

SECURITIES AND EXCHANGE COMMISSION

FORM 10KSB/A

Annual and transition reports of small business issuers [Section 13 or 15(d), not S-B Item 405]
[amend]

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FILER

TREASURE MOUNTAIN HOLDINGS INC

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-KSB/A
(AMENDMENT NO. 1)

ANNUAL REPORT UNDER SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2004

TRANSITION REPORT UNDER SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number 000-32741

Vyteris Holdings (Nevada), Inc.
(formerly Treasure Mountain Holdings, Inc.)
(Name of small business issuer in its charter)

NEVADA
(State or Other Jurisdiction
of Incorporation Or Organization)

84-1394211
(I.R.S. Employer
Identification No.)

13-01 Pollitt Drive
Fair Lawn, New Jersey
(Address of principal executive office)

07410
(Zip Code)

(201) 703-2299
(Issuer's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Exchange Act:
None

Securities registered pursuant to Section 12(g) of the Exchange Act:
Common stock, par value \$.001 per share
(Title of class)

Check whether the issuer (1) filed all reports to be filed by Section 13 or 15(d) of the Exchange Act during the past twelve months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES NO

Check if there is no disclosure of delinquent filers pursuant to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB.

State issuer's revenues for its most recent fiscal year. \$242,322

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of a specified date within the past 60 days. (See definition of affiliate in Rule 12b-2 of the Exchange Act.)

The aggregate market value of voting common equity held by non-affiliates as of February 25, 2005 was approximately \$5,420,534. The number of shares outstanding of the registrant's Common Stock, as of February 25, 2005, was 48,750,000 shares (does not give effect to a one for ten reverse stock split effected on May 2, 2005).

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the 2005 Annual Meeting of Stockholders are incorporated by reference in Part III hereof.

Transitional Small Business Disclosure Format (Check one): Yes No

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EXPLANATORY NOTE

On April 25 2005, the stockholders of Vyteris Holdings (Nevada), Inc. adopted amendments to the Registrant's Articles of Incorporation which have the effect, among other things, of:

- o changing its corporate name from Treasure Mountain Holdings, Inc. to Vyteris Holdings (Nevada), Inc. (the "Registrant" or the "Company");
- o approving a one for ten reverse stock split of our common stock, such that each ten shares of our common stock will be converted into one share of our common stock;
- o increasing the number of authorized shares of the Registrant's common stock to 100,000,000 shares;
- o authorizing the issuance of 7,500,000 shares of Series B Convertible Preferred Stock; and
- o authorizing the issuance of up to 42,500,000 shares of preferred stock which may be issued, from time to time, pursuant to terms established by our Board of Directors.

These amendments were effected on May 2, 2005 by means of the filing of a

Certificate of Amendment to our Articles of Incorporation with the Secretary of State of the State of Nevada. The Registrant has amended Items 1, 3, 5, 6 and 8 of this Annual Report on Form 10-KSB/A as originally filed to give effect to these amendments to the Registrant's Articles of Incorporation. We have not otherwise amended these Items to give effect to any events occurring between the date on which we originally filed our Annual Report on Form 10-KSB and the date hereof.

We are also amending our Annual Report on Form 10-KSB as originally filed in order to provide responses to Part III of Form 10-KSB.

We are also updating the signature page, the Exhibit Index referenced in Item 13 of Part IV, and Exhibits 23.1, 31.1, 31.2, 32.1 and 32.2 and including Exhibits 10.17 and 10.18.

Pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended, the complete text of each of Items 1 and 3 of Part I, Items 5, 6 and 8 of Part II and Items 9, 10, 11, 12, 13 and 14 of Part III, as amended, is set forth below. We have also reproduced, but not modified or updated, Items 2 and 4 of Part I and Items 7-8B of Part II in this Amendment No. 1. This Amendment No. 1 speaks as of the original filing date of the Form 10-KSB and reflects only the changes to Parts I, II and III discussed above. No other information included in the Form 10-KSB including the information set forth in our financial statements and the footnotes thereto, has been modified or updated in any way.

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PART I

ITEM 1. DESCRIPTION OF BUSINESS.

BUSINESS DEVELOPMENT

Vyteris Holdings (Nevada), Inc. (formerly Treasure Mountain Holdings, Inc.) was organized in Utah as Treasure Mountain Mining Company in 1954 to engage in the business of mining, milling, processing and marketing various minerals, primarily tungsten. The Company engaged in the mining business for a period of time after inception and acquired various mineral leases, but became relatively inactive for several years until approximately 1997. In 1997, the Company's name was changed to Treasure Mountain Holdings, Inc., it was re-domiciled as a Nevada corporation and the Utah corporation was subsequently dissolved. In May 2005 the Company's name was changed to Vyteris Holdings (Nevada), Inc.

On September 29, 2004, the Company completed a business combination in which Vyteris, Inc. ("Vyteris, Inc."), a Delaware corporation, merged with a wholly-owned subsidiary of the Company (the "Merger"). As a result of the Merger, Vyteris, Inc. became the Company's wholly-owned subsidiary and the former stockholders of Vyteris, Inc. became stockholders of the Company. At the time of that business combination, the Company had no active business. As a result, the Company's principal business after that business combination became the business in which Vyteris has been engaged since its formation in November 10, 2000.

On May 2, 2005, we amended our Articles of Incorporation to change our name from Treasure Mountain Holdings, Inc. to Vyteris Holdings (Nevada), Inc. We also filed amendments to our Articles of Incorporation which, among other things, increased the number of shares of Common Stock that we are authorized to issue to 100,000,000 shares, authorized the issuance of 7,500,000 shares of Series B Preferred Stock, authorized the issuance of an additional 42,750,000 shares of preferred stock which may be issued, from time to time, pursuant to terms established by our Board of Directors and authorized a ten for one reverse stock split effective May 2, 2005. All share references in this Annual Report on Form 10-KSB/A give effect to this reverse stock split.

The terms "Company," "Vyteris," "Treasure Mountain," "us," "we" or "our" refer to each of Vyteris Holdings (Nevada), Inc., Vyteris, Inc. and the combined company. We refer to our holding company as "Vyteris Holdings" and "Vyteris Holdings (Nevada)".

After the Merger, the former stockholders of Vyteris, Inc. owned 98.2% of the outstanding common stock of the Company. The former directors of the Company resigned immediately prior to the Merger and the directors of Vyteris, Inc. immediately prior to the Merger became the sole directors of the Company. Similarly, the former officers of the Company resigned immediately prior to the Merger and the executive officers of Vyteris, Inc. immediately prior to the Merger became the sole officers of the Company. As a result of the Merger, although Vyteris Holdings (Nevada), Inc. is the parent company, the financial information included in this Annual Report on Form 10-KSB/A for periods prior to the Merger relates to Vyteris, Inc. as it is the accounting acquiror. The effects of the Merger on the consolidated financial statements of Vyteris, Inc. were not material.

Vyteris, Inc., formerly Drug Delivery Technologies, Inc., was incorporated on July 19, 2000 in the State of Delaware.

Our principal executive offices and manufacturing facilities are located at 13-01 Pollitt Drive, Fair Lawn, New Jersey 07410 and our telephone number is (201) 703-2299. Our website is located at WWW.VYTERIS.COM. Vyteris, Inc. had no operating activity prior to November 10, 2000 and operates in one business segment.

The Vyteris/ Vyteris Holdings Merger Agreement (the "Merger Agreement") provided for the following:

- o Each outstanding share of Vyteris common stock was automatically converted into the right to receive 0.419 shares of the Company's common stock. Immediately prior to the consummation of the Merger, there were 45,233,047 shares of Vyteris, Inc. common stock outstanding. Accordingly, the shares of Vyteris, Inc. common stock outstanding immediately prior to the consummation of the Merger have been converted into 18,952,647 shares of the Company's common stock.

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- o Each outstanding share of Vyteris, Inc. Series C convertible redeemable preferred stock was automatically converted into the right to receive one share of the Company's Series B convertible redeemable preferred stock. Each share of the Company's Series B convertible redeemable preferred stock is convertible into a number of shares of the Company's common stock equal to (i) 0.419 multiplied by (ii) the number of shares of Vyteris, Inc. common stock into which one share of Vyteris, Inc. Series C convertible redeemable preferred stock was convertible prior to the consummation of the Merger. The Vyteris, Inc. Series C convertible redeemable preferred stock was convertible into one quarter of a share of Vyteris, Inc. common stock if converted at any time within 18 months of March 31, 2004, one third of a share of Vyteris, Inc. common stock if converted at any time within the 18 months thereafter and two thirds of a share of Vyteris, Inc. common stock if converted at any time thereafter. Immediately prior to the consummation of the Merger, there were 7,500,000 shares of Vyteris, Inc. Series C convertible redeemable preferred stock outstanding. Accordingly, the shares of Vyteris, Inc. Series C convertible redeemable preferred stock outstanding immediately prior to the consummation of the Merger have been converted into 7,500,000 shares of the Company's Series B convertible redeemable preferred stock, which shares are currently convertible into the right to receive a total of 785,625 shares of the Company's common stock.
- o Each outstanding option and warrant to purchase one or more shares of Vyteris, Inc. common stock -- which we refer to as an existing option or an existing warrant - was automatically converted into an option or warrant to purchase one or more shares of the Company's common stock -- which we refer to as a new option or a new warrant. The number of shares of the Company's common stock covered by each new option or new warrant equals the number of shares of Vyteris, Inc. common stock covered by the corresponding existing option or existing warrant multiplied by 0.419. The exercise price of each new option or new warrant equals the exercise price of the corresponding existing option or existing warrant divided by 0.419. Immediately prior to the consummation of the Merger, there were existing options outstanding covering 3,766,911 shares of Vyteris, Inc. common stock and there were existing warrants outstanding covering 12,168,965 shares of Vyteris, Inc. common stock. Accordingly, upon consummation of the Merger, the existing options were converted into new options to purchase a total of 1,578,336 shares of the Company's common stock and the existing warrants were converted into new warrants to purchase a total of 5,098,796 shares of the Company's common stock.

By virtue of the Merger, warrants covering an additional 150,000 shares of the Company's common stock were granted to two former executive officers and directors of the Company.

BUSINESS OVERVIEW

We have developed and produced the first electronically controlled transdermal drug delivery system that delivers drugs through the skin comfortably, without needles. This platform technology can be used to administer certain therapeutics to the skin or into the bloodstream.

On May 6, 2004, we received approval from the FDA to commercially launch our first product, LidoSite. LidoSite is a topical delivery system indicated for use on normal intact skin to provide local anesthesia prior to needle stick procedures such as injections and intravenous therapies as well as superficial dermatological procedures. We have entered into a marketing agreement with B. Braun Medical, Inc., or B. Braun, to act as our exclusive, worldwide sales and marketing distributor for LidoSite. Commercial distribution of LidoSite began in January 2005. Our clinical data indicates that LidoSite reduces the pain associated with needle-stick procedures.

Our drug delivery technology cannot be applied to all drug compounds. We have screened a large number of drug compounds to ascertain if our drug delivery technology is applicable. The amount of drug required to be delivered to be effective, the size of the drug compound's molecule and the electrical charge of the drug compound, are the key determinants in establishing applicability. We are focusing our development efforts on a number of drugs within this group that target large potential markets and for which our technology may offer significant therapeutic, economic or lifestyle advantages over existing drug delivery methods. In addition to

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LidoSite, we have initiated development of two other products -- one to deliver a drug therapy for female infertility and one to deliver a drug therapy for migraine headaches. We also have a third product, at an earlier stage of development, for the active transdermal delivery of a currently marketed therapeutic drug to treat Parkinson's disease.

Our business strategy is to enter into arrangements with strategic partners for the development, marketing, sales and distribution of our future products. We expect that our strategic partners will finance some of our research and development expenses, finance the clinical trials and finance the costs of marketing, sales and distribution. In addition, we expect that our strategic partners will pay us a royalty on sales of the products and a transfer price on delivery of the manufactured products.

We recently entered into an agreement with Ferring Pharmaceuticals, Inc., or Ferring, a leading pharmaceutical company in women's health, with respect to the development, licensing and marketing of a female infertility therapy product based on our technology.

Our LidoSite product consists of a single-use, disposable patch containing a medication, lidocaine, and a small, re-usable and programmable electronic dose controller. Our compact system can be pre-programmed to deliver medication in numerous delivery profiles, from a single large dose to multiple timed and variable doses. We expect that our future products will be similarly constituted and that these advantages may increase the potential markets for targeted therapeutics, and in some cases create new markets.

The intellectual property that we own is based on significant improvements we have made to our drug delivery technology during our 14 years of research and development, ten of which were as a division of Becton, Dickinson and Company, or Becton Dickinson. We have a portfolio of U.S. and international issued patents. A significant portion of our intellectual property relates to the design and manufacture of our proprietary disposable, active transdermal patches and electronic dose controllers.

TECHNOLOGY

OVERVIEW OF ELECTROTRANSPORT, OR ACTIVE TRANSDERMAL DELIVERY

Our technology is based on a process known as electrotransport, or more specifically iontophoresis, a process that transports drugs through the skin by applying a low-level electrical current. This process differs significantly from passive transdermal drug delivery that relies on the slow, steady chemical diffusion of drugs through skin. Passive drug delivery patches have a limited number of applications: smoking cessation, birth control, hormone replacement therapy, angina and motion sickness.

By contrast, using electrotransport, certain drugs can be delivered through the skin many times faster than by passive transdermal patches. As a result, electrotransport is referred to as active transdermal delivery. Moreover, the delivery rate can be programmed or adjusted electronically. For example, active transdermal delivery can duplicate the steady or periodic delivery patterns of intravenous infusion.

Active transdermal delivery can be applied to more drugs than is possible with passive transdermal delivery. Furthermore, because the drug is only delivered when the current is on, our delivery system is precise, controllable and programmable. We believe that these attributes present a distinct advantage for the administration of many drugs where achieving precisely-controlled levels will greatly improve therapeutic outcomes as well as reduce or eliminate side

effects.

OUR APPROACH TO ELECTROTRANSPORT

Our proprietary technology is the result of over 14 years' of research while part of Becton Dickinson and after our acquisition from Becton Dickinson. Our goal, and the goal of the original developers of our technology at Becton Dickinson, was to fully realize the potential of this technology by creating irritation-free, easy to use, wearable, low-cost, and disposable systems that would be specifically designed to improve the administration of certain drugs to address high-value unmet medical needs.

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We have developed a proprietary approach encompassing a series of significant improvements to drug formulation and commercial manufacturing. We have used this approach with our first product, LidoSite. Many of our innovations center on the way we have approached designing and producing electronically controlled drug delivery patches. Our patches are pre-filled with the drug during the manufacturing process, making them easy to use. Our patches are designed to be low cost and disposable after a single use. Further, we have designed our patches so that they can be quickly and cost-effectively mass-produced using automated systems, which we believe will provide us with substantial cost efficiencies as we scale up our operations. Our patch design enables us to produce patches that are small and discreet.

