

# AQUAPRIN™

The global pharmaceutical industry is a knowledge-based industry. The pharmaceutical market is growing at 8% yearly, and is forecast to grow to more than \$700-billion by year-end 2026.

Aspirin has always been and still is the **“Gold Standard”** of pain relievers. Aspirin, in tablet or powder form, (acetylsalicylic acid), is not water soluble, acidic, and slow to dissolve in the stomach. In addition, salicylates in conventional aspirin tablets are degraded during their passage through the GI-tract and during metabolism achieving only 35 to 45% absorption efficiency and taking up to 60 minutes to achieve maximum salicylate blood levels. While aspirin is a miracle drug in so many respects, being acidic and insoluble in water, it causes, in millions of patients, severe gastric distress. and sometimes, hemorrhage, (stomach bleeding), owing to direct contact between un-dissolved solid, acidic aspirin particles, and the stomach lining. Indeed, it is precisely these gastro-toxic, ulcerogenic adverse-reactions that prevent many patients from taking full advantage of aspirin’s multi-faceted benefits. Patients never get the full benefit of the pain relieving and anti-inflammatory action.

A truly soluble aspirin, which is a superior form of aspirin, does not exist in the United States except for the very high sodium content, (two grams of sodium per dose), Alka Seltzer®, which cannot be taken on a routine basis for pain relief and does not completely dissolve.

Worldwide, the market for soluble aspirins is more than a \$3 billion dollars/year.

The scientists at ASPIR-TEK have been working for over 20 years to convert common aspirin into a much more effective and safer form. What has been achieved is the most significant breakthrough in the pain reliever field in many decades. The potassium based derivative of aspirin, “AQUAPRIN” is the safest, most therapeutically effective, and fastest acting form of aspirin worldwide and in fact, is the most superior OTC pain reliever worldwide.

The AQUAPRIN formulation, developed by ASPIR-TEK, instantly dissolves the aspirin on contact with water, leaving no undissolved particles and scum and having a good taste in about 2 oz. of water. This achieves a fast acting, non-acidic, (is antacid), safer, more therapeutically effective drinkable derivative of aspirin, which greatly reduces irritation to the GI-tract, and is a more effective and efficient method of delivering plasma salicylates into the blood stream. This form achieves almost peak blood plasma levels in 7 to 10 minutes. Moreover, it contains therapeutically active levels of potassium, which acts also as an antacid in neutralizing stomach acid and helps to reduce blood pressure and improve circulation. It is already FDA approved and ready for commercialization.

**ASPIR-TEK** has developed the following products to correct the problems of the slow dissolving rate and acidic nature of Aspirin.



**AQUAPRIN** is packaged in a small foil packet (1"x 3") containing a granular formulation. When the ingredients are added to 1.5 or more ounces of room temperature to cold tap water, a chemical reaction takes place. This reaction instantly solubilizes the 650 mg of aspirin into a clear solution without any un-dissolved particles or scum and also makes it antacid instead of acidic. The result is a great tasting drink that will be available in five already developed flavors. The solution delivers more than DOUBLE the Salicylates of powdered or tableted aspirin for the same mg dose and about 350 mgs of Potassium. It is ready to drink in 15 to 30 seconds and reaches more than 90% of peak blood levels in about 5-7 minutes. The salicylates stay at higher blood levels for a longer duration than aspirin tablets and powders and the duration of pain relief is longer than aspirin tablets and powders or acetaminophen tablets and liquids.

## **AQUAPRIN is a “Daily Regimen”**



Packaged in a small foil packet (1" x 1"), and blister strips, which contains a granular formulation. When the ingredients are added to 1 or more ounces of water or any other drink, a chemical reaction takes place. This reaction instantly solubilizes the 81 mg of aspirin into a clear tasteless solution without any un-dissolved particles or scum. The results are a much safer and therapeutically effective delivery of aspirin for the prevention of heart attacks and strokes. It is also recommended for the reduction of colon cancer, breast cancer and many other diseases.

