

#### SOURCING NEW PHARMACEUTICALS FROM NATURE

Dr André P. Boulet, PhD

President

August 2016

A preliminary prospectus containing important information relating to the securities described in this document has been filed with the securities regulatory authorities in the provinces of Québec, Ontario, Alberta and British Columbia. A copy of the preliminary prospectus, and any amendment, is required to be delivered with this document. The preliminary prospectus is still subject to completion. There will not be any sale or any acceptance of an offer to buy the securities until a receipt for the final prospectus has been issued. This document does not provide full disclosure of all material facts relating to the securities offered. Investors should read the preliminary prospectus, the final prospectus and any amendment for disclosure of those facts, especially risk factors relating to the securities offered, before making an investment decision.

## **Devonian Health Group Inc.**



#### Cautions

An investment in the Units is speculative and involves a high degree of risk. An investment in the Units is suitable only for those purchasers who are willing to risk a loss of some or all of their investment and who can afford to lose some or all of their investment. Prospective investors should carefully consider the risk factors described in and incorporated by reference into the preliminary prospectus dated August 12, 2016 (the "Prospectus").

You should rely only on the information contained in or incorporated by reference in the Prospectus.

Orletto, Devonian and the Agent have not authorized any other person to provide you with different or inconsistent information. If anyone provides you with different or inconsistent information and the Agent are not making an offer to sell the Units in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this document and in the Prospectus is accurate only as of the dates in which expectus is accurate only as of the dates in which expects a required by Applicable Securities Regulations, none of Devonian, Orletto, the dates in which expects are required by Applicable Securities Regulations, none of Devonian, Orletto and the agent are not with a supplicable securities Regulations, or is under any duty to publicable or revise any forward-looking statements.

#### **Defined Terms**

Capitalized terms used herein and not defined have the meanings given to them in the Prospectus.

#### **Forward-Looking Statements**

Certain statements contained in this document constitute forward-looking information and forward-looking statements (collectively, "forward-looking statements") pursuant to the Applicable Securities Regulations. All statements, other than statements of historical fact, contained in this document and in the Prospectus are forward-looking statements, including, without limitation, statements regarding the future financial position, business strategy, budgets, projected costs and plans and objectives of or involving Orletto, Devonian or the Resulting Issuer. The use of any of the words "anticipate", "intend", "continue", "expect", "may", "will", "plan", "project", "shouldry, "sbelieve" and similar expressions are intended to identify forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results or events to differ materially from those anticipated in such forward-looking statements. Orletto and Devonian believe the expectations reflected in those forward-looking statements are reasonable but no assurance can be given that these expectations will prove to be correct and such forwarding-looking statements speak only as of the date of this document and the Prospectus.

Forward-looking statements are subject to risks, uncertainties and assumptions, including those discussed elsewhere in the Prospectus under section "Risk Factors". Some of the risks which could affect future results and could cause results to differ materially from those expected in the forward-looking statements contained herein and in the Prospectus include, but are not limited to: the development and the revenues generated, the regulatory approvals, the capacity for Devonian or the Resulting Issuer, as the case may be, to develop alternative periodic candidates, the commercialization process, the success of third-party strategic collaborators, the breakthrough designation by the FDA and market approval, the fast track designation by the FDA, the intense competition from other companies, the competition from product for which no prescription is required, the ongoing obligations and continued regulatory review, the compliance with recently enacted and future legislation, the third-party coverage and reimbursement and health care cost, the termination or suspension of, or delays in the commencement or completion of, any necessary future studies, the development process of clinical drug, the reliance on third parties to conduct its clinical trials, the availability and supply of raw material, the protection of intellectual property right, the potential infringement on others' intellectual property rights, the possibility to never become profitable, the need and ability lawsuit brought, the potential future acquisition, the achievement of growth, the ability to rever become profitable, the intention not to pay any dividend, there can be no assurance that an active market for the Scounties that may fluctuate, the intention not to pay any dividend, there can be no assurance that an active market for the Common Shares of the Resulting Issuer will be sustained, the sale of Warrant Shares issued upon the exercise of Warrants or other security could encourage short sales by third parties which could further depress the

With respect to forward-looking statements contained in this document and in the Prospectus, Orletto and Devonian have made assumptions regarding, among other things, the ability to complete the Offering, the ability to attract and retain qualified individuals and equipment in a timely manner, the level of future capital expenditure required to exploit and develop botanical pharmaceutical and derma-cosmeceuticals products, the ability to obtain future financing on acceptable terms, and the state of the debt and equity markets in the current economic environment.