To complement our patch design, we have approached the design of electronic controllers with the goal of assuring that they can be small, wearable, simple to operate and programmable to handle simple as well as complex drug delivery routines. The dose controller contains a miniature battery and circuitry that controls delivery rate and is capable of recording information on the amount and time of drug delivered. We believe the controllability and programmability offered by our technology are distinct competitive advantages that will enable our products to deliver more consistent and predictable results for a broad range of existing and new drugs. Using this technology, we believe we can create a variety of cost-effective, wearable, drug delivery systems that are discreet and easy to use in both a clinical environment as well as for day-to-day self-medication programs such as hormone treatment and pain management.

PRODUCTS

After careful analysis of many FDA-approved drugs suitable for iontophoresis, we have, thus far, identified the following four initial areas in which to concentrate our product development efforts: o local anesthesia, our LidoSite product;

- o female infertility;
- o migraine; and
- o Parkinson's disease.

We have signed a worldwide marketing and license agreement with B. Braun for our first product, our LidoSite product. We recently signed a second agreement, a development, licensing and marketing agreement for a female infertility product, with Ferring, a leading pharmaceutical company in woman's health. We plan to initiate clinical studies for our female infertility product in 2005. We completed a Phase I clinical study on our migraine product in 2004. There are several other products for treatment of osteoporosis, deep vein thrombosis, congestive heart failure, nausea and muscular dysfunction for which we are analyzing market need, technical feasibility and degree of difficulty in developing.

FIRST COMMERCIAL PRODUCT: LIDOSITE

Many patients, parents, and medical professionals see the pain of needle insertion as a significant concern. Pharmaceutical companies are developing products, including pulmonary insulin, nasal flu vaccine, and oral heparin, ostensibly to avoid needle-based administration. In a 2001 national survey by Omnitel Bruskin Research, 63% of parents considered children's visits to the doctor uncomfortable, and 1 in 5 said the pain associated with needle injections was a major concern. According to our internal research, there are over 250 million needle-stick procedures performed annually in U.S. hospitals, 33 million of which are pediatric, and an estimated 80 million pediatric immunization procedures performed in physicians' offices.

In an attempt to numb the skin prior to needle-stick procedures, clinicians have used local anesthesia products based on passive transdermal technology -- i.e., patches and creams. Such products have enjoyed some commercial success but have significant drawbacks because they are very slow to take effect, 60 to 90 minutes, and achieve limited depth of anesthesia.

Our LidoSite product uses our technology to achieve more rapid, deep local anesthesia prior to needle-stick procedures. We have received FDA approval to begin selling our LidoSite product in the United States. Commercial distribution of LidoSite began in January 2005. .

Our LidoSite product delivers lidocaine, along with a small quantity of epinephrine, a drug that helps lidocaine work faster and last longer by accelerating the onset of anesthesia and extending the duration of pain reduction. The system consists of a patch that adheres to the skin and contains the medication and a small reusable battery-powered, wearable electronic dose controller that connects to the patch. Placebo-controlled clinical studies have shown that use of our LidoSite product will significantly reduce the pain of both pediatric and adult needle-stick procedures, including blood draws and catheter insertions into a vein, as well as other skin incision or puncture procedures.

Our agreement with B. Braun calls for the Company to be responsible for manufacturing and delivering the LidoSite product to B. Braun at one site in the United States designated by B. Braun. Title and risk of loss transfer to B. Braun upon delivery of the LidoSite product by the Company. The Company has no storage obligations once the product has been delivered to B. Braun. B. Braun will be responsible for marketing, distribution and international registration and will have the right to distribute the product in such manner as it shall determine.

Commercial distribution of LidoSite began in January 2005. Our projected maximum production capacity is 2 million units per year on our current equipment. At this production level we do not anticipate making the units cost-effectively and expect to post a loss from the sale of LidoSite in the first year. In order to manufacture the product cost-effectively we need to increase our manufacturing efficiency. We are in the process of executing a manufacturing capacity expansion plan, which we believe will result in increased efficiency, through the leasing of additional manufacturing space and the acquisition of a second manufacturing line that is expected to operate at four to five times the capacity of our current equipment. This manufacturing expansion plan is expected to be completed in the second quarter of 2006. Our manufacturing expansion plan may be adversely impacted by unanticipated cost overruns and/or shortages of supply over which we have no control.

B. Braun, a multinational medical products company based in Melsungen, Germany, has over \$2.7 billion in worldwide revenue, and operates in over 50 countries with more than 28,000 employees. B. Braun is a U.S. market leader in regional anesthesia products with a U.S. sales force comprised of 100 dedicated sales representatives and more than 1,000 sales representatives through its distributor network. B. Braun markets a wide variety of healthcare products including infusion pumps, medical filters, needle-free intravenous systems, wound care products, surgical and anesthesia trays used for pain control, catheters, urological solutions and other medical and surgical supplies. We believe that B. Braun's focus on pain management, critical care and anesthesia products and its global marketing reach, make it an excellent distribution partner for our LidoSite product.

TARGET MARKETS FOR OUR LIDOSITE PRODUCT.

We believe the need for rapid dermal anesthesia is present in a broad and diverse array of market segments. The roll out of market adoption is planned to occur in four phases:

- o U.S. HOSPITALS - Launched in January 2005. B. Braun is positioning our LidoSite product for use with pediatric patients, 5-17 years old, and adults in hospitals to provide local dermal anesthesia prior to intravenous therapy starts, blood draws and other similar needle stick procedures.
- o OTHER U.S. MARKETS - Planned launch in 2005. These markets include dermatological and medical clinics.
- o FOREIGN MARKETS - Planned launch in 2006.

- o U.S. IMMUNIZATION MARKET - Planned launch in 2007. Targeted for children younger than five years, we intend to conduct clinical trials and apply to the FDA to extend our labeling to the younger segment to be able to serve more of the market for clinic and physician-office based immunizations, of which we estimate there are approximately 80 million performed annually in the U.S., based on birthrate statistics from the Department of Health and Human Services.

We have set forth above our best estimates of the timing of various aspects of this roll-out. Our estimates represent "forward-looking statements." Actual results could differ materially from such estimates as a result of various risks and uncertainties, including the risks described in "Risk Factors" in Item 6 of this Annual Report that could materially impact the timing of this roll-out.

KEY ADVANTAGES OF OUR LIDOSITE PRODUCT

We believe that our LidoSite product will have substantial advantages over other local anesthesia products available on the market because our clinical trials have shown it consistently prevents pain to a greater depth, thereby being useful for a wider range of procedures, reliably takes effect within 10 minutes as compared to 60 to 90 minutes for passive patches or creams, and is easy to use.

TRENDS SUPPORTING THE MARKET OPPORTUNITY FOR OUR LIDOSITE PRODUCT

Currently, the principal means of administering local dermal anesthesia, such as lidocaine, is by needle injection, which is fast, effective and long lasting. However, lidocaine injection, although widely-used for adult dermatological procedures, such as skin biopsy, and prior to the placement of large-bore hypodermic needles, such as for spinal punctures, is rarely used in children for the many routine needle-sticks associated with blood draws, intravenous catheter insertions and immunization.

The unmet clinical need for an alternative to lidocaine injection is evidenced by the market acceptance of a topically applied lidocaine cream, EMLA(R), marketed by Astra Zeneca. EMLA was introduced in 1997. According to IMS, sales of EMLA have increased each year since its introduction and approached \$80 million in 2002. According to the Journal of the American Academy of Dermatology (April, 2001), EMLA takes 60 to 90 minutes to achieve anesthesia. Despite this, EMLA has gained widespread acceptance as an alternative to lidocaine injection, especially in pediatric hospitals and clinics. Even when EMLA is given enough time to become effective, that is, 60-90 minutes, anesthesia is limited to a depth of 2-3 mm according to the Journal of the American Academy of Dermatology (April, 2001). We believe the onset time required and the depth of anesthesia achieved makes this product less suitable or impractical for many potential applications. Yet, despite the many drawbacks to EMLA, it has captured significant market share and growth since its introduction. We believe this is primarily due to its being the only legitimate alternative to an injection of lidocaine for topical anesthesia. Clinical trials have shown that our LidoSite product:

- o works faster -- 10 minutes;
- o provides deeper anesthesia -- 6-10 mm; and
- o is better suited for applications in the clinic, where time and staff productivity are important.

We anticipate that our LidoSite product will be priced competitively with EMLA on a per procedure basis.

ADDITIONAL PRODUCT PIPELINE

FEMALE INFERTILITY

We are in the early stages of development of a product to treat female infertility. It is designed to deliver an FDA-approved hormone which induces ovulation when delivered in short, timed pulses throughout the day and night. Current delivery methods fall short of this objective because they are inconvenient, costly and invasive. To be effective, medication must be delivered in multiple daily doses continuously for 14 days during a female's

28-day cycle. Women seeking the benefits of this therapy must either receive multiple injections per day or wear an uncomfortable intravenous pump. We believe that our potential infertility product would offer the possibility of administering this hormone in multiple transdermal pulses automatically, around the clock, in a convenient and comfortable manner.

According to a 2002 study from Business Communications Company, Inc., the total U.S. market for the treatment of infertility was \$2.1 billion in 2001 and is expected to grow to \$5.2 billion in 2006. We have already completed pre-clinical testing of this product and have demonstrated the feasibility of delivering multiple infusions of this hormone via iontophoresis through in vivo animal studies. Our data demonstrates that we can achieve blood hormone levels using pulsed iontophoretic delivery that are comparable to that achieved by multiple injections.

We have entered into a license and development agreement and a supply agreement with Ferring for an infertility product. The principal terms of the agreement call for Ferring and the Company to share the development costs, for Ferring to pay for the costs of the clinical trials and regulatory filings, for Ferring to make milestone payments to us, for Ferring to pay us a royalty based on sales and for Ferring to pay us a transfer price for manufacturing the product.

The remaining steps before marketing approval of this product include the successful completion of Phase I, Phase II and Phase III clinical trials. We estimate that this will take at least four to six years to complete.

MIGRAINE

The treatment of migraine requires rapid onset of medication. A class of compounds known as "triptans" is currently considered the best treatment. We believe that a significant opportunity exists to improve the efficacy of triptan therapy for migraines by changing the method by which triptans are administered. Taken orally, triptans often fail to deliver sufficient quantities of medication in the short time frame required to optimally treat migraine onset. Further, they often fail to prevent the second episode, known as recurrence, that many migraine patients suffer within 12 to 18 hours after a first attack. Our technology's programmed delivery capability allows rapid delivery into the bloodstream, to act fast in treating the headache, followed by a steady low-level maintenance dose to potentially prevent recurrence. This can be accomplished automatically in a non-invasive, convenient product. We know of no other product in the market or under development with this dual capability. This profile of delivery represents a unique and significantly improved therapy and we believe it could be a potentially effective way of preventing recurrent migraine headaches.

According to The Gale Group (PRNewswire, June 1999), approximately 23 million people in the U.S. suffer from severe migraine headaches. According to a report from Decision Resources, sales of prescription drugs to treat migraine totaled approximately \$1.9 billion in 1999 in the world's largest pharmaceutical markets, the U.S., the United Kingdom, France, Germany, Italy and Spain. That report also estimated that such sales would grow to \$3.1 billion by 2009. Many who suffer from migraine claim they cannot work or function during an attack; others feel extremely ill or depressed. We believe that being able to deliver a rapid dose followed by a steady, low-level maintenance dose non-invasively, over an extended period, would benefit many migraine sufferers. We initiated Phase I clinical investigations of a migraine product in July of 2004, and we are currently seeking to put a marketing, development and supply agreement in place with a potential partner. The remaining steps before marketing approval of this product are successful completion of additional pre-clinical studies and Phase I, Phase II and Phase III clinical studies. We estimate that it will take five to seven years, if not longer, before this product can be marketed for sale, although we cannot assure investors that further time will not be required or that we will ever reach commercialization of this product.

PARKINSON'S DISEASE

Parkinson's disease is a progressively debilitating illness, which breaks down areas of the brain that are thought to control the coordination of body movements. While the cause of this disease is unknown, the symptoms are believed to be caused by the brain's inability to produce dopamine, a naturally produced chemical that is responsible for healthy function of the human nervous system.

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Parkinson's is generally treated with dopamine or drugs that stimulate dopamine production called dopamine agonists, either alone or in combination. There are significant disadvantages and side effects associated with the oral delivery of dopamine agonists. We believe these side effects can be greatly reduced with our drug delivery technology. We have conducted preliminary research with a drug commonly used in the treatment of Parkinson's disease. Because active transdermal delivery has been shown to provide steady and highly precise delivery of drugs, as evidenced in our clinical trials and various research studies, we believe that an active transdermal product could benefit greatly the treatment of Parkinson's disease by providing a more steady and controlled level of drug in the blood stream than is possible by the ingestion of pills, which typically produce characteristic high, followed by low, blood levels of the drug as they are taken, digested and metabolized by the body. Bypassing the gastro-intestinal tract may reduce the incidence of nausea, and achieving a steady concentration of the drug in the blood stream may reduce the incidence of hallucination and nightmare. In addition, use of a once-a-day patch, in lieu of orally dosing three times per day, may improve patient convenience and compliance and may provide greater flexibility and control of dosing.

According to the National Parkinson Foundation, Inc.'s website, as many as 1.5 million Americans are currently afflicted with Parkinson's disease. The

remaining steps before marketing approval of this product are successful completion of additional pre-clinical studies and Phase I, Phase II and Phase III clinical studies. We estimate that this will take five to seven years, or longer.

We are currently engaged in pre-clinical development studies involving dopamine agonists.

OTHER THERAPEUTIC AREAS

We believe that the ability to provide painless, non-invasive programmable medication delivery has wide applicability in a variety of healthcare settings and for a wide variety of compounds and therapies. Our research and business development efforts are geared towards quantifying the opportunities and moving forward with the most promising of them. Examples of additional opportunities are: osteoporosis, deep-vein thrombosis, nausea, muscular dysfunction and congestive heart failure.

OUR STRATEGY

Our goal is to exploit our proprietary technology through the development and commercial introduction of a number of successful products incorporating pharmaceuticals into our drug delivery systems. Our business strategy is to identify unmet medical needs, define products that address those needs, evaluate the market potential of the defined products, develop such products through an appropriate clinical stage, partner with strong marketing companies, complete the development of such products in collaboration with our partners, manufacture such products, and commercially launch such products through our marketing partners.

We focus our efforts to apply our platform technology in therapeutic areas where our approach to drug delivery can substantially improve a drug therapy, offering advantages over existing methods of delivering the same drug. We intend to partner with pharmaceutical and other healthcare companies that are market leaders in the specific therapeutic areas and which can provide immediate market access and financial support during the later stages of clinical studies. Currently, we are focused on FDA-approved drugs. We believe this approach reduces clinical risks and eliminates certain costly and time consuming pre-clinical and clinical studies, thereby shortening time to approval and materially reducing costs.

To achieve our objectives, we plan to implement the following business strategy:

- o APPLY OUR DRUG DELIVERY TECHNOLOGY TO SPECIFIC THERAPIES WHERE IT CAN IMPROVE DELIVERY AND EFFICACY WHILE REDUCING SIDE effects. We plan to use our proprietary technology to create products that provide fundamental improvements in therapy, greatly improving drug efficacy, eliminating side effects and reducing patient discomfort and inconvenience, thereby improving compliance and lowering healthcare costs.