## **AQUAPRIN “Children & Teenagers”**



Packaged in small foil packets, (1" x 1.5"), and blister strips, which contains a crystalline formulation. When the ingredients are added to 1 or more ounces of water or any other drink of any quantity, a chemical reaction takes place. This reaction instantly solubilizes the 81 mg of

aspirin into a clear tasteless solution without any un-dissolved particles or scum. The results are a much safer and therapeutically more effective delivery of aspirin for children & teenagers.

ASPIR-TEK's mission is to be a highly profitable leader in the OTC and prescription pain management field, and to capture a lucrative segment of the Analgesic, Arthritic, Osteoporosis, cardio protective, and migraine market. AQUAPRIN, and other line extension products will have significant competitive and efficacious advantages over all other analgesics and OTC pain relievers.

ASPIR-TEK is engaged in the validation, setting up of a manufacturing facility, and continuous product improvement of AQUAPRIN, whose formulation and manufacture depend mainly upon considerable skill and "know-how." The main formulation and manufacturing process technology patent for the product has been granted. The product is protected for at least 17 years. Provisional and other patents have been applied for. Since the additional patents, which we feel confident of being granted, will allow the Company to enjoy a considerable period of exclusive franchise.

ASPIR-TEK expects to be a leader in the pain management field, and to capture a substantial segment of the analgesic, cardio protective, anti-thrombotic and antipyretic pharmacotherapeutic market, owing to AQUAPRIN and other line extension products significant competitive advantages. AQUAPRIN is an instantly dissolving, fast-acting, non-acidic, safer, more potent drinkable derivative of aspirin, which virtually eliminates irritation to the GI-tract, and is a more effective and efficient method of delivering salicylates into the blood stream, achieving almost peak blood plasma levels in 7 to 10 minutes. Moreover, it contains therapeutically active levels of potassium, which acts also as an antacid in neutralizing stomach acid. Potassium also lowers blood pressure and helps to dilate blood vessels allowing for better blood circulation.

**AQUAPRIN** is superior to any other solubilized aspirin form and is superior to any other OTC analgesic. One patent has been granted and additional patents are in the process of being applied for. It is expected that patents will be granted within 12 months after application because of prior discussions with the patent office. More important is the intellectual property and the know-how that will remain company secret and which will not be put into patent form for the entire world to see.

The Company is not a "start-up." Its founders, since 1992, have, and continue performing all the costly research, development and packaging engineering, product stability, shelf-life testing and quality-control on AQUAPRIN. The product and several line extensions are now ready for scale-up and commercialization. AQUAPRIN will be manufactured in accordance with the current FDA Analgesics Monograph, appearing in the "permitted combinations" section of the Federal Register and in the USP under the "Effervescent Aspirin" monograph. It is The Company's secret

intellectual property know-how and long experience in this field that assures investors of success and no serious competition from others.

**Aquaprin's** leader in the OTC and prescription pain management field, and to capture a lucrative segment of the Analgesic, Arthritic, Osteoporosis, cardio protective, and migraine market. AQUAPRIN and other line extension products will have significant competitive and efficacious advantages over all other analgesics and OTC pain relievers.

The company will also Initiate clinical studies, when funding permits, in order to meet FDA and FTC requirements to make marketing claims of “**fastest acting, Safest, and most therapeutically effective**” analgesic, (NSAID), on the market. The Company possesses significant product formulations and manufacturing know-how plus experience for the pharmaceutical products comprising its core business.

## **Product Applications**

**AQUAPRIN** — For Arthritis Pain, Severe Body Pains, Tooth-Aches, Migraines

Whether caused by tension, stress and anxiety, or the result of adverse muscular-skeletal or dental events, fever or eyestrain, headaches practically dominate the hierarchy of pain and discomfort. A fortified, fast acting analgesic and anti-pyretic such as AQUAPRIN should quickly acquire a reputation for potent efficacy in the marketplace. Clinical data has shown that this form of aspirin is much faster acting and safer than any other form of pain reliever.

Effective in treating the common headache, and other aches and pains, aspirin is the only product proven to relieve the inflammation of arthritis and rheumatism, the cause of the severe pain of these diseases. For this same reason, aspirin has long been the drug of choice in combating inflammatory pain from exertion and sports activities. AQUAPRIN, the potassium salt of aspirin, (potassium acetylsalicylate), is greatly more effective than aspirin tablets or powders.