Orletto and Devonian have included the above summary of assumptions and risks related to forward-looking information provided in this document and in the Prospectus in order to provide investors with a more complete perspective on Orletto, Devonian and the Resulting Issuer's current and future operations and such information may not be appropriate for other purposes.

Readers are cautioned that the foregoing lists of risk factors are not exhaustive. The forward-looking statements contained in this document and in the Prospectus are expressly qualified by this cautionary statement. Except as required by Applicable Securities Regulations, none of Orletto, Devonian or the Resulting Issuer undertakes any obligation or is under any duty to publicly update or revise any forward-looking statements.

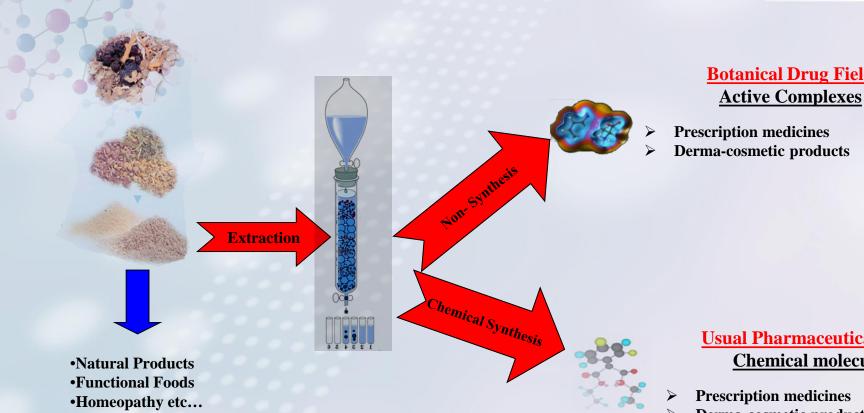
No securities regulatory authority has expressed an opinion about these securities and it is an offence to claim otherwise. The Prospectus constitutes a public offering of these securities only in those jurisdictions where they may be lawfully offered for sale and therein only by persons authorized to sell such securities. The securities offered under the Prospectus have not been and will not be registered under the United States Securities Act of 1933, as amended (the "1933 Act"), or any state securities laws. Accordingly, these securities may not be offered or sold within the United States (as such term is used in Regulation S under the 1933 Act) except in compliance with exemptions from the registration requirements of the 1933 Act and applicable state securities laws. Neither the Prospectus nor this presentation constitute an offer to sell or a solicitation of an offer to buy any of the securities offered hereby within the United States

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# **ACTIVE INGREDIENTS' ORIGIN**





# **Botanical Drug Field**

### **Usual Pharmaceutical Field** Chemical molecules

**Derma-cosmetic products** 

# Pharmaceutical Drug Discovery



### The Issues:

- Pharmaceutical decline of R&D productivity (1)
- Cost to bring a new drug to market: \$ 2.6 billion(2)
- Patent Expiration: By 2020, \$259 billion of sales at risk from patent expiration

### Solutions : Botanical Drugs

- Botanical drugs are cleared for specific indications just like a regular drug<sup>(4)</sup>;
- Botanical drugs are coded and accessible for medication reimbursement plans;
- Marketing exclusivity for either 5 years (if it is a new chemical entity) or 3 years from the time of approval, even in the absence of patent protection (5);
- Generic copy is hardly obtainable<sup>(6)</sup>.



Guidance for Industry: Botanical Drug Products; issued June. 2004. Guidance for Industry: Botanical Drug Products; issued June 2004

## **Investment Opportunity**



- ▶ Botanical Drug is an emerging field within the pharmaceutical world:
  - ► 2013-20 Regular drugs CAGR: +5.1% (1)
  - ▶ 2015-20 Botanical drugs CAGR: +117.9% (2)
- Therapeutic approaches targeting unmet medical needs;
- Late-stage botanical drug targeting underserved anti-inflammatory markets;
- Market-ready derma-cosmetic products;
- Robust, global intellectual property platform;
- Global barrier to generic entry via extraction/production;
- ► Management is experienced in drug development, biotechnology, finance and venture capital startups.

