

The Saskatchewan Functional
Food Network, Annual Meeting
2004

The Commercialization Process

From Discovery to Market

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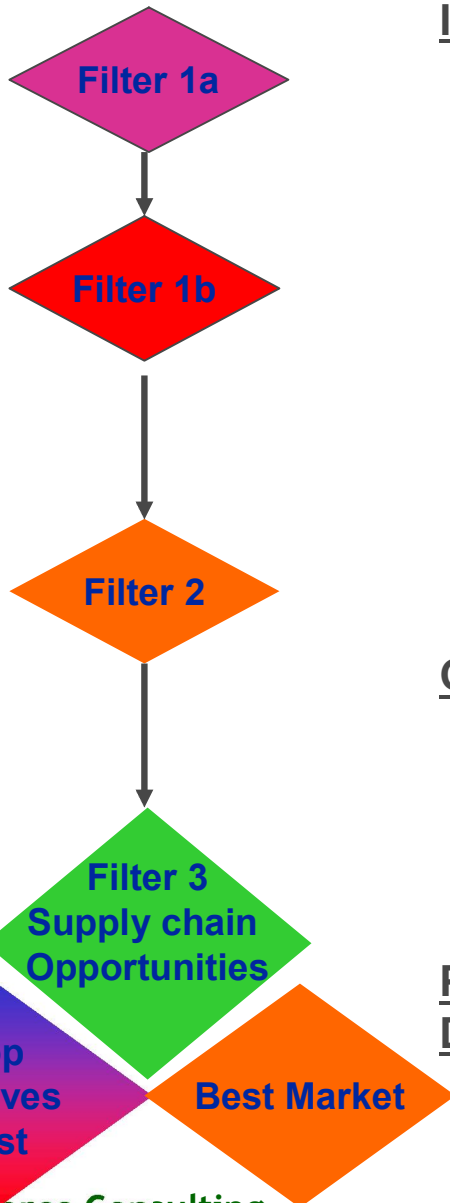
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Opportunity Evaluation

- Investment companies have 300+ offers/year
- Evaluation of research ideas within a company needs dedicated activity to focus resources
- Defined process, well understood, objective, compares opportunities
- Fewer opportunities than in previous years



The Screening Process



Initial screening criteria:

- Disease ranking list: (large market, regulatory barriers)
- Availability of science data
- Is the active compound/ingredient developed?
- Fits corporate strategy
- Possible IP potential?
- Entry barriers
- Financial success/profits
- Time to market
- Clear regulatory path
- Consumer awareness
- Potential to attract partners if needed

Geographical Evaluation:

- Large easy market to enter?
- A Canadian trading partner?
- Major cultural issues?, language issues?
- Geographical distance from Canada

Potential for Canadian

Development/Sustainability:

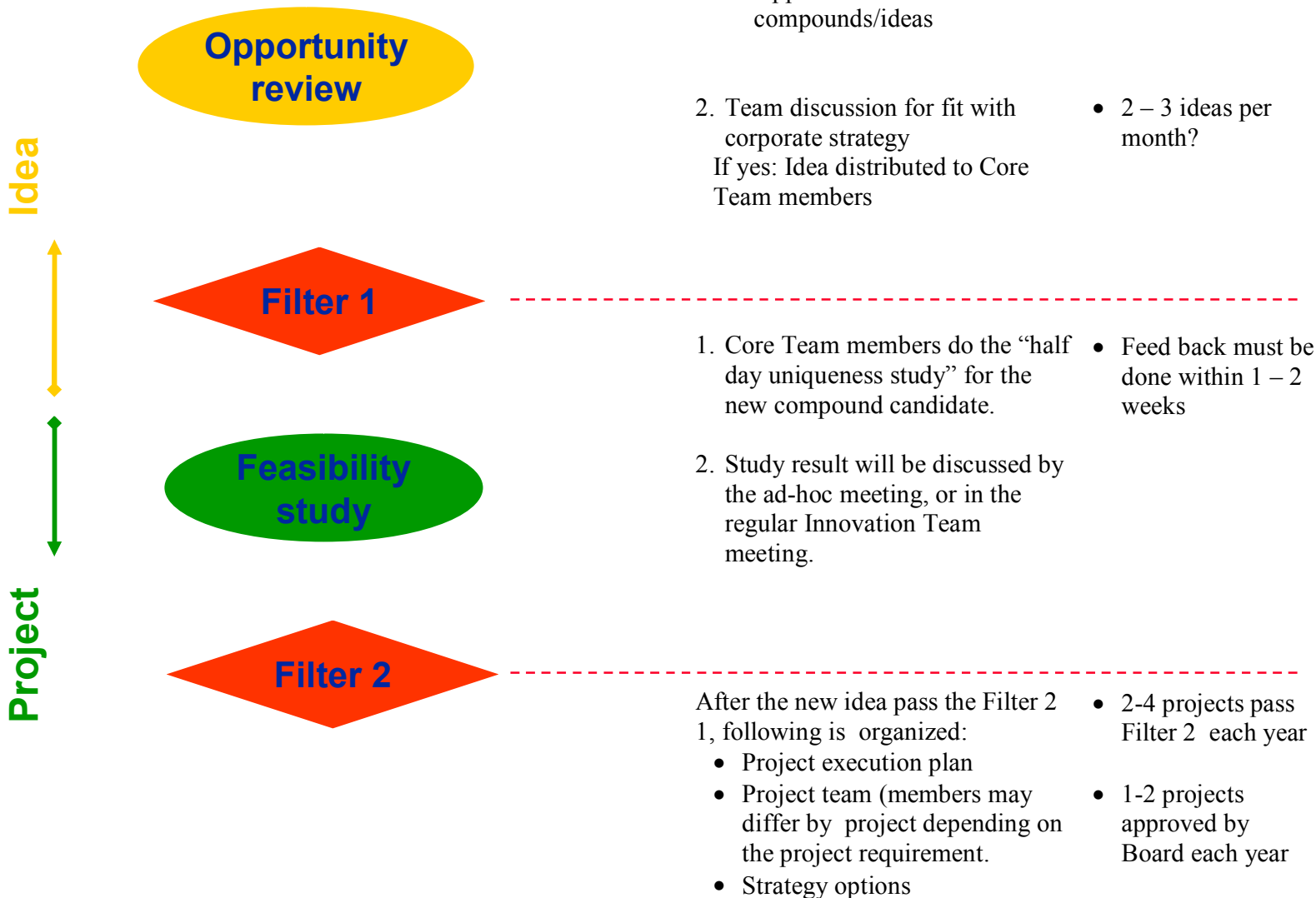
- Final list of compound/ingredients
- Focus on “best” market/region
- Consider the entry position on supply chain; “active”, food or distribution



The Screening Process

- **Filter 1:** = Key diseases, scientific data for “active”, high consumer need, large health care costs, existing markets
- **Filter 2:** = Geographical rankings, based on existing trade, ease to enter market, cultural and physical distance
- **Filter 3:** = Where are the possibilities on the supply chain? Often actives developed first, then food applications.





Canada's Nutrition Industry Value Chain

Segments:	Raw Material Providers	Manufacturers/ Processors & Branded Suppliers	Distribution	Consumer Sales Channels	
1. Conventional Foods \$62.9 bil	?? Food Material Suppliers	?? Companies	Distributors/Brokers 200+ Companies	<u>Retail Stores</u> 6,000 Retail store ? Mass Market (MM) -2000? Supermarkets - ?? Drug	80%
2. Functional Foods \$1.8 bil	?? Food Material Suppliers	215 Companies	Distributors/Brokers ~20 Companies	<u>Direct Sales</u> <u>Mail order</u> Catalog, Internet, TV <u>Multi Level Marketing</u> - Companies <u>Medical & Alternative Health Practitioners</u>	20%
3. Organic Foods \$1.3 bil	3,100 Organic Farmers 320 Processors, Handlers	??? Companies			



Opportunities matrix..Outcome Ranking

- Technology
- Commercial
- Financial
- Legal
- Regulatory
- Market

BUSINESS OPPORTUNITIES REVIEW				
Attribute	Rating	Opportunity		
		Policosanol	Glucosamine	Fish Oils
<u>Technological</u>				
Strong science/rationale	20	15	12	20
Strong raw material position	5	5	5	5
<u>Commercial</u>				
Capacity for production/processing	5	5	5	5
In line with corporate strategy	10	10	5	5
Dominant or able to achieve dominant position in <5 years	5	3	5	5
Good fit to existing Canadian food manufacturers	5	3	2	3
Able to be commercialised quickly	5	5	5	5
No limitation to different food segments	2	1	1	1
Long term sustainable growth	5	5	5	5
<u>Financial</u>				
Minimum revenues of > \$20 Mio after 5 years	10	10	5	10
Able to generate significant profits >15%	10	5	2	5
Risk of failure low	5	5	2	3
<u>Legal (1)</u>				
Patentable or proprietary knowledge	10			
Long patent life	5			
<u>Regulatory</u>				
Low toxicity/high margin of safety	10	10	8	10
Able to receive regulatory passage in short time in key markets	5	5	5	5
<u>Market</u>				
Consumer awareness exists or building	3	3	3	3
Existing market for active or FF	5	3	4	5
	125	93	74	95