It has also been recently discovered that aspirin can relieve migraine headaches in 25-50% of sufferers. This is even truer with the fast blood levels achieved with AQUAPRIN. The relief level is probably much higher though not confirmed. AQUAPRIN is unique in this respect since other OTC analgesics such as acetaminophen (Tylenol) or ibuprofen (Motrin) have proven to be mostly ineffective.

It is estimated that the cost of treating the 18-million migraine sufferers is well over \$1-billion /year, with about another \$500-million going to pay for headache remedies. Once Aquaprin's higher blood-levels and sustained bioavailability become recognized in the marketplace, it should become the drug of choice for migraine sufferers.

**ASPIR-TEK** has already contacted various Emergency Medical Services and found them responsive to the idea of making Aquaprin a permanent, integral part of their emergency medical arsenal. The Company will continue targeting Aquaprin toward EMS emergency treatment of severe cardiac, thrombotic, and associated traumatic events. This would include police and emergency vehicles, hospital emergency rooms and trauma centers, as well as physicians and pharmacists. People who are prone to stroke and heart attack will want to have quickly accessible to them an "Quick-Prin" device to counter oncoming strokes and heart attacks.

## **Emergency Use**

"There are two situations in which aspirin can be life-saving: The first is "early" aspirin, when the drug is given on first contact with a patient with chest pain, who may be having a coronary thrombosis. An extension of this is "immediate" aspirin, i.e., the subject himself takes the drug as soon as the sudden onset of severe chest pain is experienced. Aquaprin achieves peak blood levels in less than 10 minutes and reaches more than 60% blood levels in a few minutes.

"Patients who are judged, for any reason, to be at high risk of experiencing a cardiovascular or thrombotic event should be instructed to carry Aquaprin at all times, which can be administered immediately after experiencing severe chest pains.

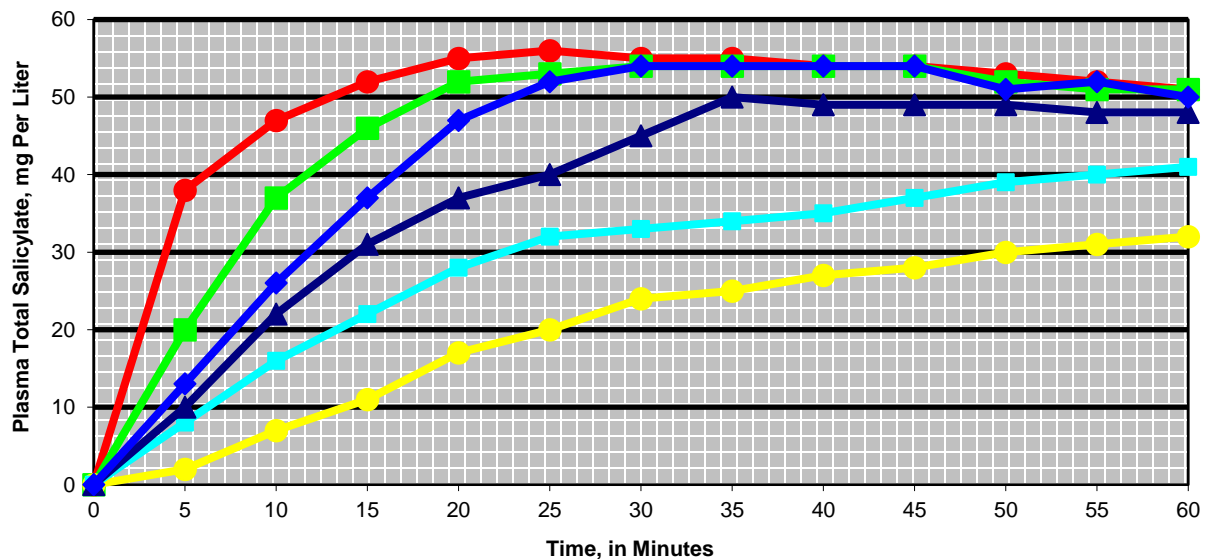
"It would seem reasonable to give this advice to all patients at increased vascular risk, including those who take a small daily prophylactic dose of aspirin. The development of severe chest pain, despite daily exposure to aspirin, indicates that some "sensitive" platelets must have entered the circulation and a coronary thrombus may be forming. Thus, an extra dose of 800 mg of a solubilized aspirin could well be life-saving."