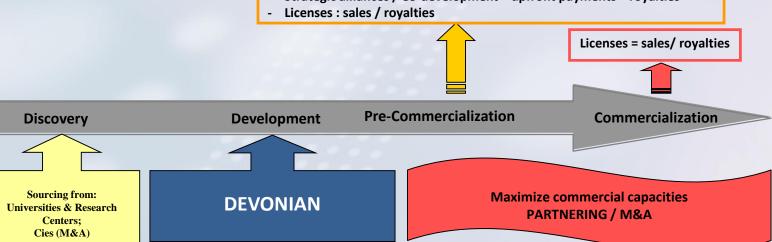


## **DEVONIAN'S BUSINESS MODEL**



## A Royalty Driven Botanical Drug Company

- Strategic alliances / Co-development = upfront payments + royalties



- We do not do the discovery work;
- ❖ We do not do research work:
- ❖ We do not have laboratory infrastructures: we sub-contract to external laboratory services companies;
- ❖ We do not do the marketing work;
- ✓ We develop until we can license and/or co-develop the product.

#### **Management Fundamentals**

- ✓ Low overheads
- ✓ Risk management
- ✓ Maximise business value

# Near Term Pipeline of Opportunities



#### **Pharmaceuticals**

- ✓ Phase 2a Ulcerative Colitis clinical trial completed
  - Biological activity demonstrated
- ✓ Phase 2 clinical trial planned for Q4 2016/Q2 2017;
- ✓ Potential strategic alliance for specific indication/territory;
- ✓ Co-development of new product(s)



#### **Derma-Cosmetics**

- ✓ Market-ready women anti-aging products: day, night and eye creams
  - Out-licensing process ongoing
  - Expected sales 2016/2017
- ✓ Pipeline : Men's anti-aging, sun-care products



## Senior Management and Technical Team Member



#### André P. Boulet, PhD, President & CEO

Many years of experience in drug development, regulatory affairs, market access, financing and restructuring in the pharmaceutical and biotech industries with, among others, Hoechst Marion Roussel Inc., Marion Merrell Dow Canada Inc. and Nordic Laboratories Inc. (now Sanofi Canada). Expertise in biotechnology and finance with SIPAR Inc. and as partner of BioCapital Investment Limited Partnership.

### François Michaud, CPA, CA; CFO

Many years of experience in finance with private & public companies. Former CFO at BioSyntech Inc. and two other private equity-backed IT & Manufacturing companies. Corporate finance roles at DS Smith Plc; Quebecor Inc.; Robert Fleming & Co. (now JP Morgan & Co.) and KPMG LLP.

#### Theophilus J. Gana, MD, PhD; VP Clinical Res & Dev.

Many years of experience in pharmaceutical drug development within Isoclinika, Inc. (subsidiary of Isotechnika Group) and Biovail Corporation.

#### Guy Chamberland, PhD; VP Reg. Affairs

Many years of experience in clinical & regulatory affairs as VP Research & Dev at Curaphyte Technologies Inc.; VP Clinical and Regulatory Affairs at Victhom Human Bionics; VP Product Dev. & Regulatory Affairs at Angiogene Inc.; Director Regulatory Affairs at Aeterna Laboratories.

#### Nathalie Boucher, PhD; Director Research & IP

Many years of experience in plant extraction & vegetal physiology. Formerly project leader in plant physiology application to environmental biotechnology at Lab-Bell Inc. Lecturer in Biochemistry at University du Québec à Trois-Rivières.



### **Board of Directors**



#### André P. Boulet, PhD, President & CEO

Many years of experience in pharmaceutical drug development, biotechnology and finance (VC).

#### Jean Bourgouin, MD

Expertise in pharmaceutical clinical development. Former VP, Scientific Affairs, Aventis; Vice President Scientific Affairs and Chief Medical Officer at Wex Pharmaceuticals Inc. and VP Scientific Affairs at Bradmer Pharmaceuticals Inc.

#### Germain Carriere, MBA

Expertise in Corporate Finance. Former President & CEO, Desjardins Securities Inc.; Vice-Chairman, Corporate Strategy at National Bank Financial.

#### **Pierre Colas**

Expertise in Corporate Finance. Former VP & Managing Director Investment Banking, Industrial Alliance Securities Inc.; Senior Vice-president Investment banking at Desjardins Securities Inc.