The Key issues

- Strong efficacy
- Regulatory path clear
- IP strong and extendable if possible
- Safety and tox. profile manageable
- Time-lines well understood
- Potential and forecasts reasonable



The Regulatory Trap

- Dietary supplement
- GRAS food additive
- Time and costs
- (It usually takes longer and costs more than forecast)
- Who does the work, who manages the work?



Dietary Supplement or Food Additive?

Determination of Dietary Supplement Status

An annotated algorithm

This algorithm provides the basis for determination of dietary ingredient status based on requirements set forth by the Food, Drug and Cosmetic Act and enforced by FDA regulations. Some steps may require expert legal/regulatory interpretation.

1. Is the product a

FDCA 201 (ff) (1) /U.S.C. 321

- A. Vitamin
- B. Mineral
- C. Herb or other botanical
- D. Amino acid
- E. Dietary substance used by man to supplement diet by increasing the total dietary intake (*See Note 1 regarding ruling for a synthetic Co Q10 analog*)
- F. Concentrate, Metabolite, Constituent, Extract or combination of any ingredient described in clause (A), (B), (C), (D), or (E)

YES

NO



Go to 2



Safety and Toxicology

Published Toxicological on Substance in General	Yes	Review
Acute Toxicity Rat	Yes	\$3,000
Operators safety	Yes	\$12,000
Observations on safety in humans	Yes	Review
Toxicological and Safety Data on Substance	Yes	
Genotoxicity	Yes	\$50,000
Subchronic Toxicity Studies	Yes	
Subchronic Toxicity Rat	Yes	\$150,000
Subchronic Toxicity Dog	?	\$220,000
Embryotoxicity/ Teratogenicity Study in Rats	Yes	\$80,000
Two Generation Study Rat	Yes	\$350,000
Metabolic Studies		
ADME Study Rat	Yes	\$25,000
ADME Study Human	?	\$75,000
Additional Safety Studies Performed with Substance		
Bioavailability Study Rat	Yes	\$20,000
Bioavailability Study Human	?	\$30,000
SAFETY / GRAS EVALUATION (Panel)		
GRAS Panel Evaluation of the Safety for Proposed Uses	Yes	\$50,000



Product Science Support

- Initial dossier for DS
- Dossier for GRAS
- On-going trials
 - New indications and extensions
 - Claim substantiation (labeling)
 - Claim substantiation (advertising)
 - New foods
 - PR and media activity



Product technical support required

- Formulation
- Matrix
- Stability
- Bioavailability
- Analytical methods
- Taste and testing
- Kosher, Hallal



Food Company's Expectations

(also for DS)

- Prototype formulae
- Stability
- Advertising claim support
- PR/advertising to raise consumer awareness
- Taste testing/consumer acceptability
- Exclusivity.....?



To Brand or Not To Brand an Active

- INTEL inside story
- Aspartame...Sunette
- Ingredient brand vs Umbrella brand
- Cost.....global >\$500mio
- Time... decade needed
- Extension of product life after patent?
- Bond to distributors/partners



Corporate/Product Branding

SourceOne

- Links product to company
- Design elements have meaning
- Groups actives from several supplier partners
- Consumer branding efforts

Supplier of the Month

SourceOne Global Partners Gets Off To Fast Start

It's been a notable first year for SourceOne Global Partners. Launched in the spring of 2003 by industry veteran Jesse Lopez, the company has established partnerships with four established suppliers and launched several branded ingredients into the marketplace.

Among those ingredients are LJ100 Tongkat Ali, a standardized extract of Eurycoma longifolia jack that is said to be the most potent available, and Sytrinol, a citrus-based ingredient designed to lower cholesterol. Both of these ingredients are the results of partnerships—with HP Ingredients (Bradenton, FL) in the case of LJ100, and with KKG Synergize (London, ON) in the case of Sytrinol—and both have reached the consumer marketplace in branded products from Source Naturals (Scotts Valley, CA).

A year after the company's founding, "We're ahead of our plan," said Lopez, president and CEO of the Chicago-based company. "We've been very fortunate in developing strategic relationships that have delivered value to our customers far beyond our expectations."