[Professor Elwood is honorary professor at The Department Of Epidemiology & community medicine, University of Wales College Of Medicine, and Professor Stillings is honorary professor at the Department Of Bio-organic Chemistry, University of Hull].

## Superiority Of AQUAPRIN Over Competition

<u>Characteristics</u>	<u>Aspirin Tablets &amp; Powders</u>	<u>AQUAPRIN</u>	<u>Improvement</u>
% Absorption into Bloodstream	35-45%	100%	110% More
Time to Therapeutic blood Levels	20-30 Minutes	2 Minutes	10X Faster
Time to Peak blood levels	45-60 Minutes	7-10 Minutes	6X Faster
% In Blood Stream After 5 Minutes	Less than 5%	70-80%	70% More
Time to Start Working on Pain	20-30 Minutes	2 Minutes	10X Faster
Level of Pain Relief	Normal	More than Twice	2X Faster
Duration of Pain Relief	3-4 Hours	5-6 Hours	>2 Hours
Time to Relieve Headaches	25-40 Minutes	5 to 10 Minutes	5X Faster
Effectiveness in relieving Migraine	Low	High	Proven
Gastric Irritation	0-25% of Patients	1-2% of Patients	20X Less
Gastric Damage Score	2.0	.15	92% Less
Effect on Gastric Mucosa	Acid	Antacid	Safer
Dosing Method	2 Tablets + Glass of Water	2 or more oz.	Less Water

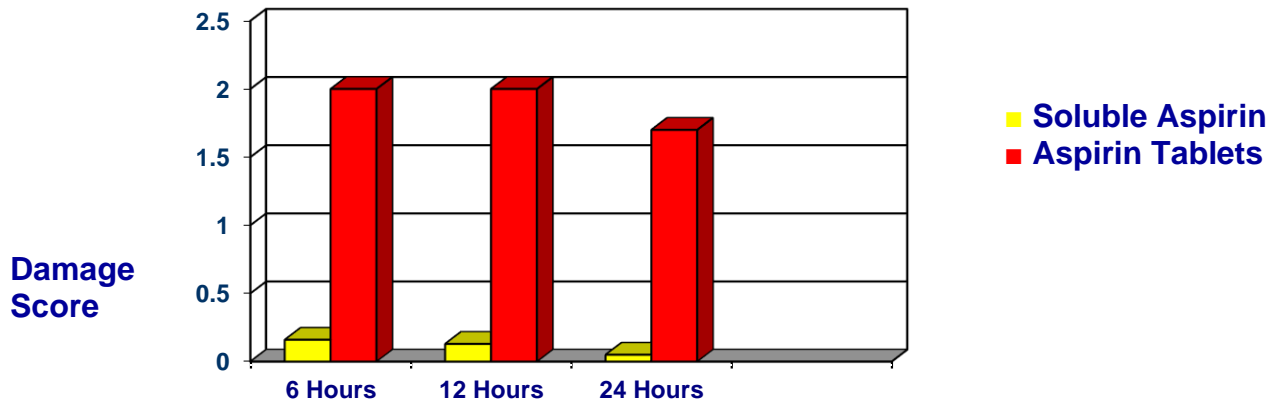
**AQUAPRIN Absorption Rate Compared with Published Data for Other Aspirin Formulations**



Plasma total salicylate concentrations following the oral injection of various preparations of aspirin. Each dose was equivalent to 640 milligrams of aspirin in all cases.

## Solubilized Aspirin Causes Less Gastric Irritation than Tablets

Mean gastric damage score for 30 volunteers taking a solubilized aspirin vs. solid aspirin tablets at 6,12, and 24 hours.



This randomized, double blind, crossover study in 30 volunteers involved visual inspection by gastroscopy at various

### Period Between Sampling

Data shown drawn from a study by: (Jaiswal et al IUPHAR 9<sup>th</sup> International Congress of Pharmacology, 1984) Study done using “Disprin” brand soluble aspirin.