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We believe our patented platform drug delivery technology is applicable to a broad range of pharmaceuticals. Our goal is to use our technology to develop pharmaceutical products that are programmable, non-invasive, safe and effective, as well as offer consistent, predictable and reproducible results.

We intend to develop pharmaceutical products based on FDA-approved drugs that can substantially improve the therapeutic value of drugs currently delivered by oral means, injection, infusion or other means; expand market penetration for existing therapeutics currently delivered by oral means, injection, infusion or other routes; extend existing patent protection or offer new patent protection, providing important competitive advantages to our strategic partners and ourselves; and enable the commercialization of drugs or therapies that cannot be effectively administered through other drug delivery methods.

- o REDUCE DEVELOPMENT RISK AND COSTS BY FOCUSING ON APPROVED DRUGS. We plan to focus on drugs with proven safety and efficacy and that are approved for marketing by the FDA, but which have certain limitations in their existing delivery forms. We believe that working primarily with drugs that have demonstrated safety and efficacy, reduces our technical risks and development costs and therefore believe we will be able to bring new products to market faster.
- o RETAIN CONTROL OF PRODUCT DEVELOPMENT. In most cases, we plan to develop products through to at least proof of concept in humans before strategic partnering, thereby establishing more value for our products. We believe this will put us in a stronger position to

negotiate marketing agreements with prospective partners that will provide more value to us. We also plan to retain control of product development after partnering through to commercial introduction. By retaining control of product development we believe we will be able to retain a more significant share of product revenues.

- o DEVELOP MARKETING ARRANGEMENTS WITH LEADERS IN SPECIFIC THERAPEUTIC AREAS. We will seek marketing and late stage development partnerships with pharmaceutical companies that can provide established, significant market access as well as finance late stage clinical trials. Generally, we will expect our partners to handle sales, marketing and distribution while we retain manufacturing responsibility.
- o CONCENTRATE ON THERAPEUTIC AREAS WITH LARGE MARKETS. We intend to focus on areas where we believe that the U.S. market potential for each of our products is at least \$200 million annually and more than \$300 million on a worldwide basis. By the use of the term "market potential", we are referring to the dollar amount that we believe consumers would be willing to spend for safe and effective products focused on a specific need. We intend to target highly profitable applications of our technology where we believe we can materially increase, or even create, the market.
- o MANUFACTURE COMPLETE PRODUCTS. We have established an experienced manufacturing team. A substantial portion of our intellectual property resides in the design and manufacturing of our proprietary products. We intend to formulate, manufacture and package the patches and outsource the manufacture of the controllers. By controlling manufacturing, we believe that we can retain a greater share of product revenues, better protect and enhance our intellectual property, position ourselves to establish manufacturing economies of scale, create capacity to support a number of product partnerships, control costs, assure high quality and oversee regulatory compliance.
- o EXTEND THE APPLICATION OF OUR TECHNOLOGY. We intend to continue to further the development of our technology, through university collaborations and licensing and technology collaborations, to extend the ability of our technology to deliver larger molecules, and other high-value applications. We intend to continue to seek patent protection in the U.S. and elsewhere for our technological advances.

CLINICAL STUDIES

We have received FDA approval for the sale of our LidoSite product in the United States. Prior to receiving FDA approval, LidoSite underwent extensive clinical and laboratory testing, culminating in the completion of Phase III clinical studies in the fourth quarter of 2001. Those Phase III clinical studies involved 15 sites within the U.S. and over 1,000 human applications of our system, testing various aspects such as safety, wearability, pain sensation and reliability. Under the appropriate Investigative New Drug provision of the Food, Drug and Cosmetic Act, we conducted the following studies of our lidocaine system in humans.

PHASE I CLINICAL STUDIES.

Phase I clinical studies were initiated as early as 1995 and consisted of several series focused on:

- o finalizing the design of the system;
- o seeing how deep the numbness goes;
- o looking at the amount of drug that gets into the blood stream;
- o determining if it matters where you place the patch on the body;
- o making sure the lidocaine that is administered does not contaminate the blood samples that are drawn from the site where the patch was on the skin; and
- o comparing the performance of the patch to EMLA lidocaine cream.

PHASE II CLINICAL STUDIES.

One study of 48 pediatric, i.e., patients 5-18 years old, was conducted in a major mid-west children's hospital to measure the pain sensation, or lack thereof, associated with actual clinical use of the our lidocaine system. The participants were patients that needed to have a needle placed through their skin and into a vein because of the need to draw blood or the need to insert an intravenous catheter for infusion of IV medication. During these studies, which

were randomized and placebo-controlled, clinical investigators noted pain scores during needle penetration. From these studies, we were able to conclude that the system could be used easily on these patients and a statistically significant pain reduction was noted over the placebo patches.

PHASE III CLINICAL STUDIES.

We conducted four Phase III clinical studies to demonstrate the efficacy and safety of our lidocaine delivery system when used for local dermal anesthesia on intact skin. These large-scale studies consisted of two studies involving puncture of the skin by needles and two dermatological studies involving minor incisions of the skin or the use of lasers to treat skin conditions. In all, over 650 patients were evaluated in the four studies. The two large-scale studies consisted of a double-blind evaluation of our lidocaine delivery system in pediatric patients, ages 5 to 17, and a double-blind evaluation of the system in adult patients. In children aged 5 to 17 as well as adults, the study results demonstrated that those treated with our lidocaine delivery system reported significantly less pain than subjects treated with a placebo system. When we refer to a "double-blind evaluation," we are referring to a testing procedure in which both the patients and the administrators were unaware of which patients were receiving placebos and which patients were using our lidocaine system.

REGULATORY STATUS OF OUR LIDOSITE PRODUCT

Our LidoSite product is considered a "combination" product by the FDA, as it consists of a drug-filled patch and a device, our controller. For a combination product, approval by the FDA requires that a New Drug Application ("NDA") and a 510(k) notification be submitted to the FDA. In addition, an acceptable Pre-

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approval Inspection, or PAI, of our facility, quality systems and data documentation by the FDA was required. We have reached the following milestones with respect to the FDA approval process of our LidoSite product:

- o JULY 25, 2003. We received an "approvable" letter from the FDA indicating that the NDA for the drug component of the LidoSite product, i.e., the lidocaine-filled patch, was approvable pending a successful PAI, submission of certain additional information requested by the FDA and final determination of labels and labeling.
- o AUGUST 20, 2003. Our 510(k) pre-market notification of the electronic dose controller was determined by the FDA to be substantially equivalent to prior marketed devices and, therefore, cleared for sale.
- o JANUARY 30, 2004. The FDA completed its Pre-Approval Inspection, or PAI, of our facility. As a result of that inspection, the FDA's New Jersey District office recommended that the NDA be placed in an approvable status.
- o MAY 6, 2004. We received approval from the FDA to commercially launch our LidoSite product in the United States.

SALES, MARKETING AND DISTRIBUTION

Our agreement with B Braun calls for us to be responsible for manufacturing and delivery of the LidoSite product to B. Braun at one site in the United States designated by B. Braun. Title and risk of loss transfer to B. Braun upon delivery of the LidoSite product by us. We have no storage obligations once the product has been delivered to B. Braun. B. Braun will be responsible for marketing, distribution and international registration and will have the right to distribute the product in such manner as it shall determine. B. Braun, a multinational medical products company based in Melsungen, Germany, has over \$2.7 billion in worldwide revenue, and operates in over 50 countries with more than 28,000 employees. B. Braun is a U.S. market leader in regional anesthesia products with a U.S. sales force comprised of 100 dedicated sales representatives and more than 1,000 sales representatives through its distributor network. B. Braun markets a wide variety of healthcare products including infusion pumps, medical filters, needle-free intravenous systems, wound care products, surgical and anesthesia trays used for pain control, catheters, urological solutions and other medical and surgical supplies. We believe that B. Braun's focus on pain management, critical care and anesthesia products and its global marketing reach, make it an excellent distribution partner for our LidoSite product.

We currently rely on a single customer, B. Braun to generate product revenue. We granted B. Braun the right to be our exclusive, worldwide sales and marketing distributor for our LidoSite product. As a result, we are dependent upon B. Braun and its ability to effectively market our only current product. If

B. Braun is unable to sell the LidoSite product effectively, we do not have the ability to seek other customers for our LidoSite product at least until such time as satisfactory arrangements are made with B. Braun.

COMPETITION

Our LidoSite product, and any future products which we may develop, will likely compete with both conventional drug delivery methods and advanced drug delivery methods.

CONVENTIONAL DRUG DELIVERY METHODS

Traditionally, the pharmaceutical industry has relied on oral delivery and injection as the primary methods of administering drugs:

- o CONVENTIONAL ORAL METHOD. Conventional, oral drug dosage forms, such as pills and capsules, are the most common types of drug delivery. Oral drug delivery methods are easy to administer, but their efficacy can be limited because drugs must first pass through the digestive system and liver before being absorbed into the bloodstream. Orally delivered drug dosages must, therefore, be large to overcome the degradation that occurs in the gastrointestinal tract and liver. As a result, conventional

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oral dosage forms often produce higher initial drug levels than are required to achieve the desired therapeutic effects, thereby increasing the risk of side effects, some of which can be serious. Also, it is difficult to maintain therapeutically optimal drug levels using oral drug delivery methods. Further, oral drug delivery methods can require patients to follow inconvenient dosing routines, which may diminish patient compliance with self-medication schedules.

- o INJECTION METHODS. Injectable drug dosage forms generally provide rapid onset of therapeutic action and offer many of the same advantages as conventional oral drug dosage methods. Injectable drug delivery methods use needles, raising the possibility of needle-stick injuries, as well as the risk of infection to the caregiver and the patient. The use of needles also increases patient anxiety due to the pain of injection. Further, patients often find self-injectable therapies unpleasant. As a result, injected drugs for many chronic and subchronic diseases meet with varying degrees of patient acceptance and compliance with the prescribed regimens, which can lead to increased incidence of medical complications and potentially higher disease management costs. In addition, some elderly, infirm or pediatric patients cannot administer their own injections and require assistance, thereby increasing both the inconvenience to these patients and the cost of therapy.

ADVANCED DRUG DELIVERY TECHNOLOGIES

The limitations of conventional forms of drug delivery, such as oral and injection methods, have driven demand for advanced drug delivery alternatives that are safer, more effective and more convenient. Advanced drug delivery technologies have improved oral and injection methods as well as offering new means of administering drugs, such as through the skin and the respiratory system. Advanced drug delivery technologies include sustained release pills and injectables, passive transdermal patches and infusion pumps, as well as pulmonary, nasal, intravaginal and ophthalmic methods. In some cases, these technologies offer better control over the release of drugs into the bloodstream, thereby improving therapeutic efficacy and reducing side effects and risks. In other cases, advanced drug delivery technologies make therapies easier to administer and support more complex therapeutic regimens. Innovative drug delivery technologies can offer many advantages over traditional methods, including ease of use and administration, greater control of drug concentration in the blood, improved safety and efficacy, improved patient compliance, expanded indications for certain therapies, and totally new therapies using drugs that cannot be delivered otherwise.

The following is an overview of advanced drug delivery technologies and other alternative methods that could be direct or indirect competitors of our LidoSite product and any of our potential future products:

- |X| SUSTAINED RELEASE ORAL DOSAGE FORMS are designed to release the active ingredients of the drug into the body at either a predetermined point in time or at a predetermined rate over an extended period of time, generally do not work fast and may be partially destroyed by the liver and stomach before they get into the blood stream.
- |X| PASSIVE TRANSDERMAL PATCHES allow absorption of drugs through the skin and generally provide a convenient method of administering

drugs at a steady rate over an extended period of time, but onset of action may take hours after application, and absorption of the drug may continue for hours after the patch is removed, which can increase side effects. Additionally, because human skin is an effective barrier, most drug formulations will not passively permeate the skin in therapeutic quantities. There is also an element of variability associated with passive transdermal systems due to variations in skin characteristics.

- |X| SUSTAINED RELEASE INJECTABLE PREPARATIONS allow conventional injectable drugs to be incorporated into a biodegradable material that is then injected and absorbed slowly into the surrounding tissue. These preparations reduce the frequency of injections by creating a small "depot" of the drug beneath the skin that is slowly absorbed by the body, thus increasing the interval between injections. They can turn a conventional once-a-day injection into a once weekly or even longer regimen.

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- |X| CONTINUOUS INFUSION PUMPS are small implantable or externally-worn battery-powered pumps that introduce drugs directly into the body, using a needle or catheter inserted into tissue just below the skin or directly into the blood stream or spinal space. They use conventional drugs, and provide rapid onset of action as well as sustained or programmed delivery of medication. These are costly, complex electromechanical devices reserved mostly for treatment of chronic conditions such as the delivery of insulin for certain diabetes patients and for chronic intractable pain management for the treatment of certain forms of spasticity.
- |X| PULMONARY AND NASAL METHODS. Both pulmonary, or inhalation, delivery and nasal sprays are designed to provide fast action or to deliver drugs that are destroyed by the gastro-intestinal tract. Variations in a user's respiratory tract, often brought on by everyday occurrences such as a cold, infection or even changes in climate, can markedly affect the amount of drug inhaled from each spray. Nasal sprays can also cause irritation in some patients and usually it is not possible to adjust the amount of dose delivered in each sniff or spray. In addition, the patient cannot control dosage over a period of time, and patients and caregivers may have difficulty maintaining desired therapeutic effects.
- |X| TRANSMUCOSAL. Transmucosal technology enables drugs to be delivered through the body's mucosal surfaces. There are four means by which drugs can be delivered in this fashion: orally, nasally, rectally and vaginally. In limited situations, drug absorption through mucosal surfaces is effective because mucosal tissue is usually rich in blood supply, providing the means for rapid drug transport to the systemic circulation.
- |X| JET INJECTION. Jet injection drug delivery technology uses stored mechanical energy from either a spring or compressed gas cylinder to ballistically deliver a liquid or powder through the skin without a needle. Liquid jet injection has been used for many years with minimal success. A new technology allows the administration of small amounts of drugs in dry powder form through the skin using a specially engineered device, which propels the drug using a high-powered jet of helium gas. The gas accelerates the dry drug particles, enabling penetration of the skin.

Competition for our drug delivery products may come from any of these technologies.

The attractiveness of the local anesthesia market has compelled new entrants to challenge EMLA's market share and expand the market still further. One company, Iomed, Inc., has introduced an iontophoretic lidocaine delivery system into the market that is faster-acting than EMLA. However, we believe that Iomed's product, marketed under the label Numby Stuff(R), is complex and difficult to administer. Numby Stuff uses two separate, large electrode patches: a drug patch and a grounding patch. The drug patch does not come pre-filled with the drug; rather, it must be saturated with a specific liquid formula of lidocaine called Iontocaine(R), which is drawn from a vial prior to use. Both electrode patches in the Numby Stuff system must then be manually connected to the power supply/controller using "alligator" clip wires. The electronic controller is a benchtop model that is manually controlled by a nurse or doctor and cannot be conveniently worn by the patient. We believe that we will be able to compete with EMLA on the basis of speed of delivery, depth of delivery, suitability for clinics and price.