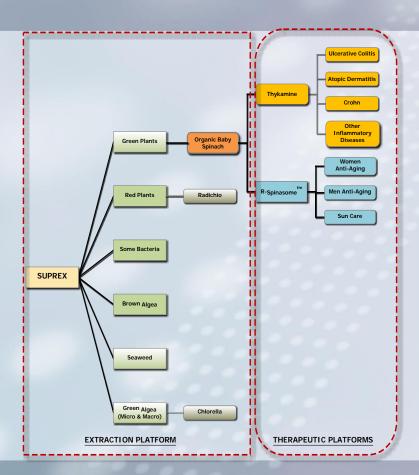
### **Matthew Peppler**

Expertise in financing early-stage disruptive technologies corporations focused in the areas biotechnology, pharmaceutical and medical instruments. President, Popgun Trading Inc.



# A Breakthrough Technology





- A potential large variety of plants could be used in the SUPREX Extraction Platform;
- Possible sourcing of new innovative compounds as Therapeutic Platforms;
- Possible sourcing of new innovative derma-cosmetic products.
- Broad Patent Protection: 38 patents issued or pending (4 families)



## THYKAMINE<sup>tm</sup>: INFLAMMATION UNDER CONTROL



- Mixture of galactolipids & proteins;
- Potent anti-inflammatory activity:

Pre-clinical studies have demonstrated that Thykamine<sup>tm</sup> has:

- A potent anti-inflammatory activities;
- A potent anti-oxidative activities;
- A potent immunomodulatory activities ;
- A safety profile in toxicology studies allowing the conduct of clinical trials in humans.

Phase I clinical study in Human (healthy volunteers) has demonstrated that Thykamine<sup>tm</sup> by intrarectal administration, is<sup>(1)</sup>:

\* Safe and well tolerated up to 1500mg.

Phase II clinical study in patients with Ulcerative Colitis has demonstrated that Thykamine<sup>tm</sup> by intrarectal administration, is<sup>(2)</sup>:

- \* Safe and well tolerated up to 1000mg;
- \* Indication of biological activity at 250mg per day.

# Therapeutic Opportunity: Inflammation



► Inflammation is very common in several diseases such as asthma, diabetes and cardiovascular diseases etc.;

■ Devonian targets 2 low hanging fruits with less expensive and shorter time to market therapeutic indications :

► Atopic Dermatitis:

**❖** 2015-20 : Dermatological Botanical Drugs expected CAGR of 61.2% (¹);

- **▶** Ulcerative Colitis:
  - **❖** 2015-20 : Gastrointestinal Botanical Drugs expected CAGR of 46.1% <sup>(1)</sup>.



# **Atopic Dermatitis** – What is it?



- Atopic Dermatitis = Eczema<sup>(1)</sup>
- Chronic inflammation of the skin<sup>(2)</sup>
  - Inadequately responsive to Topical Therapy;
  - Prevalence<sup>(2)</sup>:

► Children : 15-30%;

► Adult : 2-10%.

■ Co-occuring disorders<sup>(2)</sup>:

► Asthma : 25%;

**▶** Rhinitis : 34%;

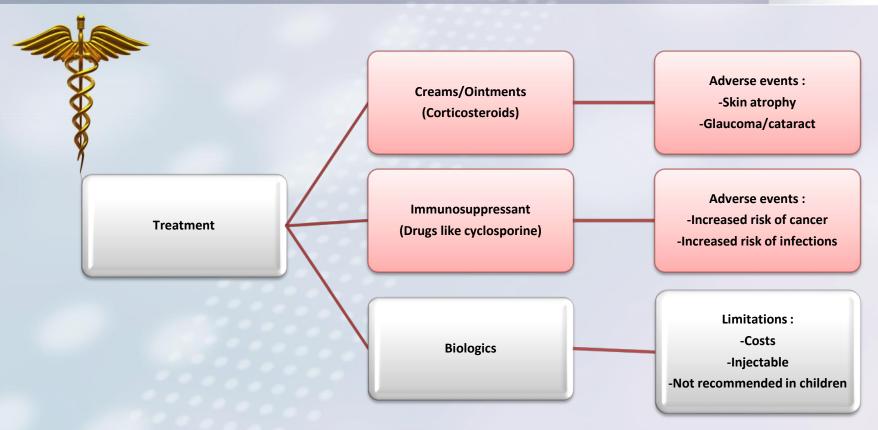
► Food Allergies : 15%;

- ► Kids more prone to bacterial infection and impairs their quality of life.
- Unmet Medical Needs.