## **Market Overview**

Americans consume over 80-million aspirin tablets a day, not including 81-mg tablets for daily cardiovascular prophylaxis regimen.

- In the United States, 60-million people suffer from arthritis and another 50-million from other forms of chronic pain. Therefore, despite a 25% incidence of adverse-reactions among arthritics and the fact that 20% of Americans have trouble swallowing pills, the American public nevertheless consumes approximately 29-billion tablets annually. The Company's current product concepts directly address the needs of these approximately 60-million consumers and patients.
- The large baby boom segment of the U.S. population is growing older. This aging makes it more prone to specific health problems -- the most prevalent of which is arthritis. Soon, people who are 50+ years old will consume over 50% of the analgesic products in the market. Since aspirin is the most effective product for the treatment and prevention of inflammation, its market share will grow significantly for at least two more generations.

AQUAPRIN is designed to overcome the adverse-reactions of high-dosage aspirin therapy -- gastric distress -- is positioned to capture a significant share of the US aspirin, and in addition the entire OTC pain reliever market. Since existing aspirin products, even with their painful side effects, currently hold a 12% market share of non-prescription analgesic usage, a 20% penetration by this highly improved product into this aspirin segment would yield sales of more than \$100-million annually.

The reputation of aspirin continues to be on the rise. Recent studies (see [Appendix](#)) have shown that the common aspirin is being proven effective against a myriad of health problems beside the usual headache, general aches and pains, and fever. They demonstrate aspirin's effectiveness as a heart attack and stroke-preventative, in attenuating the onslaught of Alzheimer's disease, and as an effective tool against diabetes, miscarriages, and some cancers. This rediscovery of aspirin and its benefits has given it broad and increasing positive media coverage in the last 5 years. Thus, AQUAPRIN, a major novel aspirin derivative breakthrough is expected to garner an instantaneous and growing cross-section of consumer constituencies.

## **Market Size (Sales Per Year /2022)**

- The pain reliever market in the US alone exceeds \$18 billion annually in the US.
- Over the counter pain relievers alone exceed \$5 billion annually in the US.
- Worldwide, the aspirin market well exceeds \$50 billion annually.
- COX-2 inhibitors for arthritis generated more than \$4 billion annually until recently. Because of the safety concerns of the COX-2 inhibitors and the retraction of “VIOX” from the market, the market share for COX-2 inhibitors has fallen from 26% of the market to about 11%.
- AQUAPRIN is believed to be a safe & effective COX-2 inhibitor for arthritis
- With appropriate marketing and endorsements, the sales potential for AQUAPRIN is estimated at > \$1 billion in the US alone.

## **Marketing Strategy**

Market conditions favoring the new field of Pain Management are now assuming an expansive dimension of therapeutic and commercial opportunity, and Aspir-tek’s AQUAPRIN is destined to assume a position of market leadership. It is especially noted that other major analgesic products are introducing liquid versions of their pain relievers. Liquid versions are beginning to take hold, which is especially good for AQUAPRIN , since it is in liquid form, although much more effective and competitive. Indeed, AQUAPRIN , uniquely fast acting and safer to the stomach, exhibits many important pharmacological, and commercial advantages over all other aspirin products including, especially, aspirin itself. Rapid market penetration is expected owing to AQUAPRIN unique selling proposition. AQUAPRIN is also superior in effectiveness than any other OTC pain reliever.

In the US, no oral competing products exist, in terms of potency, rapid onset of action, and gastric tolerance. Neither does any competing product exists that can deliver a comparably high percentage of un-degraded salicylates per analgesic or cardio protective dose.

1. It will, for this reason, be strategically launched in such target sectors as AARP, hospitals and nursing home pharmacies, and by direct marketing, with detail samples and technical data, to medical professionals, as well as via special “2-for-1” buying incentives for distributors. Internet banners, infomercials, and consumer hot-lines will likewise be deployed after the initial 6 months, as will dedicated e-commerce, permitting direct purchase of AQUAPRIN from The Company. A special information and product campaign will be aimed toward emergency medical service organizations.