A number of other advanced local anesthesia products are currently or potentially under development. AlgoRx Pharmaceuticals, Inc., for example, is developing a jet injection lidocaine delivery system that will use a high-power jet of gas to propel a powder formulation of the drug through the skin. Other companies, such as Empi, Inc. and Life-Tech, Inc., have also developed iontophoretic systems similar to Iomed's Numby Stuff, but their systems are currently used with drugs other than lidocaine. We believe that the growing interest in local anesthesia products, despite their clinical limitations, is a positive indication of the healthcare industry's strong desire for an effective, non-invasive, local dermal anesthetic.

Alza Corporation, a Johnson & Johnson subsidiary, with its E-TRANS (R) system, is the only other company known to have developed pre-filled iontophoresis technology. Alza has chosen a very different application -- delivery of an opiate-based product for systemic pain management, for its first product. Alza has announced that it has received an "approvable" letter from the FDA. We believe that if there is eventual approval and

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market acceptance of Alza's first product, it would provide further validation of the potential value and utility of iontophoretic drug delivery, making this class of technology more attractive to the pharmaceutical and health-care industries. If the E-TRANS system is launched as a commercial product, we believe we can compete effectively against the E-Trans technology, because we believe we will offer our commercialization partners a lower cost system, since our product does not contain the expensive electronics contained in the Alza patches, and because we and Alza are addressing very different therapeutic applications. The Alza system was developed to treat pain associated with major surgery and cannot be used as a dermal anesthetic. We also believe that because Alza has incorporated the electronics into each patch, the added complexity of the product necessitates product development cycles for new applications that are significantly longer than those required by our system.

Birch Point Medical, a development stage company, currently markets in the U.S., through Smith and Nephew, a single use iontophoretic system called IontoPatch(TM), aimed at the physical therapy market. We believe that the IontoPatch product is not FDA-approved for any specific therapeutic indication and is not pre-filled with medication.

Becton Dickinson has substantial insight into the potential applications of our drug delivery technologies, and our business model, as we were operated as a division of Becton Dickinson for over ten years. Further, Becton Dickinson had a designee on our Board of Directors until May 2001.

Becton Dickinson is engaged in developing alternative drug delivery technologies and we may compete in the future with alternative technologies developed or acquired by Becton Dickinson. Under the "Transaction Agreement" that we entered into with Becton Dickinson dated November 10, 2000, Becton Dickinson is prohibited from competing directly with us in the field of active transdermal drug delivery technology (iontophoresis) for a five year period ending in November 2005. Becton Dickinson has developed drug delivery technology employing "micro-needles," tiny needles that deliver compounds into the first few hundred microns of the skin. This technology, which has not yet been commercialized, may compete directly with our current technology. We do not know whether or when Becton Dickinson will seek to commercialize this technology.

INTELLECTUAL PROPERTY

We protect our technological and marketing position in advanced transdermal drug delivery technology by filing U.S. patent applications and, where appropriate, corresponding foreign patent applications. Our success will depend in part upon our ability to protect our proprietary technology from infringement, misappropriation, duplication and discovery. Our policy is to apply for patent protection for inventions and improvements deemed important to the success of our business. We have a portfolio of United States patents and foreign patents. We have approached the design and development of our active transdermal drug delivery systems with the objective of maximizing overall delivery system efficiency while addressing commercial requirements for reproducibility, formulation stability, safety, convenience and cost. To achieve this goal, our delivery systems integrate proprietary and patented technology with commercially available, off-the-shelf components.

We have listed below, for each of our issued patents, the patent number, the title and the date on which the patent is expected to expire.

PATENT NUMBER	EXPIRATION DATE	TITLE/DESCRIPTION
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I. U.S. PATENTS

6,167,301	29-Aug-2015	Iontophoretic drug delivery device
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6,522,919	29-Aug-2015	having high-efficiency dc-to-dc energy conversion circuit
6,402,732	29-Aug-2015	Iontophoretic drug delivery device having high-efficiency dc-to-dc energy conversion circuit
6,208,891	04-Apr-2017	Disabling circuit for an iontophoretic system

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PATENT NUMBER	EXPIRATION DATE	TITLE/DESCRIPTION
6,385,488	20-May-2019	Method of increasing the reliability of iontophoresis system
6,678,555	20-May-2019	Method of increasing the reliability of iontophoresis system
6,394,994	27-Aug-2019	Method for testing the ability of an iontophoretic reservoir-electrode to deliver a medicament
6,377,848	25-Aug-2019	Methods of activating controller
6,047,208	27-Aug-2017	Method of detecting events or conditions in an iontophoretic drug delivery system
6,107,777	25-Jul-2017	Circuit for causing a voltage step in a multi-cell battery
6,009,344	25-Jul-2017	Iontophoretic drug delivery system
6,377,847	30-Sep-2013	Iontophoretic drug delivery device and reservoir and method of making same
6,228,206	30-Jul-2017	Bonding agent composition containing conductive filler and method of bonding electrode to printed conductive trace with same
5,738,647	27-Sep-2016	User activated iontophoretic device and method for activating same
5,882,677	30-Sep-2017	Iontophoretic patch with hydrogel reservoir
5,795,321	18-Aug-2015	Iontophoretic drug delivery system, including removable controller
5,498,235	30-Sep-2014	Improved iontophoretic drug delivery device
5,876,368	30-Sep-2014	Iontophoretic drug delivery device having improved controller and patch
5,688,232	28-Sep-2015	Iontophoretic drug delivery device having an improved controller
6,029,083	04-Apr-2017	Circuit and method for automatically turning off an iontophoretic system
5,935,598	18-Jun-2017	Iontophoretic delivery of cell adhesion inhibitors
5,961,483	30-Sep-2016	Iontophoretic delivery of cell adhesion inhibitors
6,629,968	10-Dec-2020	Shelf storage stable iontophoresis reservoir-electrode and iontophoretic system incorporating the reservoir-electrode
6,635,045	30-Jun-2020	Shelf storage stable iontophoresis reservoir-electrode and iontophoretic system incorporating the reservoir-electrode
5,983,133	29-Sep-2017	Iontophoresis system with voltage step-up circuit
6,350,259	18-Jun-2017	Iontophoretic electrode assembly and method for controlling delivery of drug using competing ions
6,584,389	17-Nov-2017	Low cost electrode for an iontophoretic device
5,246,418	17-Dec-2011	Iontophoresis system having features for reducing skin irritation
5,306,235	30-Sep-2012	Failsafe iontophoresis drug delivery system
4,950,229	25-Sep-2009	Apparatus for an electrode used for iontophoresis
5,320,597	06-Aug-2008	Device and method for renewing electrodes during iontophoresis
5,284,471	08-Feb-2011	Electrode and method used for iontophoresis
5,334,138	02-Aug-2011	Method and composition for increased skin concentration of active agents by iontophoresis
5,131,403	05-Jun-2011	Method for obtaining blood using iontophoresis

5,310,403	18-May-2012	Iontophoretic drug delivery device and circuit therefore
5,817,044	06-Oct-2015	User activated iontophoretic device
5,458,569	08-Jun-2013	Wearable iontophoresis system
5,302,172	12-Apr-2011	Method and composition for iontophoresis
D366,702	30-Jan-2010	Iontophoretic drug delivery controller

PATENT NUMBER	EXPIRATION DATE	TITLE/DESCRIPTION
D352,113	01-Nov-2008	Iontophoretic drug delivery system
D352,357	08-Nov-2008	Iontophoretic drug delivery system
5,954,684	30-Sep-2013	Iontophoretic drug delivery system and method for using same
5,540,669	30-Sep-2013	Iontophoretic drug delivery system and method for using same
5,494,679	27-Feb-2013	Molecules for iontophoretic delivery
5,843,015	28-Dec-2015	Molecules for iontophoretic delivery
D352,782	22-Nov-2008	Iontophoretic drug delivery system
5,645,526	30-Sep-2014	Apparatus and method for ensuring compatibility of a reusable iontophoretic controller with an iontophoretic patch
5,682,726	30-Sep-2014	Method for forming and packaging iontophoretic drug delivery patches and the like to increase stability and shelf-life
5,713,846	27-Sep-2016	Iontophoretic drug delivery system, including method for activating same for attachment to patient
5,688,231	18-Nov-2014	Iontophoresis assembly including cleanable electrical contacts
5,693,024	27-Sep-2016	Iontophoretic drug delivery system, including method for determining hydration of patch
5,899,876	27-Aug-2017	Multiple site drug delivery system
5,895,369	30-Sep-2014	Iontophoresis patch/controller interconnection using a conductive elastomer to provide noise-free electrical contact between patch and controller
5,730,715	14-Jun-2016	Device for the iontophoretic administration of bisphosphonates
5,735,810	14-Jun-2016	Device for the iontophoretic administration of bisphosphonates
5,857,994	01-Oct-2016	Awakenable iontophoretic delivery device for reducing electrical sensation upon application thereof
6,018,680	01-Oct-2016	Awakenable iontophoretic delivery device for reducing electrical sensation upon application thereof
5,792,097	27-Sep-2016	Iontophoretic electrodes and surface active agents
5,797,867	27-Sep-2016	Iontophoretic drug delivery system, including method for activating same for attachment to patient
5,919,156	27-Sep-2016	Iontophoretic drug delivery system, including unit for dispensing patches
5,873,850	29-May-2017	Locking and disfiguring mechanism for an iontophoretic system

II. FOREIGN PATENTS

735497	24-Jul-2018	Iontophoretic drug delivery system
0 934 098	22-Sep-2017	User activated iontophoretic device and method for activating same
0 934 098	22-Sep-2017	User activated iontophoretic device and method for activating same
0 934 098	22-Sep-2017	User activated iontophoretic device and method for activating same
0 934 098	22-Sep-2017	User activated iontophoretic device and method for activating same
2,249,039	29-Sep-2018	Iontophoretic patch with hydrogel reservoir
2,244,332	28-Jul-2018	Bonding agent and method of bonding electrode to printed conducted trace
69513672.0	29-Sep-2015	Improved iontophoretic drug delivery device
0 783 346	29-Sep-2015	Improved iontophoretic drug delivery device

PATENT NUMBER	EXPIRATION DATE	TITLE/DESCRIPTION
69509782.2	29-Sep-2015	Iontophoretic drug delivery device having improved controller and patch
0 783 344	29-Sep-2015	Iontophoretic drug delivery device having improved controller and patch
0 783 344	29-Sep-2015	Iontophoretic drug delivery device having improved controller and patch
0 971 769	02-Apr-2018	Circuit and method for automatically turning off an iontophoretic system
0 971 769	02-Apr-2018	Circuit and method for automatically turning off an iontophoretic system
0 971 769	02-Apr-2018	Circuit and method for automatically turning off an iontophoretic system
0 971 769	02-Apr-2018	Circuit and method for automatically turning off an iontophoretic system
P69225387.4	09-Dec-2012	Iontophoresis system having features for reducing skin irritation
0 547 482	09-Dec-2012	Iontophoresis system having features for reducing skin irritation
0 547 482	09-Dec-2012	Iontophoresis system having features for reducing skin irritation
49781/BE/98	09-Dec-2012	Iontophoresis system having features for reducing skin irritation
2026059	17-Dec-2011	Iontophoresis system having features for reducing skin irritation
0 448 299	15-Mar-2011	Method and composition for increased skin concentration of active agents by iontophoresis
0 448 299	15-Mar-2011	Method and composition for increased skin concentration of active agents by iontophoresis
0 448 299	15-Mar-2011	Method and composition for increased skin concentration of active agents by iontophoresis
0 448 299	15-Mar-2011	Method and composition for increased skin concentration of active agents by iontophoresis
2028663	15-Mar-2011	Method and composition for increased skin concentration of active agents by iontophoresis
P69221036.9	30-May-2012	Method for obtaining blood using iontophoresis
0 517 120	30-May-2012	Method for obtaining blood using iontophoresis
0 517 120	30-May-2012	Method for obtaining blood using iontophoresis
0 586 666	17-Mar-2013	User activated iontophoretic device
P69310844.4	17-Mar-2013	User activated iontophoretic device
0 586 666	17-Mar-2013	User activated iontophoretic device
0 586 666	17-Mar-2013	User activated iontophoretic device
25247/BE/97	17-Mar-2013	User activated iontophoretic device
0 586 666	17-Mar-2013	User activated iontophoretic device
2132348	17-Mar-2013	User activated iontophoretic device
2542792	17-Mar-2013	User activated iontophoretic device
2164850	18-Feb-2014	Wearable iontophoresis system
69424413.9	18-Feb-2014	Wearable iontophoresis system
0 702 579	18-Feb-2014	Wearable iontophoresis system
0 702 579	18-Feb-2014	Wearable iontophoresis system
24974/BE/00	18-Feb-2014	Wearable iontophoresis system
2802170	18-Feb-2014	Wearable iontophoresis system
2038097	12-Mar-2011	Method and composition for coiontophoresis
0 449 463	15-Mar-2011	Method and composition for iontophoresis
0 449 463	15-Mar-2011	Method and composition for iontophoresis

PATENT NUMBER	EXPIRATION DATE	TITLE/DESCRIPTION
0 449 463	15-Mar-2011	Method and composition for iontophoresis
0 449 463	15-Mar-2011	Method and composition for iontophoresis
2087087	11-Jan-2013	Molecules for iontophoretic delivery
0 552 878	12-Jan-2013	Molecules for iontophoretic delivery
0 552 878	12-Jan-2013	Molecules for iontophoretic delivery
0 552 878	12-Jan-2013	Molecules for iontophoretic delivery
0 552 878	12-Jan-2013	Molecules for iontophoretic delivery

22686/BE/99	12-Jan-2013	Molecules for iontophoretic delivery
2506543	12-Jan-2013	Molecules for iontophoretic delivery
0 934 097	19-Sep-2017	Iontophoretic drug delivery system, including method for activating same for attachment to patient
0 934 097	19-Sep-2017	Iontophoretic drug delivery system, including method for activating same for attachment to patient
0 934 097	19-Sep-2017	Iontophoretic drug delivery system, including method for activating same for attachment to patient
0 944 410	05-Sep-2017	Awakenable iontophoretic delivery device for reducing electrical sensation upon application thereof
0 944 410	05-Sep-2017	Awakenable iontophoretic delivery device for reducing electrical sensation upon application thereof
0 944 410	05-Sep-2017	Awakenable iontophoretic delivery device for reducing electrical sensation upon application thereof
0 944 410	05-Sep-2017	Awakenable iontophoretic delivery device for reducing electrical sensation upon application thereof

Iontophoresis, as a way of delivering drugs, has been well known for many years. Our patent portfolio consists of innovations that advance basic iontophoresis technology through:

- o enabling more efficient electrode designs;
- o drug formulations enhancing iontophoresis;
- o specific transdermal patch features allowing convenient use and low manufacturing cost;
- o electronic circuitry and program algorithms improving the safety and control of medication delivery; and
- o ability to deliver specific classes of molecules not previously possible.

