvements in patient symptomology were reported at the 21-day mark. This continued improvement after treatment had been suspended suggests one thing to the Company's research team: that Thykamine™ is not merely providing symptomatic relief but *could* be inducing some genuine healing with respect to this inflammatory condition.

Given the success of these results, combined with the superb safety/tolerance profile for Thykamine™, management is hopeful that the Company can obtain **"FDA Breakthrough" therapy designation** for Thykamine™ with respect to the treatment of ulcerative colitis.

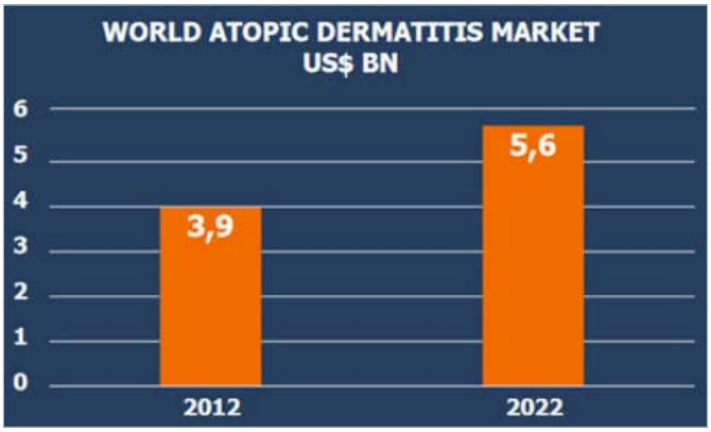
The importance of such a determination is that the FDA operates at three 'speeds' with respect to the drug approval process. There is the standard speed (slow). There is "fast track" designation, which streamlines the approval process in certain respects. Then there is the "FDA Breakthrough" designation. This is where this regulatory body expedites the approval process to the greatest degree possible.

Atopic dermatitis (eczema)

Eczema is a skin disease with which most readers are already familiar. It is a prevalent condition among adults. However, what many may not know is that eczema occurs in epidemic proportions among children, with the current rate of incidence between 15 – 30%.

As with ulcerative colitis, this is a multi-billion dollar market which continues to grow. Existing therapies are also inadequate here.

With respect to the use of Thykamine™, clinical relief in Phase II trials is also expected to be rapid, with fewer adverse effects. Perhaps of greatest importance, as a botanical drug Thykamine™ shows particular promise for pediatric treatment – making this potentially the first-choice therapy to treat the massive population of children with eczema.



Global Atopic Dermatitis Market to Grow Slightly by 2022, Fueled by New Product Launches, November 14, 2013, prepared by GlobalData

For Devonian's bottom line, at present neither of these two diseases is curable. This means that patients requiring Thykamine™ for UC or eczema will need to be regular (if sporadic) users of this medication. Producing cures for diseases is very satisfying, but not all diseases are curable – at present. Providing symptomatic treatments for incurable conditions can be even more lucrative.

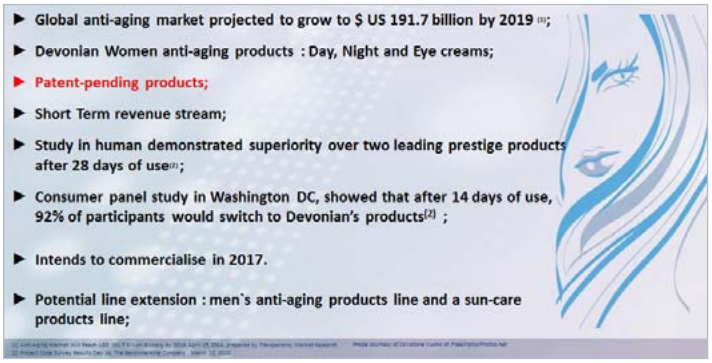
Derma-Cosmeceutical Products

For pharmaceutical companies – whether producing botanical drugs or conventional pharmaceuticals – taking a new drug through the approval process which services a valuable niche is an operational "home run". A single success can make an entire company.

However, even with encouraging preliminary results, there are no guarantees in such drug research. Devonian's management team wanted to have an additional operational division that also offered spectacular upside potential while providing the Company with a near-term revenue stream. GSD's derma-cosmeceutical division satisfies both of these criteria.