# Atopic Dermatitis – How is it currently treated? "





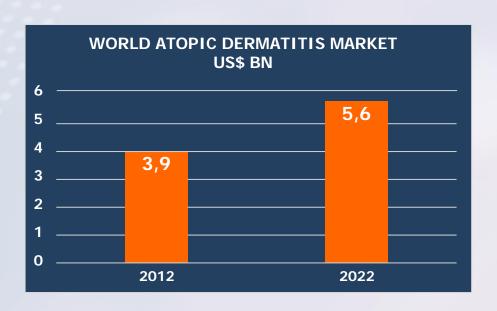
# **Atopic Dermatitis** – Billion \$ Market and Growing



## Need for new therapeutics with <sup>(2)</sup>:

- Better efficacy;
- Better tolerability;
- Safer maintenance;
- Fewer side effects.

### Market is projected to almost double by 2022°°



# **Ulcerative Colitis—What is it?**

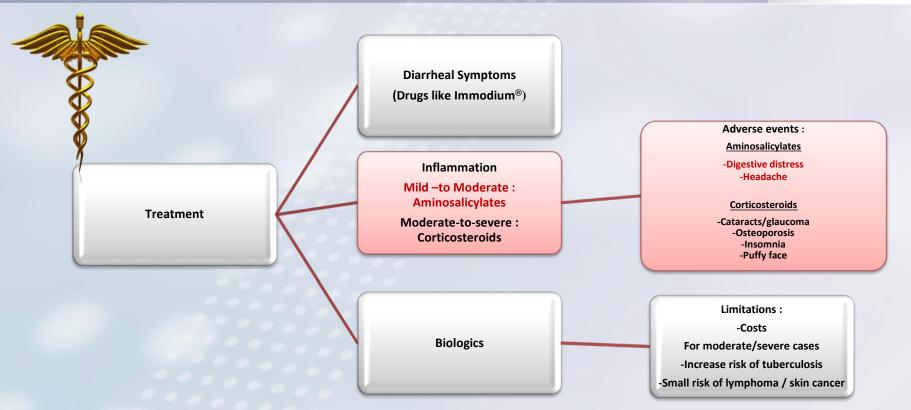


- ► Chronic inflammation of the colon/rectum;
- ► Prevalence : 37 to 246 cases per 100,000 persons (1);
- ▶ Relapsing & remitting episodes<sup>(1)</sup>:
  - Diarrhea;
  - Bloody stools :
  - Pain;
  - Fever;
  - Cramps;



# **Ulcerative Colitis** – How is it currently treated? "





<sup>\*</sup> Image courtesy of iscreationss at FreeDigitalPhotos.net

Management's understanding of the information derived from: Characterizing unmet medical need and the potential role of newiblogic treatment options in patients with ulcerative colitis and Crohn's disease: a systemic review and clinical surveys. Eur. J. Gastroenterol Hepatol. 2015 July;27(7):80; Mayo Clinic, Treatments and drugs, accessed online: http://www.mayoclinic.org/diseases-conditions/ulcerative-colitis/basics/treatment/con-20043763; Cleveland Clinic Center for Continuing Education, Ulcerative Colitis, accessed online: http://www.oregon.gov/oha/pharmacy/therapeutics/docs/ps-2010-04-ulcerative-colitis/; and Ulcerative-colitis/; and Ulcerative-colitis/ and Crohn's disease: a systemic review and clinical surveys. Eur. J. Gastroenterol Hepatol. 2015 July;27(7):80; Mayo Clinic, Treatments and drugs, accessed online: https://www.nayoclinic.org/diseases-conditions/ulcerative-colitis/; and Ulcerative-colitis/pasics/treatment/con-20043763; Cleveland Clinic Center for Continuing Education, Ulcerative Colitis, accessed online: https://www.oregon.gov/oha/pharmacy/therapeutics/docs/ps-2010-04-ulcerative-colitis/; and Ulcerative-colitis/; and Ulcerative-coliti

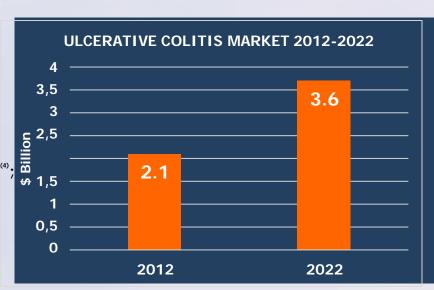
# **Ulcerative Colitis** – Billion \$ Market and Growing