We believe these patented features provide for improved clinical performance and provide a competitive advantage in manufacturing cost and quality. Some areas in which we have a particular concentration of patents are components, designs and formulations resulting in little to no skin sensation during delivery, delivery of cell adhesion inhibitors via iontophoresis, creating safe, single-use patches that cannot be inadvertently reused, and patches that can be used with drugs having limited aqueous stability.

The issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims of the patent. The patent positions of pharmaceutical, biotechnology and drug delivery companies, including our company, are uncertain and involve complex legal and factual issues. Accordingly, we cannot assure investors that our patents will prevent other companies from developing similar products or products which produce benefits substantially the same as our products, or that other companies will not be issued patents that may prevent the sale of our products or require us to pay significant licensing fees in order to market our products. If our patent applications are not approved or, even if approved, if such patents are circumvented or not upheld in

a court of law, our ability to competitively exploit our patented products and technologies may be significantly reduced. Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued. As a consequence, we do not know whether any of our patent applications will be granted with broad coverage or whether the claims that eventually issue or that relate to our current patents will be circumvented. Since patent applications in the United States can be maintained in secrecy until patents issue, and since publication of discoveries in scientific or patent literature often lag behind actual discoveries, we cannot be certain that we were the first inventor of inventions covered by our issued patents or pending patent applications or that we were the first to file patent applications for such inventions. Moreover, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, which could result in substantial cost to us, even if the eventual outcome is favorable. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require us to cease using the technology in dispute.

Also, patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by competitors, in

which case our ability to commercially exploit these products may be diminished.

From time to time, we may need to obtain licenses to patents and other proprietary rights held by third parties in order to develop, manufacture and market our products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially exploit such products may be inhibited or prevented. Additionally, we cannot assure investors that any of our products or technology will be patentable or that any future patents we obtain will give us an exclusive position in the subject matter claimed by those patents. Furthermore, we cannot assure investors that our pending patent applications will result in issued patents, that patent protection will be secured for any particular technology, or that our issued patents will be valid, enforceable and provide us with meaningful protection.

Although we have entered into invention assignment agreements with our employees and with certain advisors, if those employees or advisors develop inventions or processes independently which may relate to products or technology under development by us, disputes may arise about the ownership of those inventions or processes. Time-consuming and costly litigation could be necessary to enforce and determine the scope of our rights.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, through confidentiality agreements with our strategic partners, customers, suppliers, employees and consultants. It is possible that these agreements will be breached or will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. It is also possible that our trade secrets will otherwise become known or independently developed by competitors.

MANUFACTURING AND SUPPLIERS

PATCH MANUFACTURING

We have completed the design and development of all components of our single-use iontophoretic patches, including electrodes, printed circuitry, packaging and drug reservoirs. We have also designed, developed and constructed an automated manufacturing and assembly system for pre-commercial and commercial production of LidoSite patches. With this competency in place, we have the capability of developing and manufacturing other transdermal products.

Initially, we plan to conduct our manufacturing in a 14,000 square foot section of our 13-01 Pollitt Drive facility in Fair Lawn, New Jersey. We have developed and installed our first generation manufacturing line, the projected maximum production capacity of which is 2 million patches per year. Additional capacity -- namely, a second automated manufacturing line -- is under construction at our equipment supplier, with whom we have a contract and to whom, as of December 31, 2004, we had made payment of approximately \$1.6 million out of a total cost of \$1.8 million for the machinery, which should provide us with sufficient capacity for up to three years. That machinery is scheduled for delivery during 2005. We design, develop and maintain our own

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manufacturing processes, but use third parties to build the automated assembly equipment and fabricate replacement parts when necessary.

We recently executed a lease for a second facility to be utilized as we expand our manufacturing capacity. Operation of this second facility could result in substantial expenditures. See "Risk Factors -- Our need to expand our facilities will expose us to additional expenses that may materially adversely affect our results of operations" in Item 6 of this Annual Report.

ELECTRONIC DOSE CONTROLLER DEVELOPMENT AND MANUFACTURING

To date, we have gained significant expertise in the design and development of miniature, wearable electronic dose controllers using commercially available, off the shelf components assembled onto miniature circuit boards. The controller that has been developed for LidoSite is a simple, single-pulse device initiated by the push of a button, which turns on the electric current for a ten-minute interval as it delivers the drug. Sophisticated control circuitry senses the skin's electrical resistance and limits the amount of current that is delivered to a safe, comfortable level, thereby automatically adapting to a wide range of skin types and characteristics.

Although we designed and developed the controller, have assembled several prototypes and own various patents on its design, we outsource manufacturing on a non-exclusive basis to a company specializing in contract manufacturing of electronic medical devices. In this way, we can use the knowledge and facilities of the supplier towards the goal of manufacturing a high-quality, cost-effective controller available in quantities sufficient to meet market demand. Manufacturing processes and electronic components for the controller are fairly standardized and widely available.

Future versions of the dose controller for drugs other than lidocaine may incorporate features such as enhanced programmability, custom componentry including integrated circuitry, and radio frequency and telemetry technology as the designs evolve to fit various therapeutic applications and lifestyle aspects of the patient.

SUPPLIERS

Our principal suppliers are Hydrogel Design Systems, Inc., Advanced Labelworx and Altron Inc. We also purchase parts from single-source suppliers. Although we have not experienced significant production delays attributable to supply changes, we believe that, for integrated circuits and hydrogel in particular, alternative sources of supply would be difficult to develop over a short period of time. Because we have no direct control over our third-party suppliers, interruptions or delays in the products and services provided by these third parties may be difficult to remedy in a timely fashion. In addition, if such suppliers are unable or unwilling to deliver the necessary parts or products, we may be unable to redesign or adapt our technology to work without such parts or find alternative suppliers or manufacturers. In such events, we could experience interruptions, delays, increased costs, or quality control problems.

GOVERNMENTAL REGULATION

Under the United States Food, Drug and Cosmetic Act, "new drugs" must obtain clearance from the FDA before they can be marketed lawfully in the United States. Applications for marketing clearance must be based on extensive clinical and other testing, the cost of which is very substantial. Approvals -- sometimes including pricing approvals -- are required from health regulatory authorities in foreign countries before marketing of pharmaceutical products may commence in those countries. Requirements for approval may differ from country to country, and can involve additional testing. There can be substantial delays in obtaining required clearances from both the FDA and foreign regulatory authorities after applications are filed. Even after clearances are obtained, further delays may be encountered before the products become commercially available in countries requiring pricing approvals.

Product development generally involves the following steps which are required by the regulatory process:

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- o preclinical development, during which initial laboratory development and in vitro and in vivo testing takes place;
- o submission to the FDA of an investigational new drug application (IND) for the commencement of clinical studies;
- o adequate and well-controlled human clinical trials -- Phase I, II and III studies --to establish the safety and efficacy of the product;
- o submission of an NDA to the FDA requesting clearance to market the product and comparable filings to regulatory agencies outside the United States if the product is to be marketed outside of the United States; and
- o clearance from the FDA -- and foreign regulatory authorities, if applicable -- must be obtained before the product can be marketed.

Medical devices are subject to comparable regulatory requirements.

Each of these steps can take several years and can cost tens of millions of dollars. Failure to obtain, or delays in obtaining, regulatory clearance to market new products, as well as other regulatory actions and recalls, could adversely affect our financial results.

The packaging, labeling and advertising of pharmaceutical products are also subject to government regulation. The FDA recommends preclearing advertising materials prior to the launch of a product, and the launch materials for products receiving an accelerated FDA clearance must be precleared by the FDA. With an accelerated FDA clearance, all labeling and advertising must be submitted to the FDA 30 days prior to use, unless the FDA determines otherwise. In addition, the FDA may require that additional clinical studies - Phase IV studies - be completed after clearance to market a product has been granted.

Our research and development, manufacturing and distribution operations involve the use of hazardous substances and are regulated under international, federal, state and local laws governing health and safety and the environment. We believe that our operations comply in all material respects with applicable environmental laws and worker health and safety laws; however, the risk of environmental liabilities cannot be eliminated and we cannot assure investors that the application of environmental and health and safety laws to us will not require us to incur significant expenditures. We estimate that the annual

expenditures related for compliance with applicable health and safety and environmental laws is approximately \$0.1 million.

EMPLOYEES

At December 31, 2004, we had a staff of 73 employees, of which two are part-time employees and 71 are full-time employees. Of those 73 employees, 23 are in manufacturing and process development, 19 in regulatory, quality and analytical services, 15 in research and development, 2 in business development and marketing and 14 in administration and management. We believe that our relations with our employees is good.

INVESTOR INFORMATION

Our Internet website address is WWW.VYTERIS.COM. We make available, free of charge on our website, by clicking on the SEC filings link on our home page, our annual report on Form 10-KSB, quarterly reports on Form 10-QSB, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as soon as reasonably practicable after electronically filing such material with, or furnishing it to, the Securities and Exchange Commission (the "SEC").

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ITEM 2. PROPERTIES.

We sub-lease approximately 27,000 square feet of manufacturing, warehouse, laboratory and office space in Fair Lawn, New Jersey from Becton Dickinson. This sub-lease expires in 2006 and is renewable at Becton Dickinson's option. These facilities include manufacturing space sufficient to house our current patch manufacturing and packaging equipment, and a second manufacturing line currently being built to our specifications. Our facilities also contain prototype labs for simultaneous production of clinical supplies of multiple products, and nine additional labs for research and development and quality control purposes.

We recently entered into a lease for additional space located at 17-01 Pollitt Drive in Fair Lawn, New Jersey, approximately 200 yards from our headquarters building. The lease covers approximately 26,255 square feet of space. We intend to utilize the majority of this space as a second manufacturing facility. The lease term expires in March 2015.

ITEM 3. LEGAL PROCEEDINGS.

In January 1999, Alza Corporation filed an opposition in the European Patent Office, or EPO, against European Patent No. 0 547 482, entitled "Iontophoresis System Having Features for Reducing Skin Irritation." We refer to this patent as the "`482 patent." Becton Dickinson owned the `482 patent at the time Alza filed the opposition and filed an answer challenging the opposition. Becton Dickinson subsequently assigned the patent to the Company. The EPO issued a preliminary opinion on November 11, 2000 upholding the `482 patent. During an oral hearing in the opposition on March 5, 2001, however, the EPO ruled that the `482 patent's claims lacked an inventive step, and it therefore revoked the patent. We appealed the EPO's decision. We requested oral arguments and submitted written arguments to the EPO on March 26, 2004 for its consideration of amended claims believed patentable over the prior art of record.

In August 2000, Alza filed an opposition in the EPO against European Patent No. 0 783 346, entitled "Improved Iontophoretic Drug Delivery Device." We refer to this patent as the "'346 patent." Becton Dickinson then owned the '346 patent, and subsequently assigned the patent to us. In the opposition, Alza alleged that the patent should be revoked because, among other things, each of the claims lacks novelty or an inventive step over the prior art. We responded to the opposition by amending the specification of the patent, canceling two of the patent's claims, and submitting arguments that the remaining claims are patentable over the prior art. Subsequently the opposition was heard at the EPO on October 8, 2002 and the EPO panel ruled in favor of us. Alza has appealed the EPO panel's decision and final oral arguments will be required prior to a decision on the appeal.

In September of 2004, Alza filed an opposition in the EPO against European Patent No. 0 971 769, entitled, Circuit and Method for Automatically Turning Off an Iontophoretic System, which we refer to as the "`769 patent." In the opposition, Alza has alleged that the `769 Patent should be revoked because each of the claims lacks novelty or an inventive step over the prior art. The deadline for our response has been set for March 5, 2005.

During February 2005, we received correspondence from Dr. George Nascaris, whom we believe to be the principal of Greystone Healthcare Group, Inc., and Dr. Nascaris' counsel threatening to bring a lawsuit or mediation proceeding against us. in connection with a dispute over fees which Greystone alleges should have been paid pursuant to an agreement between us and Greystone with respect to an

alternative financing transaction which neither Vyteris, Inc. nor Vyteris Holdings (Nevada), Inc. has consummated, nor is currently pursuing. We believe that Greystone's claims are without merit and that, if such a suit or proceeding is actually commenced, that Vyteris Holdings (Nevada), Inc. and Vyteris, Inc. will have substantial defenses and counterclaims against Greystone. If such a suit or proceeding is actually commenced against either Vyteris Holdings (Nevada), Inc. or Vyteris, Inc., we intend to defend it vigorously.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

During the fourth quarter of 2004, there were no matters submitted to a vote of securities holders, through the solicitation of proxies or otherwise.

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PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

The Company's common stock became eligible to be traded in the over-the-counter market in February 2002. During 2004, quotations were published on the OTC Bulletin Board under the symbol "TMHI" and in the National Quotation Bureau, Inc. "pink sheets" under Treasure Mountain Holdings, Inc. We are not aware of an active trading market in the Company's shares and, accordingly, there is no history of reported trades in the public market for the Company's shares.

Based on shares outstanding as of December 31, 2004 there are approximately 845 holders of our common stock and two holders of our Series B convertible redeemable preferred stock.

As of December 31, 2004, the Company had not adopted any equity compensation plan. The following table provides information regarding options outstanding as of December 31, 2004.

<TABLE>
<CAPTION>

Plan Category	(a) Number Of Securities To Be Issued Upon Exercise Of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available For Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A))
-----	-----	-----	-----
<S>	<C>	<C>	<C>
Equity Compensation Plans Approved by Stockholders of Vyteris, Inc.	714,277	\$1.90	2,189,196
Equity Compensation Plans Not Approved by Such Stockholders	-----	-----	-----
Total	714,277	\$1.90	2,189,196

</TABLE>

This table reflects the 0.419 conversion ratio set forth in the Merger Agreement.

This table does not include options which we are now required to grant to Vincent De Caprio, our chief executive officer, by virtue of the adoption of certain amendments to our articles of incorporation. Under the terms of Dr. De Caprio's employment agreement, he is entitled to receive additional stock options to assure that he retains four percent beneficial ownership for a specified period of time. Upon filing these amendments, we granted to Dr. De Caprio options covering an additional 833,308 shares of our common stock.

DIVIDEND POLICY

We have never declared or paid any dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain future earnings, if any, to finance operations and the expansion of our business. Any future determination to pay cash dividends will be at the discretion of the board of directors and will depend upon our financial condition, operating results, capital requirements and other factors the board of directors deems relevant, including the provisions of any applicable credit agreements.

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

THE FOLLOWING DISCUSSION AND ANALYSIS SHOULD BE READ IN CONJUNCTION WITH THE OTHER FINANCIAL INFORMATION AND CONSOLIDATED FINANCIAL STATEMENTS AND RELATED NOTES APPEARING ELSEWHERE IN THIS FORM 10-KSB/A. THIS DISCUSSION CONTAINS FORWARD-LOOKING STATEMENTS THAT INVOLVE RISKS AND UNCERTAINTIES. OUR ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE ANTICIPATED IN THE FORWARD-LOOKING STATEMENTS AS A RESULT OF A VARIETY OF FACTORS, INCLUDING THOSE DISCUSSED IN "RISK FACTORS" AND ELSEWHERE IN THIS FORM 10-KSB/A.