**2.** The Company recognizes the difficulty for a new product to secure prominent shelf-space in drugstores. Its strategy will, therefore, depend on vigorous sales promotion and highly visible point-of-purchase displays at high-traffic consumer corridors. The company feels that the product is so superior to all other OTC pain relievers, that once tried with free samples, the public will demand the product. Also, local-media coupons and direct marketing will be creatively deployed by the Company to get its products distributed. The company will also make a strategic alliance with a major marketing organization to generate and implement a sales and marketing program. The company will also engage a pharmaceutical distribution company.

**3.** The Company's strategic marketing plan includes English/Spanish promotional, packaging and medicinal insert formats. Overall Hispanic growth demographics show manifold increases in every quadrant of this population sector over the past 3 decades. AQUAPRIN bilingual debut also translates into easier brand-recognition and penetration of Mexican, Central and South American markets as soon as practicable, and without having to revamp or redesign product packaging or advertising.

**4.** Once The Company's brand name is established in the market, the public will express its awareness of AQUAPRIN benefits by seeking out and purchasing the product on its own initiative. Since there exists no alternative sodium-free soluble analgesic product, AQUAPRIN should enjoy a market monopoly.

**5.** A prescription dose form will be marketed through doctors.

## **Competition**

AQUAPRIN has very little to no competition whatsoever pertaining to a true soluble pain reliever as to its pharmacological merits. And the proprietary technology, trade secrets and "know-how" involved in its manufacture are unknown to anyone in the industry.

AQUAPRIN is only up against the brand names which have over several decades entrenched themselves in the minds of consumers. However, after a period of aggressive marketing, education and consumer recognition, AQUAPRIN will quickly ascend to the top ranks of the analgesic pantheon.

In Europe, where soluble aspirins dominate, most are fine suspensions, and not completely dissolved solutions. The majorities are sodium-based, take a few minutes to dissolve and taste bad, or they are calcium-based, preventing total dissolution of the aspirin. There is also a French soluble analgesic product, *Aspégic*; however, it contains the exotic *dl*-form of lysine, and could never win FDA approval here. None of these foreign products can in any event be marketed in the USA since they do not fall within any FDA-approved monograph. In addition, *Aspégic*, was removed from store shelves.

The only soluble form of aspirin sold in this country is Alka-Seltzer which has excessive sodium, (1.2 grams per 650 mg. dose), and cannot be used for chronic pain daily doses or by older people who are on sodium restricted diets. It also generates distending amounts of gas. AQUAPRIN is on the other hand, a 100% potassium-based, *low-effervescence* product.

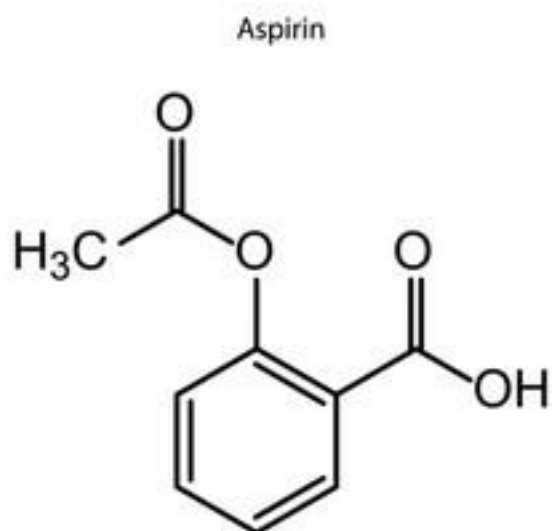


Fig. 1 — Gastrectomy specimen from patient with chronic duodenal ulcer. Two regular aspirin tablets administered 45 minutes prior to surgery. Each of these aspirin particles was found to be firmly adherent to the gastric mucosa, but not imbedded within it, as often happens. Damage was found under each particle.



Fig. 2 — Gastric mucosa, showing damage found under aspirin particle. At the center of the lesion is a deep, circular erosion. There is surprisingly little hyperemia surrounding the lesion. This may be due to the early tying off of the gastric arteries during the operation.