### Market is projected to almost double by 2022(1)

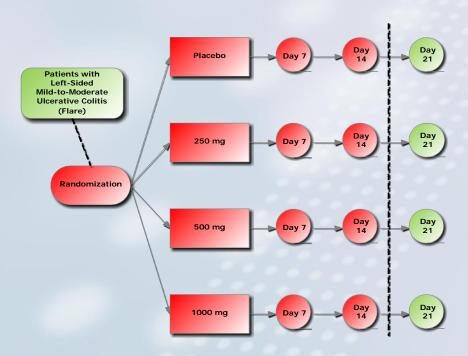
### Unmet medical needs with current therapeutics approaches:

- Calcineurin & TNF-antagonist effects wear off over time (2);
- Significant treatment failures with some biologics (3);
- 10 year cumulative risk of colectomy is still approx. 9.8%



# **THYKAMINE<sup>tm</sup>: PHASE IIa Clinical Study in Ulcerative Colitis**<sup>®</sup>





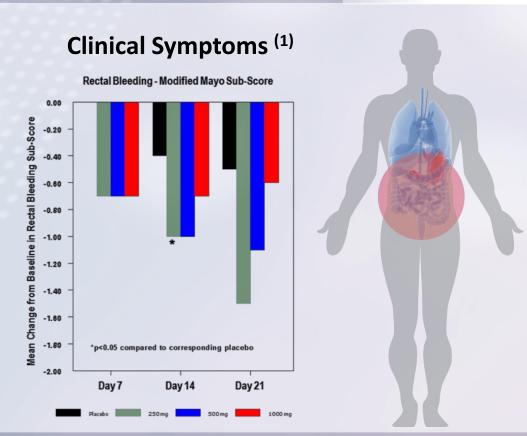
- ► Thykamine<sup>tm</sup> intrarectal administration daily at bedtime;
- Safety assessed throughout the study;
- Symptoms/Inflammatory Biomarkers/Quality of Life assessed on D0, D7 and D14 (on therapy);
- ➤ Assessments also done 7 days following the last treatment ( Day 21 i.e. 7 days without the drug).

### **THYKAMINE**<sup>tm</sup>: Phase IIa Results



# **Primary Endpoint – Safety**

- ✓ Safe;
- ✓ Well tolerated;
- Maximum tolerated dose was not observed.



# **Thykamine<sup>tm</sup>: Phase 2a Ulcerative Colitis Clinical Study Results**



- ► Excellent safety profile of Thykamine<sup>tm</sup> rectal enema;
- ► Effect in a <u>14 day treatment</u>:
  - Impact on symptoms;
  - Decreased inflammatory and disease's biomarkers;
  - Feasibility of conducting a larger sample-sized Phase 2b study.
- ✓ Seeking FDA Breakthrough Therapy Designation.



### Thykaminetm: COMPETITIVE ADVANTAGES vs CURRENT THERAPIES(1,2,3,4)



### Old Drugs ( > 20 yrs)

### **Aminosalicylates (5-ASA)**

Asacol  $HD^{\mathbb{R}}$ ; Pentasa $^{\mathbb{R}}$ ; Rowasa $^{\mathbb{R}}$ 

- ✓ Rx : up to 8 weeks
- ✓ 1 to 4,8 gr / 3 to 4 X per day
- ✓ All generics (Low costs)