MERGER

On September 29, 2004, the Company completed a business combination in which Vyteris, Inc. merged with a wholly-owned subsidiary of the Company. As a result of the Merger, Vyteris, Inc. became the Company's wholly-owned subsidiary and the former stockholders of Vyteris, Inc. became stockholders of the Company (See Item 1 of this Annual Report on Form 10-KSB/A.) At the time of that business combination, Vyteris Holdings (Nevada), Inc. had no active business. As a result, Vyteris Holdings (Nevada), Inc.'s principal business after that business combination became the business in which Vyteris, Inc. has been engaged since its inception in November 10, 2000.

After the Merger, the former stockholders of Vyteris, Inc. owned 98.2% of the Company's common stock. The former directors of the Company resigned immediately prior to the Merger and the directors of Vyteris, Inc. immediately prior to the Merger became the sole directors of the Company. Similarly, the former officers of the Company resigned immediately prior to the Merger and the executive officers of Vyteris, Inc. immediately prior to the Merger became the sole officers of the Company.

The consolidated balance sheet as of December 31, 2004 and 2003 and the consolidated statements of operations for the years ended December 31, 2004, 2003, 2002 and for the period from November 10, 2000 (inception) to December 31, 2004 consolidate the historical financial statements of Vyteris Holdings (Nevada), Inc. with Vyteris, Inc. after giving effect to the Merger, with Vyteris, Inc. as the accounting acquiror, by recording the transaction as the issuance of Vyteris, Inc. stock for the net monetary assets of Vyteris Holdings (Nevada), Inc. accompanied by a recapitalization with no goodwill or other intangibles recorded. Vyteris Holdings (Nevada), Inc. had been engaged in the development and operations of mining properties until 1957, when the operations were abandoned and Vyteris Holdings (Nevada), Inc. became inactive. Vyteris Holdings (Nevada), Inc. has been in the developmental stage since that date.

OVERVIEW OF THE COMPANY

We have developed and produced an electronically controlled transdermal drug delivery system that delivers drugs through the skin comfortably, without needles. This platform technology can be used to administer certain therapeutics either directly to the skin or into the bloodstream.

We are a development stage enterprise and, as yet, have not generated any revenues from product sales of our drug delivery system. Since we began operations on November 10, 2000, we have devoted the majority of our resources to the development of our first product, LidoSite. We have been unprofitable since our inception and have incurred a cumulative loss of \$56.0 million through December 31, 2004. These losses have resulted principally from expenses incurred in research and development activities. From inception on November 10, 2000 through December 31, 2004, we have incurred approximately \$34.8 million of research and development expenses, \$12.8 million of general and administrative expenses and \$10.3 million of interest expense, partially offset by revenues of \$0.9 million, interest income of \$0.4 million and \$0.6 million of cash realized through the sale of approximately \$7.2 million of our New Jersey net operating losses. Losses are expected to continue.

Our current business model is to exploit our proprietary technology through the development and commercial introduction of pharmaceutical products. We do not have sufficient capital or the sales and distribution capabilities to perform on our own, all of the steps involved in the commercial introduction of a pharmaceutical product and therefore must partner with pharmaceutical companies that can provide the necessary capital and the sales and distribution know-how and resources. Once we sign a development and

marketing agreement with a partner, our objective is to generate revenues from three sources: development fees and related milestone payments during the

product development and pre-commercialization phase, royalties on product sales made by our partners and manufacturing income from the supply of product to our partners.

The process of attracting development and marketing partners begins with one or more feasibility studies. Conducting feasibility studies is a normal recurring part of our business. Our business objective in conducting feasibility studies is to demonstrate the viability of our technology for the development of the product and thereby interest potential partners in entering into development, marketing and supply partnerships with us. Certain feasibility studies are funded by our potential development partners, while others are conducted at our own expense. We set the price for revenue producing feasibility studies at what we anticipate our actual costs to be. We do not expect to make a profit on such activities. Revenue generating feasibility studies have been limited to date and do not occur regularly and are not expected to produce significant revenues for us.

The business decision making process for choosing a product for development and partnering includes the evaluation of the size of the potential market for the product, the current and expected competition for that product, the expected selling price, the expected cost to manufacture, the sales and distribution capabilities of our potential partner, the patent status of the drug compound, the patent status of our technology with respect to the product, and the cost, timing and degree of difficulty to commercialize the product.

Our drug delivery technology is unproven in the market place; our LidoSite product is the first such product to be approved for commercial sale by the FDA. The unproven nature of our technology in the market place is the principal challenge we face in attracting a development and marketing partner. In certain instances we will perform feasibility studies on our own and use the data from those studies to attract the interest of potential partners.

In our development and marketing partnerships we will look to minimize our cash contribution to the development, clinical trials and FDA approval processes and maximize our revenues based on the commercial sales of the products. Each product is different in terms of the costs and time to develop, the clinical trials required, the FDA approval process, the projected manufacturing costs and the projected product pricing and sales levels. Therefore, each development and marketing partnership is expected to have materially different economics for our partners and us.

Developing pharmaceutical products is an inherently risky business. A pharmaceutical product can fail at any point during the development cycle. Pharmaceutical products can also fail after regulatory approval, as new safety information on the product becomes known after widespread use or as competitive products emerge.

As we intend to be the manufacturer of each new product, we will have to make significant investments in manufacturing equipment, test materials and facilities for each new product. Certain of our manufacturing lines require long lead times to construct. As a result, we may be required to invest in equipment well before we are able to use that equipment.

We currently conduct all of our product development, manufacturing and administrative activities at one location in Fair Lawn, New Jersey. We have recently entered into a lease for a second facility that is within walking distance of our current facility.

On May 6, 2004, we received approval from the FDA to commercially launch our first product, LidoSite. LidoSite is a topical delivery system indicated for use on normal intact skin to provide local anesthesia for needle stick procedures such as injections and intravenous therapies as well as superficial dermatological procedures. Our clinical data indicates that LidoSite reduces the pain associated with needle-stick procedures.

Our business model with respect to LidoSite was different than our current model. With the LidoSite product we completed the entire development and FDA approval process without a partner, seeking a partner for sales and distribution only.

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In 2002, we entered into a license, development and distribution agreement with B. Braun for our transdermal lidocaine delivery system, LidoSite. Upon signing the agreement, B. Braun made an upfront, non-refundable license fee payment of \$0.3 million to us, and purchased \$0.5 million of our common stock. B. Braun has an option to invest another \$0.5 million in equity upon commencement of sales of LidoSite.

The principal terms of the agreement provide that:

- o B. Braun will be responsible for the cost of marketing and selling the LidoSite product.

- o We will be responsible for the costs of manufacturing the LidoSite product.
- o B. Braun will have minimum purchase requirements of 636,000 LidoSite patches during 2005, 1,140,000 LidoSite patches during 2006, 1,995,000 LidoSite patches during 2007 and 2,992,500 LidoSite patches during 2008. Thereafter, B. Braun and we will negotiate the minimum purchase requirements annually.
- o B. Braun is obligated to pay us 60% of B. Braun's net selling price for the LidoSite product during 2005 and 2006, and 50% of the net selling price thereafter. Such payments are to be made on a calendar quarterly basis and are to be made within 45 days following the close of each calendar quarter.
- o We are obligated to sell the controller units to B. Braun at the lesser of \$30.00 or, at the price at which we purchase the controllers from a third party.
- o B. Braun is obligated to provide us with a binding, quarterly purchase order for the LidoSite patch and LidoSite controller at least 120 days in advance of the commencement of the quarter, together with a rolling forecast of orders of the succeeding three quarters. B. Braun is obligated to purchase at least 75% of the quantity of products set forth in the rolling forecast.

The license, development and distribution agreement with B. Braun is terminable upon a failure by the Company or B. Braun to comply with or perform any material provisions of the agreement. Upon termination, B. Braun will have the right to continue to purchase LidoSite patches and controllers for sale to those customers to whom B. Braun had contractual commitments. If the contract is terminated due to the failure of the Company to comply with contractual terms, then the Company is obligated to transfer and assign its rights in the NDA and 510(K) to B. Braun, B. Braun's license will become perpetual and B. Braun will acquire the right to manufacture or have manufactured the LidoSite patches and controllers.

Commercial distribution of LidoSite began in January 2005. Our projected maximum production capacity is 2 million units per year on our current equipment. At this production level we do not anticipate making the units cost-effectively and expect to post a loss from the sale of LidoSite in the first year. In order to manufacture the product cost-effectively we need to increase our manufacturing efficiency. We are in the process of executing a manufacturing capacity expansion plan, which we believe will result in increased efficiency, through the leasing of additional manufacturing space and the acquisition of a second manufacturing line that is expected to operate at four to five times the capacity of our current equipment. This manufacturing expansion plan is expected to be completed in the second quarter of 2006. Our manufacturing expansion plan may be adversely impacted by unanticipated cost overruns and/or shortages of supply over which we have no control.

In November 2000, Becton Dickinson transferred to us certain assets in exchange for common stock, preferred stock and a royalty agreement. Included in the transferred assets were certain patents. The royalty agreement requires us to pay a royalty to Becton Dickinson equal to the greater of 5% of revenues earned by us from the LidoSite product after November 20, 2005 or 20% of the royalties earned by us from the sale of products subsequent to November 10, 2005 that substantially use any of those certain patents.

Since our inception in November 2000, we have conducted feasibility studies on several potential products. These activities have resulted in one development and marketing agreement to date, the agreements with Ferring described below. In September 2004, we entered into two agreements with Ferring covering a product for female infertility. One of the agreements is a License and Development Agreement and the other, a Supply Agreement.

The principal terms of the License and Development Agreement and, the Supply Agreement, provide that:

- o We are responsible for all product development activities. Product development activities include all activities associated with the design, engineering and laboratory testing of the physical product and its manufacturing processes, including hardware, software, materials, components, specifications, procedures and manufacturing equipment.
- o Ferring is obligated to reimburse us for 50% of our product development costs, provided such costs do not exceed 110% of the amount budgeted.
- o Ferring is responsible for all regulatory filings.

- o Ferring is responsible for the conduct of, and cost of, clinical trials. Clinical trials include experimental testing of the product on humans in a clinical environment according to FDA guidelines to demonstrate safety and efficacy and ultimately gain FDA approval. This includes all activities associated with design of the experimental trials, selecting the test centers, personnel costs associated with carrying out the trials, acquisition and analysis of data from the trials, and presentation or publication of the data in a format suitable for submission to the FDA.
- o Ferring is obligated to pay up to \$9 million on the occurrence of certain events. \$250,000 of such fees had been earned by us and paid by Ferring as of February 8, 2005. Subsequent payments are due as follows:
 - o Successful development in animals of a twelve-hour patch: \$250,000.
 - o Election by Ferring to initiate Phase II Trials: \$2,500,000.
 - o Election by Ferring to initiate Phase III trials: \$3,500,000.
 - o The first submission in the United States of the NDA or approval by a regulatory authority in the United Kingdom, France, Germany, Spain and Italy, of an application to market the female infertility product: \$2,000,000.
 - o Receipt of FDA approval to market the female infertility product: \$500,000.
- o Ferring is also obligated to make revenue share payments to us and to pay a transfer price to us. The combination of the revenue share and transfer price payments to us are estimated by us to range from a low of 7% to a high of 20% of the revenues Ferring derives from the sales of the female infertility product (actual results could be materially higher or lower than this range). The statements made in this paragraph are "forward-looking statements" and there are no assurances that these projections will be attained. These forward-looking statements are subject to risks and uncertainties, including the risks outlined in this paragraph and under the "Risk Factors" identified below. Our potential revenue will depend upon on several factors, including the selling price per unit charged by Ferring, the gross sales of the product made in each year, the number of units sold and the contract year. In turn, the preceding factors are themselves dependent upon other factors, including but not limited to, the final patch and controller design, the number of patches to be used in a day, the number of days per course of therapy and the amount of drug to be loaded into each patch in order to achieve therapeutic levels of the active ingredient. As we are several years away from commercial launch of this product, we cannot predict with any degree of certainty the actual amount of revenues that we will derive from the Ferring agreements.

We have funded our operations from inception on November 10, 2000 through December 31, 2004 through an initial \$9 million equity investment made by Spencer Trask Specialty Group, LLC, or STSG; \$24 million of debt financing from STSG and its related parties, which was converted into common and preferred stock on March 31, 2004; \$15 million in gross proceeds from the sale of common stock and warrants through a private placement; \$8 million in gross proceeds from the sale of bridge notes, also referred to as the December Notes, subsequently converted to equity and warrants through a private placement; \$0.8 million received in connection with the B. Braun agreement; and \$0.6 million of cash realized through the sale of approximately \$7.2 million of our New Jersey net operating losses under a program sponsored by the State of New Jersey. In addition, STSG has agreed to provide us with up to \$5 million in a working capital facility.

On December 31, 2004 our cash position was \$6.4 million. We expect that our cash position of \$6.4 million, together with the funds to be made available to us under the working capital facility, will be sufficient to finance our operations at least through July 2005. We may need to raise additional funds, however, in order to fund operating contingencies, to develop new applications of our technologies, to respond to competitive pressures and/or to acquire or invest in complementary businesses, technologies or services. Additional funding may not be available on favorable terms or at all.

Our discussion and analysis of our financial position and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. Our significant accounting policies are described in Note 2 to the consolidated financial statements. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported revenues and expenses during the period.

We consider certain accounting policies related to revenue recognition, accrued expenses, stock-based compensation and operating expenses to be critical to our business operations and the understanding of our results of operations.

REVENUE

PRODUCT REVENUE. Through December 31, 2004, we have not had any product revenue. We will recognize product revenue, net of allowances for anticipated returns, provided that (1) persuasive evidence of an arrangement exists, (2) delivery to the customer has occurred, (3) the selling price is fixed or determinable and (4) collection is reasonably assured. Delivery is considered to have occurred when title and risk of loss have transferred to the customer. The price is considered fixed or determinable when it is not subject to refund or adjustments.

FEASIBILITY STUDIES. We conduct feasibility studies to demonstrate the viability of our technology to interest potential partners to enter into a development, marketing and supply partnership. Revenues on feasibility studies are measured using the proportional performance method of accounting. Such studies are typically completed within a one- to three-month period. Revenue producing feasibility studies do not occur regularly, are priced at what we anticipate the actual costs will be and are not expected to produce material revenues or a profit. When applying the proportional performance method, we rely on total expected input (contract) costs in order to determine the amount of revenue earned to date. We follow this method because reasonably dependable estimates of the revenue applicable to various contract milestones can be made. We monitor estimates of total contract revenues and cost on a routine basis throughout the contract period. The cumulative impact of any change in estimates of the contract revenues or costs is reflected in the period in which the changes become known. In the event that a loss is anticipated on a particular contract, provision is made for the estimated loss in the period in which the anticipated loss becomes known. We issue invoices related to fixed price contracts based on either the achievement of milestones during a project or other contractual terms. Differences between the timing of billings and the recognition of revenue based upon the proportional performance method of accounting are recorded as revenue earned in excess of billings or deferred revenue.