Lancet 2:1222, 1938  
 Brit.M.J. 2:7, 1955  
 Lancet 1:539, 1959  
 New ENGLAND J.M. 258:219, 1958

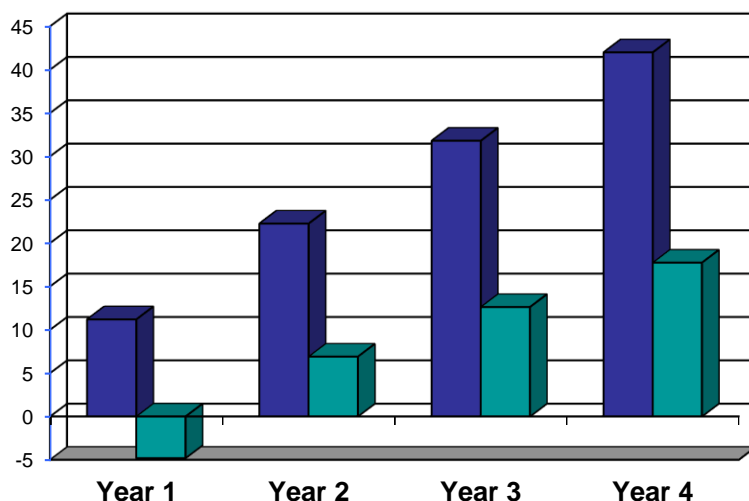
**QUICK-PRIN** too, will be unique not only on US drugstore shelves, but will also find its way into the handbags, wallets and hip-pockets of headache- or pain-prone American consumers, especially those with cardio-thrombotic concerns. Anyone who has already suffered a first heart attack or stroke, or justifiably fears such adverse events, will appreciate the convenience of carrying a product of such strength and efficacy as **QUICK-PRIN** with them at all times. And no water is necessary for them to enjoy its rapid-acting cardio-protective, analgesic and other benefits. Moreover, there exists no equivalent alternative remedy.

Needless to say, the competitive environment for most drug products changes very quickly. The Company will be vigilant and constantly monitor the market for the purpose of identifying current and future competitors.

claims of “fastest acting, Safest, and most effective” analgesic on the market.

14. License distribution for European and Asian markets.

### Sales and Profit Projections



*Sales projection begins 14 months after raising up to 20 million dollars.*

■ Sales  
■ Profit/Loss

#### Management Estimates are:

Year 1 Sales: \$11,200,000	Profit/Loss: \$497,000
Year 2 Sales: \$22,250,000	Profit/Loss: \$6,887,000
Year 3 Sales: \$31,800,000	Profit/Loss: \$12,622,400
Year 4 Sales: \$41,800,000	Profit/Loss: \$17,741,240

- Detailed cash flow projections available, contact us for more Information.

## APPENDIX

### The Salicylates

Aspirin (1) is just one of a family of products called salicylates. They are based on salicylic acid, and include methyl salicylate (3), commonly known as oil of wintergreen and sodium salicylate (4) a readily soluble form of salicylic acid.

Salicylates are found naturally in many plants including willow and poplar trees, pansy, milkwort, olive, jasmine, myrtle and in small quantities in fruits such as orange, strawberry, apple, cherry, plum, raspberry and grape.

Aspirin possesses a number of properties that make it the most often recommended drug. It is an analgesic, effective in pain relief. It is also an anti-inflammatory agent, providing some relief from the swelling associated with arthritis and minor injuries. Aspirin is also an antipyretic compound, which means it reduces fever. Each year, more than 40 million lb of aspirin is produced in the US alone, a rate that translates to about 300 tablets per year for every man, woman and child. However, it is not so innocuous a drug as one might imagine from its widespread use and ready availability. Repeated use may cause gastrointestinal bleeding.

<http://www.bris.ac.uk/Depts/Chemistry/MOTM/aspirin/aspirin.htm> / Steve download colour molecule

<http://micro.magnet.fsu.edu/pharmaceuticals/pages/aspirin.html> = aspirin crystals

<http://micro.magnet.fsu.edu/primer/techniques/phasegallery/stomachcancer.html> stomach cancer

<http://www.geocities.com/euthman/images/gastcarc.html> -- stomach cancer

The antipyretic and analgesic properties of salicylates have resulted in widespread usage in herbal preparations since the time of Hippocrates in 400BC and probably much earlier.

More information can be found at: <http://www.aspirin-foundation.com>