### Lialda<sup>®</sup>:

- ✓ Rx : up to 8 weeks
- ✓ 2,4-4,8 gr / Once-a-day

#### Corticosteroid

### **Uceris**®

- ✓ Rx : up to 8 weeks
- ✓ Once-a-day

### **Novel Drug**

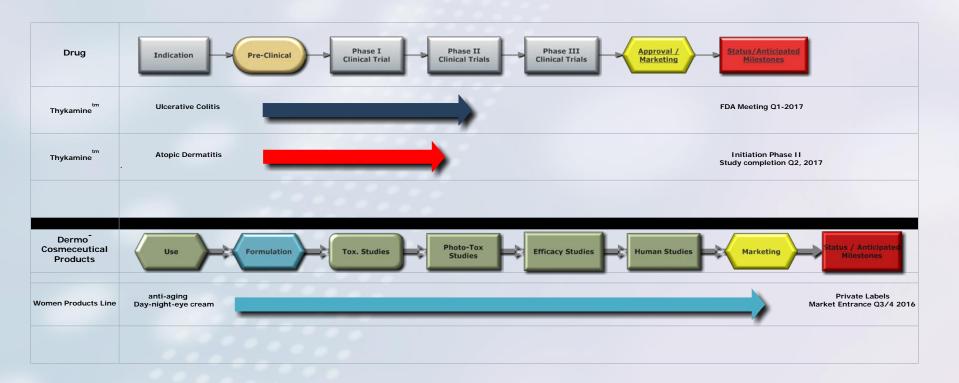
### **Thykamine**<sup>tm</sup>

- ✓ Non-Chemical Therapy;
- ✓ Rx : expected 4 weeks;
- ✓ Once-a-day ( 250 mg to 750 mg);
- ✓ Fast onset of action;
- Potential 1<sup>st</sup> line therapy in Ulcerative Colitis;
- ✓ Fewer Adverse Effects;
- As a Botanical Drug: difficult to copy «Copycat-proof
- ✓ May be effective for multiple inflammatory diseases;
  - > Asthma
  - Cardiovascular Diseases
  - Diabetes



# Pipeline





### **Derma-Cosmeceutical Products**



Global anti-aging market projected to grow to \$ US 191.7 billion by 2019 (1);

**Devonian Women anti-aging products: Day, Night and Eye creams;** 

- Patent-pending products;
- **Short Term revenue stream;**
- Study in human demonstrated superiority over two leading prestige products after 28 days of use(2);
- Consumer panel study in Washington DC, showed that after 14 days of use, 92% of participants would switch to Devonian's products<sup>(2)</sup>;
- Intends to commercialise in Q3-Q4, 2016.
- Potential line extension: men's anti-aging products line and a sun-care products line;

# Strategic Plan



- ► Maximizing the value of Devonian by developing Thykamine<sup>tm</sup> (and other candidates) to end of Phase II clinical status;
- ► Value is achieved in 2016/17 through the market entrance of our derma-cosmeceutical products and build a pipeline;
- ► Value is achieved in 2017 through the completion of Thykamine<sup>tm</sup> Phase II clinical trial in atopic dermatitis;
- ► Value is achieved in 2017 through a strategic alliance of Thykamine<sup>tm</sup> to a pharmaceutical company for the dermatology applications;
- ▶ Use our proprietary technology to initiate collaboration with other companies for new product discovery.



# **Term Sheet Summary**



Target: Min \$ 6M and Max of \$ 10M

✓ Pre-Money value : \$30M

✓ Terms of financing: \$0,75 / Unit: 1 Common share + ½ Warrant

✓ Each full exercisable Warrant @ \$1,10 for 24 months

	Min (\$ 6M)	Max (\$ 10M)
Common Shares	8,000,000	13,333,333
Warrants	4,000,000	6,666,666
Over-Allotment Option (15%)	<del></del>	2,000,000



### **Use of Proceeds**



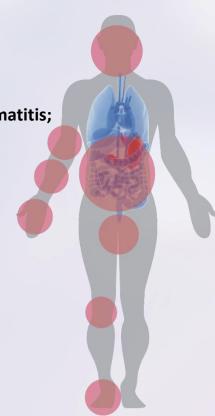
### Round of financing: Minimum \$6M/Maximum \$10M

#### Minimum \$6M

- ► Completion of a large Phase 2 clinical trial of Thykamine<sup>tm</sup> in patients with atopic dermatitis;
- **▶** Business development activities related to Thykamine<sup>tm</sup> licensing;
- Meet general corporate requirements.

### Maximum of \$10 million - Additional developments to be undertaken:

- Completion cGMP extraction qualification;
- Development of oral and suppository formulations;
- Structural characterization/mechanism of action;
- R&D: potential pharmaco-kinetic markers.



### WHY INVEST IN DEVONIAN



- Unique extraction technology platform
  - Strong IP to develop other drugs;
  - Roadblock to generics.
- ► Lower cost, lower risk botanical pharmaceutical focus
- High value business model
  - Develop products to high value point post proof-of-concept;
  - Out-license marketing rights;
  - Retain manufacturing & IP responsibilities.
- Experienced team







Thank you

**Devonian Health Group Inc.** 

#### Farm to Pharm™



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In accordance with Section 13.7(4)(b) of National Instrument 41-101 – General Prospectus Requirements, all the information relating to Devonian's comparables and any disclosure relating to the comparables, which is contained in this document to be provided to potential investors, has been removed from this template version for purposes of its filing on SEDAR.