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DEFERRED REVENUE. Non-refundable upfront fees are deferred and recognized as revenue on a straight-line basis in accordance with the contract terms and generally over the lives of the agreements.

REVENUES FROM REIMBURSEMENT OF DEVELOPMENT COSTS. In accordance with Emerging Issues Task Force Issue 01-14, Income Statement Characterization of Reimbursements Received for "Out-of-Pocket" Expenses Incurred, we recognize revenues for the reimbursement of development costs when we bear all the risk for selection of and payment to vendors and employees.

ACCRUED EXPENSES

As part of the process of preparing our consolidated financial statements, we are required to estimate certain expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated expenses for which we accrue include professional service fees, contract service fees and fees paid to contract research organizations in connection with the conducting of clinical trials. Our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. In the event that we do not identify certain costs which have begun to be incurred or we under-estimate or over-estimate the level of services performed or the costs of such services for a period, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often estimated. We make these estimates based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

STOCK-BASED COMPENSATION

As permitted by Statement of Financial Accounting Standards ("SFAS") No. 123, Accounting for Stock-Based Compensation, we elected to follow Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ("APB No. 25") and related interpretations in accounting for our employee option plans. Under APB No. 25, no compensation expense is recognized at the time of an option grant if the exercise price of the employee stock option is fixed and equals or exceeds the fair market value of the underlying common stock on the date of the grant and the number of shares to be issued pursuant to the exercise of such options are fixed on the date of the grant.

We account for options issued to non-employees under SFAS No. 123 and Emerging Issues Task Force Issue No. 96-18, Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. The fair value of options issued to non-employees is recorded as an expense and we periodically re-measure the option value until the option is exercised, expired or forfeited.

Currently there is no active trading market for our common stock. Additionally, prior to the Merger, Vyteris, Inc. was a private company. Therefore determining the fair value of our common stock involves significant estimates and judgments. In considering the fair value of the underlying stock when we grant options, we consider several factors, including third party valuations and the fair values established by market transactions. Stock-based compensation includes estimates of when stock options might be exercised and stock price volatility. The timing for exercise of options is out of our control and will depend, among other things, upon a variety of factors, including our market value and the financial objectives of the holders of the options. We have limited historical data to determine volatility in accordance with Black-Scholes modeling. In addition, future volatility is inherently uncertain and the model has its limitations. These estimates can have a material impact on stock-based compensation expense in our consolidated statement of operations but will have no impact on our cash flows.

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OPERATING EXPENSES

RESEARCH AND DEVELOPMENT EXPENSES. Since inception on November 10, 2000, our research and development activities have been focused primarily on completing the development of, gaining regulatory approval for, and preparing for the commercial launch of our first product, LidoSite.

All costs related to the development of, and gaining regulatory approval for a product, and all costs incurred in preparing for the commercial launch of a product that must be approved by the FDA before commercial sales can commence, are expensed as incurred, including raw materials costs, manufacturing labor and allocation of overhead. Products manufactured with raw materials acquired subsequent to FDA approval will be capitalized as inventory. Our research and development expenses associated with LidoSite will be reduced in the first part of 2005 and subsequent periods as a result of this accounting treatment; however, we do not expect our total cash outlays to be less.

GENERAL AND ADMINISTRATIVE EXPENSES. Since inception on November 10, 2000, our general and administrative activities have been focused primarily on supporting our LidoSite product, attracting pharmaceutical partners, capital-raising activities, maintenance of our patent portfolio, building our staff and, more recently preparing ourselves to be part of a publicly-held company.

RECENTLY ISSUED ACCOUNTING STANDARDS

As permitted by SFAS, No. 123, we currently account for share-based payments to employees using APB No. 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of Statement No. 123 (revised 2004), Share-Based Payment, an Amendment of Financial Accounting Standards Board, FASB, Statements No. 123 and 95's, fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of adoption of Statement No. 123 (revised 2004) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted Statement No. 123 (revised 2004) in prior periods, the impact of that standard would have approximated the impact of Statement No. 123 as described in the disclosure of pro forma net income and earnings per share to our consolidated financial statements. Statement No. 123 (revised 2004) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. We cannot estimate what those amounts will be in the future because they depend on, among other things, when employees exercise stock options.

In November of 2004, the FASB issued SFAS No. 151, Inventory Costs, an Amendment of ARB No. 43, Chapter 4 ("SFAS No. 151"). SFAS No. 151 clarifies that abnormal amounts of idle facility expense, freight, handling costs and spoilage should be expensed as incurred and not included in overhead. SFAS No. 151 also requires that allocation of fixed production overheads to conversion costs should be based on normal capacity of the production facilities. The provisions in SFAS No. 151 are effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Companies must apply the standard prospectively. We do not believe that the impact of this new standard will have a material effect on our prospective financial condition or results of operations.

In December 2004, the FASB issued SFAS No. 153, Exchanges of Non-Monetary Assets, an Amendment of APB No. 29 ("SFAS No. 153"). SFAS No. 153 amends APB Opinion No. 29, "Accounting for Nonmonetary Transactions." Earlier guidance had been based on the principle that exchanges of nonmonetary assets should be based on the fair value of the assets exchanged and APB No. 29 included certain exceptions to this principle. However, SFAS No. 153 eliminated the specific exceptions for nonmonetary exchanges with a general exception for all exchanges of nonmonetary assets that do not have commercial and economic substance. A nonmonetary exchange has commercial substance only if the future cash flows of our company is expected to change significantly as a result of the exchange. SFAS No. 153 is effective for nonmonetary exchanges occurring in fiscal periods beginning after June 15, 2005. We do not believe that the impact of this new standard will have a material effect on our prospective financial condition or results of operations.

CONSOLIDATED RESULTS OF OPERATIONS

The following table sets forth the percentage increases or decreases in certain line items on our consolidated statement of operations for the years ended December 31, 2004 and 2003.

	YEARS ENDED DECEMBER 31,	
	2004 VS. 2003	2003 VS. 2002
Revenues.....	21.2%	32.1%
Research and development.....	31.1%	21.2%
General and administrative.....	65.8%	(15.1)%
Interest expense, net.....	327.9%	117.6%
Net loss.....	80.1%	16.4%

COMPARISON OF THE YEARS ENDED DECEMBER 31, 2004 AND 2003

REVENUES

Our revenues from inception (November 10, 2000) through December 31, 2004 have been minimal, totaling \$0.9 million and derived primarily from research feasibility studies for pharmaceutical companies and, in 2004, from the reimbursement of development costs. Total revenues were \$242,000 in 2004 compared to \$200,000 in 2003, an increase of 21.2% or \$42,000. The increase in revenues in 2004 relates to reimbursement of development costs of approximately \$138,000 and the recognition of approximately \$11,000 of deferred non-refundable upfront fees partially offset by a decrease of \$107,000 in feasibility study income earned during the period.

We recently entered into an agreement with Ferring for the development, licensing and supply of a product for female infertility. Product development activities and related revenues commenced during the fourth quarter of 2004. We received a license fee payment of \$0.15 million during 2004 and an additional \$0.1 million in the first quarter of 2005. Additionally, we could receive up to an additional \$8.75 million in payments upon the completion of significant milestones during the implementation of the development plan. When the product is commercially launched, we will receive revenue share payments based upon a percentage of net sales; however, commercial launch is several years away. In addition, a percentage of our product development activities will be reimbursed. License fees revenues will be deferred and recognized over the term of the agreement and reimbursement of product development activities will be recognized as incurred. This agreement may be canceled on short notice and may be terminated in the event that we do not maintain at least three months' cash, as defined in the agreement, during the development period.

We expect our revenues to increase beginning in the first quarter of 2005 with the commencement of sales of our LidoSite product by B. Braun in January 2005. First year sales are projected to be less than \$5 million during our first year of distribution. Our current production capacity is limited, as we will be launching LidoSite from a pilot manufacturing operation and, therefore, our revenues during 2005 from LidoSite will be constrained by our production capacity.

RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses were \$11.5 million for 2004, compared to \$8.7 million in 2003, an increase of 31.1% or \$2.7 million. This increase is primarily attributable to increases in our production, quality control and quality assurance staff in anticipation of the commercial launch of LidoSite, and expenditures for raw materials for practice production runs, as well as continued spending on stabilizing raw material suppliers and in preparation of the FDA's inspection of our facility and processes. We intend to continue to invest a significant percentage of our capital in our research and development efforts.

All costs related to the development of, and gaining regulatory approval of our LidoSite product, and all costs incurred in preparing for its commercial launch that must be approved by the FDA before commercial sales can commence, were expensed as incurred in 2004, including raw materials costs, manufacturing labor

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and allocation of overhead. Subsequent to the FDA's approval to commence commercial sales of LidoSite in the first part of 2005, all such costs will be capitalized as inventory. We expect that our research and development expenses associated with LidoSite may be reduced in the first part of 2005 and subsequent periods as a result of this accounting treatment; however, we do not expect our total cash outlays to be less.

GENERAL AND ADMINISTRATIVE EXPENSES

General and administrative expenses totaled \$4.1 million in 2004, compared to \$2.5 million in 2003, an increase of 65.8% or \$1.6 million. This increase of \$1.6 million is principally attributable to Merger related expenses incurred in 2004, additional headcount and various general and administrative costs required to operate as a public company.

INTEREST EXPENSE, NET

Interest expense, net, was \$7.6 million in 2004, compared to \$1.8 million in 2003, an increase of 327.9%, or \$5.8 million. This increase of \$5.8 million is principally attributable to non-cash interest expenses. Non-cash interest expense totaled \$6.2 million for 2004. The non-cash interest expenses related to our 8% convertible secured promissory notes due December 31, 2004, which we refer to as the December Notes; such expenses reflect the costs of the offering of the December Notes, the fair value of the warrants we issued to the investors in that offering, the fair value of the warrants issued to the placement agent in that offering and the beneficial conversion feature associated with the December Notes. Management estimated that the warrants issued to the investors with the December Notes had an aggregate fair value of approximately \$1.9 million and that the beneficial conversion feature had a value of \$2.4 million. These costs were recognized as interest expense during 2004.

Deferred financing costs of approximately \$2.4 million relating to the December Notes private placement transaction were initially capitalized and amortized over the term of the December Notes. Amortization expense of \$1.9 million was included in interest expense in the accompanying consolidated statements of operations in 2004. Upon the conversion of the December Notes into common stock, we recorded \$0.5 million of non-cash deferred financing costs in additional paid-in capital.

Effective upon the cancellation of all outstanding shares of the Vyteris, Inc. Series A convertible stock on September 29, 2004, the holders of our Series B convertible redeemable preferred stock were entitled to receive, ratably, an annual 8% cumulative dividend out of funds legally available therefore, payable quarterly. We have classified our Series B convertible redeemable preferred stock as a long-term liability in the accompanying consolidated balance sheets. Accordingly, we recorded interest expense of \$0.15 million for the period September 30, 2004 to December 31, 2004.

COMPARISON OF THE YEARS ENDED DECEMBER 31, 2003 AND 2002

REVENUES

Total revenues were \$200,000 for 2003 compared to \$151,452 for 2002, an increase of 32.1% or \$48,548. The increase of \$48,548 was related to an increase in feasibility study income earned during the period. Revenue generating feasibility studies do not occur regularly and are not the revenue base on which we plan to build our business.

We signed a License, Development and Distribution Agreement with B. Braun on September 20, 2002. Upon execution of that agreement, B. Braun made a

milestone payment of \$0.3 million to us and invested \$0.5 million in our common stock. The agreement also provides B. Braun with the option to invest up to \$0.5 million to purchase additional shares of common stock upon the commercial introduction of LidoSite. The \$0.3 million milestone payment will be recognized as revenue ratably over the ten-year contract term beginning with the commercial introduction of LidoSite.

OPERATING EXPENSES

RESEARCH AND DEVELOPMENT EXPENSES. We incurred \$7.2 million of research and development expenses during 2002. During 2003, our research and development expenses increased by 21.2%, or \$1.5 million, to \$8.7 million. During 2002 most of our research and development activities were devoted to the preparation and filing of our NDA for LidoSite. During 2003 our research and development efforts were focused upon the stabilization of suppliers of raw materials for LidoSite, responding to the FDA on our NDA for LidoSite, preparing and validating our systems and processes for our FDA inspection, increasing our production and quality staff and preparing our facility for the commercial manufacture of our LidoSite product.

GENERAL AND ADMINISTRATIVE EXPENSES. General and administrative expenses totaled \$2.9 million in 2002. General and administrative expenses declined by 15.1% to \$2.5 million in 2003. This decline was primarily related to the fact that the costs of maintaining and defending our patent portfolio were materially less in 2003 than in 2002.

INTEREST EXPENSE, NET

During 2002 and 2001, we issued approximately \$11.0 million aggregate principal amount of debt instruments, resulting in interest expense of \$0.8 million for the year ended December 31, 2002. During 2003, we issued an additional \$13.0 million aggregate principal amount of debt instruments, resulting in interest expense of \$1.8 million for the year ended December 31, 2003.

LIQUIDITY AND CAPITAL RESOURCES

From inception (November 10, 2000) through December 31, 2004, we have used \$42.9 million in cash in our operating activities. The principal factor in this use of cash has been our net loss, which aggregated \$56.0 million since our inception date through December 31, 2004. Our cumulative net loss, in turn, has resulted principally from \$34.8 million of expenditures we have incurred in our research and development efforts, \$12.8 million of general and administrative expenses and \$10.3 million of interest expense. Partially offsetting our cumulative net loss is depreciation and amortization expense of \$8.6 million and a \$5.0 million increase in accounts payable, accrued expenses and amounts due to related parties.

From inception (November 10, 2000) through December 31, 2004, we used \$3.0 million of cash in investing activities, reflecting purchases of equipment, the largest component of which is our second manufacturing line. We have nearly completed the payments of our second manufacturing line: through December 31, 2004, we had paid \$1.6 million of the total purchase price of \$1.8 million. We can expect a significant increase in equipment purchases when and if it becomes necessary to add additional manufacturing capacity.

We have funded our operations and equipment purchases through our financing activities, producing \$52.3 million in net cash from inception (November 10, 2000) through December 31, 2004. Our principal stockholder, STSG, contributed \$9 million at our inception; we used those funds to fund our initial operations after we acquired the transdermal systems unit of Becton Dickinson from Becton Dickinson. From that time until 2004, STSG remained our principal source of capital. During 2002 we financed our operations through the issuance of \$9.7 million of convertible debt to STSG and other related parties, as well as through a \$0.5 million equity investment by B. Braun and an up-front license fee payment by B. Braun of \$0.3 million. During 2003, we issued \$10 million of convertible debt and \$2.9 million of secured debt to STSG and other related parties.