In the case of SourceOne Global Partners, the term "new" is not synonymous with "unknown quantity." Lopez has

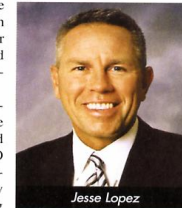
more than 25 years in the natural products industry. "Even though we're a new company, we have tremendous experience that we've leveraged with our global partnerships," Lopez said.

SourceOne Global Partners characterizes itself as "a new breed of ingredient supplier, partnering with manufacturing



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Jesse Lopez

clients to introduce powerfully branded, science-driven products to market with a unique product positioning and compelling consumer presence. SourceOne Global Partners was conceived as a company whose core competency would be to integrate legitimate science with strong trade and consumer branding.

We partner with leading suppliers worldwide to source and offer patented ingredients supported by proprietary science as part of turnkey marketing program that dramatically increases the odds for market success."

"We've been very fortunate in developing strategic relationships"

—Jesse Lopez

An example of the SourceOne Global Partners marketing approach is the Sytrinol logo, introduced in February. "To communicate the appeal of Sytrinol, the logo has to attract attention and then leave a lasting impression," said Lopez. "The Sytrinol logo mirrors the SourceOne corporate logo developing an

identity link between the company and our products. The green font correlates with the corporate identity and yellow quarter circle represents the product's citrus origins."

SCIENTIFIC BASIS

Science is another key component in SourceOne Global Partners' approach, and the company recently completed the first of three phases of a double-blinded, randomized 24-week study on 120 hypercholesterolemic subjects. The results from the completed 12-week (phase I) Sytrinol clinical trial proved to be consistent with previous clinical studies on Sytrinol's heart health benefits. Sytrinol came to market with more than 12 years of research including in vitro, in vivo, and in clinical studies, behind it.

Similarly, SourceOne Global Partners is conducting studies of LJ100, funded by the government in Malaysia, where the ingredient is harvested. Commented Stephen Sturm, senior project manager of Source Naturals, "These valuable



ongoing studies not only enhance the credibility of the product, they reinforce our commitment to its success by providing the support necessary to grow the market for LJ100."

Thanks to Sytrinol and an exclusive marketing agreement for North America, Europe, and Australia with the Ginkgo Group on its Ginnovay product line—which includes natural vitamin E and cholesterol-lowering phytoosterols—SourceOne Global Partners has built "a very strong platform of cardiovascular health," said Lopez.

As a result, the company is being approached by other suppliers of heart health ingredients, he added. The company is about to announce the establishment of a scientific advisory board that will reinforce that platform, Lopez said.



Umbrella Branding

CYVEX Nutrition

- Cohesive design links all products
- Good for trade positioning
- Shows continuity of new products or pipeline

What happens to sales when you start using super ingredients?



Up, up and away!

Avoflex™ (ASU) Vegetable alternative to chondroitin/glucosamine	LactoCalcium™ Milk minerals with 28% calcium, reduces risk of osteoporosis*	CYVEX NUTRITION YOUR RAW MATERIALS PARTNER 1851 Kaiser Ave., Irvine, CA 92614 1-888-99-CYVEX (992-9839) www.cyvex.com sales@cyvex.com
BIOVIN® Whole Grape Extract A full spectrum antioxidant	BIOCOSANOL™ Rice Policosanol Natural choice for cholesterol control*	
ARTHROCOLL™ Chicken Collagen Type II An innovation in joint support*	BioVnca™ Vinpocetine Maximizes memory and brain power*	

Cyvex Nutrition, Inc. *These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Circle Reader Service #43



What is Additives Value to Food Company

- Adds value to the food
- Shows leadership
- Gains market share
- Opens up new market segment
- Defends existing position
- Adds profits



What Value to the Consumer?

- Healthy lifestyle now
- Prevention of disease
- Maintain existing health
- Is the story believable?
- How much extra is consumer willing to pay?



What is the Value from NGO/Co.?

- Partnership
- Synergy
- Goodwill/relationship to the Corp.
 - March of Dimes :NTD/folate
 - Am. Cancer: lycopene
 - Helen Keller:lutein
 - Am.Heart Assoc:Fish oils (EPA/DHA)
- Credibility



Summary

- Have an organized/focused process for developments and pipeline management
- Science, regulatory and IP have the major impacts
- Know the value to your customer
- Know the value to the consumer
- Use synergy/partnerships to drive success, get value for dollars
- Use NGO and government science/support where possible



Good luck

Thank you.....questions?

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