When it comes to pharmaceutical dermatology products, the most-lucrative niche is the "anti-aging" market. This is a market which has previously been projected to reach $191.7 billion in size by 2019.

As with the Company's Thykamine™ breakthrough, this is not simply about targeting a large market. It's about targeting a large market with **a superior product line**. Devonian's clinical testing and market research

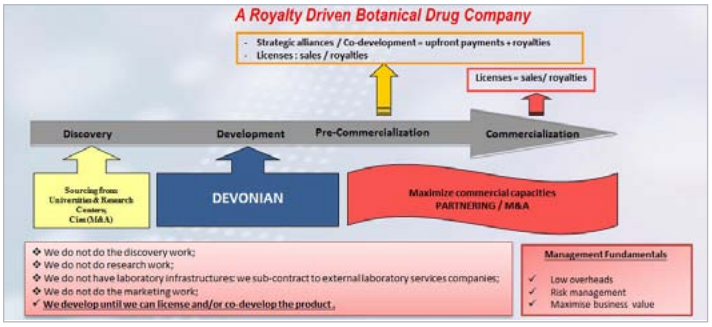


both strongly suggest that GSD's derma-cosmeceuticals are capable of seizing significant market share.

However, this is *not* the Company's business model. Here the practicality of the Devonian management team shines through. This is a junior bio-pharma company. GSD is already demonstrating its drug-development prowess, and is well on its way to taking its lead drugs all the way through the drug approval process.

What then? Marketing, lots of marketing – lots of expensive marketing. Despite its dynamic botanical drug pipeline, Devonian is a lean, mean machine. At current staffing levels, GSD has **a microscopic burn-rate below $2.5 million per year.**

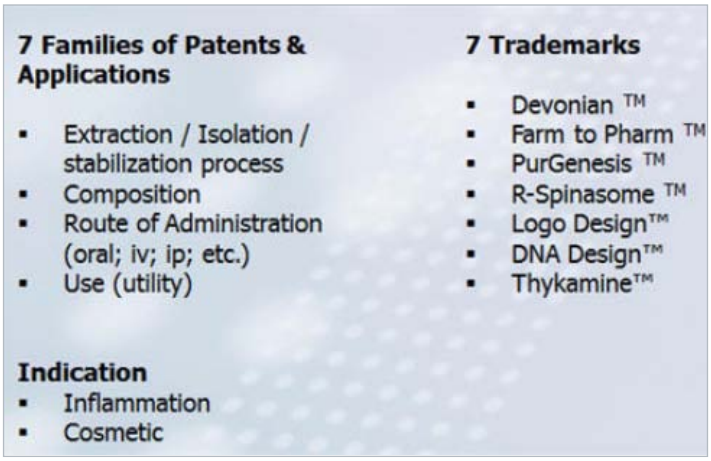
Management is focused on maximizing shareholder value, not maximizing its operations budget. Its strategy for doing so is elegant in its simplicity.



Don't engage in (preliminary) research and discovery. *Don't* invest in laboratory infrastructure – sub-contract everything. *Don't* do post-development marketing. Let other companies engage in those investments. Devonian's expertise is in drug development. This is the exclusive operational focus.

GSD is already nearing the marketing stage for its Thykamine™ botanical therapies. Its derma-cosmeceutical products are already market-ready. The next step is strategic alliances or joint ventures to unlock the value of these botanical products: delivering optimum upside potential to shareholders while minimizing capital expenditures and dilution.

Exclusive (botanical) extraction technology. A robust drug pipeline, which is targeting several multi-billion dollar markets, with extremely promising clinical results. Devonian's IP portfolio is growing rapidly, yet (fully-diluted) its current market cap is a tiny $23.5 million.



Despite GSD's small market cap and microscopic operating budget, the Company's drug pipeline is being developed under the rigorous standards which apply to all officially-approved pharmaceutical products – including the Company's line of derma-cosmeceuticals. Devonian is perhaps the only pharmaceutical company currently using double-blinded/single-blinded comparative clinical trials for its derma-cosmeceutical product line.

A pharmaceutical revolution is taking place. The drug pipeline for conventional pharmaceutical products is failing to meet the (growing) drug needs of our aging populations. Devonian Health Group believes the future of pharma is in botanical drugs: farm to pharm™. Given the Company's operational successes to date, it's a recipe for success which may be appetizing to a lot of investors.

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