On March 31, 2004, we consummated a transaction with STSG and a related entity. We issued to STSG and such related party an aggregate of 23 million shares of Vyteris, Inc. common stock (which were converted into 9,637,000 shares of the Company's common stock upon consummation of the Merger) and 7.5 million shares of Vyteris Series C convertible redeemable preferred stock (which were converted into 7.5 million shares of the Company's Series B convertible redeemable preferred stock upon consummation of the Merger) in exchange for (i) the cancellation of \$20.4 million principal amount of convertible, secured promissory notes, \$2.9 million principal amount of secured promissory notes and \$2.6 million of accrued and unpaid interest, (ii) the return of 3,000,000 shares of Vyteris, Inc. Series B convertible redeemable preferred stock and (iii) the

warrants to purchase 852,665 shares of common stock. This transaction reduced our debt by approximately \$25.9 million, increased our preferred stock by approximately \$4.6 million and increased our common stock and paid-in capital by approximately \$21.3 million. On the same date, we completed a 1:4 reverse stock split of the Vyteris, Inc. common stock. All share figures presented in this Annual Report give retroactive effect to that stock split.

During March, April and May, 2004, we issued \$8.0 million of bridge notes, maturing December 31, 2004 (our "December Notes" or our "Bridge Notes"). Additionally, \$0.5 million principal amount of convertible debt issued to related parties in the first quarter of 2004 converted into that financing. Spencer Trask Ventures, Inc., an affiliate of our controlling stockholder, acted as placement agent in that transaction and received a 10% placement fee, a 3% non-accountable expense allowance and warrants to purchase 2,549,250 shares of Vyteris, Inc. common stock at \$1.00 per share (which were converted into warrants to purchase 1,068,135 shares of the Company's common stock at \$2.39 per share upon consummation of the Merger) as compensation for acting as placement agent. We also issued warrants to the investors to purchase 4,248,750 shares of Vyteris, Inc. common stock at \$1.00 per share (which were converted into warrants to purchase 1,780,226 shares of the Company's common stock at \$2.39 per share upon consummation of the Merger). During September 2004, the \$8.5 million of December Notes converted into a total of 8,497,500 shares of Vyteris, Inc. common stock (which were converted into 3,560,453 shares of the Company's common stock upon consummation of the Merger).

In an offering consummated in September 2004, we received gross proceeds of approximately \$15 million -- including debt incurred in September 2004 which was subsequently converted into equity -- upon the sale of common stock and warrants. We issued to the investors a total of 10,040,076 shares of Vyteris, Inc. common stock (which were converted into 4,206,792 shares of the Company's common stock upon consummation of the Merger) and also issued warrants to the investors to purchase 2,510,019 shares of Vyteris, Inc. common stock at \$1.875 per share (which were converted into warrants to purchase 1,051,698 shares of the Company's common stock at an exercise price of \$4.47 per share upon consummation of the Merger). Spencer Trask Ventures also acted as one of the two placement agents in that offering. The placement agents received a 10% placement fee, a 3% non-accountable expense allowance and warrants to purchase 2,510,019 shares of Vyteris, Inc. common stock at \$1.50 per share (which were converted into warrants to purchase 1,051,698 shares of the Company's common stock at \$3.58 per share upon consummation of the Merger) as compensation for acting as placement agents. We realized net proceeds from the offering of \$12.3 million.

Immediately prior to the offering, Spencer Trask agreed to provide us (or, at its option, cause a related party to provide us) with up to \$5.0 million in working capital loans in the form of 11.5% secured demand promissory notes (the "Working Capital Facility"). Pursuant to the terms of the Working Capital Facility, amounts drawn under the facility must be repaid on or before November 15, 2005. As consideration for the commitment of the Working Capital Facility, we issued 1,000,000 shares of Vyteris, Inc. common stock (converted into 419,000 shares of the Company's common stock upon consummation of the Merger) to Spencer Trask and recorded the fair value of these shares as deferred financing costs of \$1.3 million. Each time funds are loaned to us under the Working Capital Facility, we will be required to issue to the lender a common stock purchase warrant to purchase such number of shares equal to the quotient obtained by dividing (i) 40% of the amount loaned by (ii) 3.58. The warrants are exercisable for five years from the date of issuance and have an initial exercise price of \$3.58 per share. The Working Capital Facility enables us to borrow up to the lesser of \$5.0 million or the sum of qualifying accounts receivable and inventory. At December 31, 2004, our qualifying accounts receivable and inventory were de minimus, pending commencement of the commercialization of our first product. Management estimates that it will borrow funds under this Working Capital Facility in the second quarter of 2005. As of December 31, 2004, no amounts have been loaned to us under the Working Capital Facility. If used, the Working Capital Facility will be secured by a first priority lien on all of our assets.

CASH POSITION

As of December 31, 2004, we had a cash balance of \$6.4 million and working capital of \$6.2 million as compared with a cash balance of \$2.3 million and negative working capital of (\$25.0) million at December 31, 2003. The increase in working capital is primarily due to the March 31, 2004 recapitalization transaction with STSG and a related entity, the issuance of \$8.5 million of

Bridge Notes and \$12.3 million net proceeds from the offering of common stock and warrants in September 2004.

We expect that our cash position of \$6.4 million at December 31, 2004 together with the funds to be made available to us under the Working Capital Facility will be sufficient to finance our operations at least through July 2005. We may need to raise additional funds, however, in order to fund operating contingencies, to develop new applications of our technologies, to respond to competitive pressures and/or to acquire or invest in complementary businesses, technologies or services. Additional funding may not be available on favorable terms or at all.

We expect that the internal and external costs of complying with the Sarbanes-Oxley Act of 2002 will be substantial.

We expect to devote substantial resources to scale-up the manufacturing process for our LidoSite product, to expand our manufacturing capacity for LidoSite and to continue the development of our infertility product. Our funding requirements will depend on numerous factors, including the following:

- o manufacturing costs of LidoSite;
- o LidoSite sales which commenced in the first quarter of 2005;
- o the time and costs required for us to scale-up our manufacturing process;
- o our ability to enter into development partnerships with pharmaceutical companies;
- o the results of the development activities on our planned new products; and
- o the cost involved in preparing, filing, prosecuting, defending, maintaining and enforcing patent claims and other patent related costs.

We have filed a registration statement with the SEC relating to the resale of shares of the Company's common stock. Since that registration statement was not declared effective by the SEC by February 25, 2005, we are obligated to pay to certain stockholders an amount equal to 1% of the purchase price paid by such stockholders for the shares owned by such stockholders which are covered by the registration statement, and for each month, or portion of a month, in which such delay continues, an amount equal to 2% of such purchase price, until we have cured the delay, with an overall cap on such liquidated damages of 10% of the aggregate purchase price paid by such stockholders for such shares. The registration statement has not yet been declared effective. Such liquidated damages could amount to up to \$2.4 million, depending upon when the registration statement is ultimately declared effective by the SEC. Payments of substantial liquidated damages will adversely affect our financial condition.

CONTRACTUAL OBLIGATIONS AND OTHER COMMITMENTS

Our contractual obligations and commitments include obligations associated with capital and operating leases, manufacturing equipment, employee agreements and university research agreements as set forth in the table below:

<TABLE>
<CAPTION>

	PAYMENTS DUE BY PERIOD AS OF DECEMBER 31, 2004				
	TOTAL	LESS THAN 1 YEAR	1-3 YEARS	3-5 YEARS	MORE THAN 5 YEARS
<S>	<C>	<C>	<C>	<C>	<C>
Operating lease obligations.....	\$ 3,567,239	\$ 442,843	\$ 743,746	\$ 567,545	\$ 1,813,105
Manufacturing equipment.....	173,400	173,400	--	--	--
Capital lease obligations.....	31,620	20,288	11,332	--	--
Employee agreements.....	570,479	570,479	--	--	--
University research agreement	89,145	83,625	5,520	--	--
Total.....	\$ 4,431,883	\$ 1,290,635	\$ 760,598	\$ 567,545	\$ 1,813,105

</TABLE>

Effective as of September 28, 2004 upon cancellation of all outstanding shares of the Vyteris, Inc. Series A convertible preferred stock, the holders of the Company's Series B convertible redeemable preferred stock are entitled to

receive an annual cash dividend of 8% of the then applicable redemption price, as defined, out of funds legally available, payable quarterly. The dividends with respect to the Company's Series B convertible redeemable preferred stock are cumulative (from the time that the Vyteris, Inc. Series A convertible redeemable preferred stock was retired), whether or not earned or declared and shall be paid quarterly in arrears. All of the outstanding shares of Vyteris, Inc. Series A convertible redeemable preferred stock were cancelled on September 28, 2004. We accrued dividends on the Company's Series B convertible redeemable preferred stock of \$0.15 million in the fourth quarter of 2004. We expect to accrue dividends of \$0.6 million per year.

Commencing on of the first anniversary date of the first commercial sale of LidoSite, and continuing for one year thereafter, the Company will be required to redeem on a quarterly basis an amount of the Company's Series B convertible redeemable preferred stock equal to 5% of the gross profits derived from the sale of LidoSite. During the following years, we will be required to redeem (on a quarterly basis) an amount of the Company's Series B convertible redeemable preferred stock equal to 10% of the gross profits derived from the sale of LidoSite. The redemption price of the Company's Series B convertible redeemable preferred stock is \$1.00 per share (adjusted for splits, etc.) plus any accrued but unpaid dividends.

FORWARD-LOOKING INFORMATION

This Annual Report on Form 10-KSB/A contains forward-looking statements (within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended). When used in this Form 10-KSB/A, the words "anticipate," "believe," "estimate," "will," "plan," "seeks," "intend," and "expect" and similar expressions identify forward-looking statements. Although we believe that our plans, intentions, and expectations reflected in any forward-looking statements are reasonable, these plans, intentions, or expectations may not be achieved. Our actual results, performance, or achievements could differ materially from those contemplated, expressed, or implied, by the forward-looking statements contained in this Annual Report on Form 10-KSB/A. Important factors that could cause actual results to differ materially from our forward looking statements are set forth in this Annual Report on Form 10-KSB/A, including under the heading "Risk Factors." All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements set forth in this Annual Report on Form 10-KSB/A. Except as required by federal securities laws, we are under no obligation to update any forward-looking statement, whether as a result of new information, future events, or otherwise.

RISK FACTORS

YOU SHOULD CAREFULLY CONSIDER THE RISKS DESCRIBED BELOW TOGETHER WITH ALL OF THE OTHER INFORMATION INCLUDED IN THIS ANNUAL REPORT ON FORM 10-KSB/A WHEN EVALUATING THE COMPANY AND ITS BUSINESS. IF ANY OF THE FOLLOWING RISKS ACTUALLY OCCURS, OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS COULD SUFFER. IN THAT CASE, THE PRICE OF OUR COMMON STOCK COULD DECLINE AND OUR STOCKHOLDERS MAY LOSE ALL OR PART OF THEIR INVESTMENT.

WE HAVE NEVER BEEN PROFITABLE, WE MAY NEVER BE PROFITABLE, AND, IF WE BECOME PROFITABLE, WE MAY BE UNABLE TO SUSTAIN PROFITABILITY.

From November 10, 2000 (inception) through December 31, 2004, we incurred net losses in excess of \$56.0 million, as we have been engaged primarily in clinical testing and development activities, and have had no revenues from the sale of products. We have never been profitable, we may never be profitable, and, if we become profitable, we may be unable to sustain profitability. We expect to continue to incur significant losses for the foreseeable future.

WE WILL LIKELY BE REQUIRED TO RAISE ADDITIONAL CAPITAL, WHICH IF NOT AVAILABLE TO US ON ACCEPTABLE TERMS, OR AT ALL, WILL MATERIALLY AND ADVERSELY HARM OUR BUSINESS AND THREATEN OUR CAPACITY TO REMAIN IN BUSINESS.

We anticipate that we have sufficient capital to finance operations only through July 31, 2005. Given the working capital demands that we face in order to ramp up production of our LidoSite product, we will likely be required to raise additional capital in the near future. We cannot be certain that such capital will be available to us or, if it is available to us, we cannot be certain that such capital will be available on terms that are acceptable to us. Such financing could be dilutive to existing stockholders and could result in significant financial and operating covenants that would negatively impact our business. If we are unable to raise sufficient additional capital on acceptable terms, we will be forced to restrict new product development and may be unable

to continue our manufacturing and other business operations. If we do not have sufficient capital to support the manufacture of our LidoSite product, we may be unable to remain in business.

OUR RECENT AUDITED FINANCIAL STATEMENTS CONTAIN, AN EXPLANATORY PARAGRAPH EXPRESSING UNCERTAINTY REGARDING OUR ABILITY TO CONTINUE AS A GOING CONCERN. THE INCLUSION OF THIS PARAGRAPH MAY MAKE IT MORE DIFFICULT FOR US TO RAISE ADDITIONAL CAPITAL ON ACCEPTABLE TERMS.

The report of independent registered public accounting firm accompanying the audit of the Company's consolidated financial statements for the year ended December 31, 2004 contains an explanatory paragraph expressing uncertainty regarding our ability to continue as a going concern because of our operating losses and our need for additional capital. Such explanatory paragraph could make it more difficult for us to raise additional capital and may materially and adversely affect the terms of any financing that we may obtain.

SINCE WE ARE A COMPANY WITH A LIMITED INDEPENDENT OPERATING HISTORY, IT IS DIFFICULT TO PREDICT OUR FUTURE GROWTH AND OPERATING RESULTS, THEREBY MAKING INVESTMENT DECISIONS DIFFICULT.

Our limited operating history as an independent drug delivery business makes predicting our future growth and operating results difficult. Vyteris, Inc. was incorporated in Delaware in 2000, although a substantial portion of its business was developed by Becton Dickinson from prior to 1990 until 2000.

AS A COMPANY WITH A LIMITED INDEPENDENT OPERATING HISTORY, WE HAVE NOT PROVEN THAT WE ARE CAPABLE OF MEETING THE MANY CHALLENGES THAT WE ARE LIKELY TO FACE.

You should consider the risks and uncertainties that a company with a limited independent existence will face in the rapidly evolving market for drug delivery technologies.

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In particular, you should consider that we have not proven that we can:

- o raise significant capital in the public or private markets;
- o obtain the regulatory approvals necessary to commence selling drug delivery systems that we may develop in the future,
- o manufacture products, including our LidoSite product, in a manner that enables us to be profitable or meets regulatory, strategic partner or customer requirements;
- o attract, retain and manage a large, diverse staff of engineers and scientists;
- o develop the relationships with strategic partners and key vendors that are necessary to our ability to exploit the processes and technologies that we develop;
- o develop new products and drug delivery processes and new applications for our drug delivery technology; or
- o respond effectively to competitive pressures.

If we cannot accomplish these goals, our business is not likely to succeed.

OUR DRUG DELIVERY BUSINESS MAY NOT GENERATE ANY MATERIAL REVENUES FROM SALES OF THE ONE PRODUCT THAT WE ARE CURRENTLY PERMITTED TO SELL, IN WHICH CASE OUR RESULTS OF OPERATIONS, FINANCIAL CONDITION AND LIQUIDITY WILL BE MATERIALLY AND ADVERSELY IMPACTED AND OUR OPPORTUNITIES TO DEVELOP, MARKET AND SELL OTHER PRODUCTS MAY BE JEOPARDIZED SIGNIFICANTLY.

To date, we have not generated any revenue from sales of our first drug delivery product, LidoSite. As is common in our industry, we have spent many years and substantial sums of money in developing LidoSite. To develop that product to the point where we are able to commence commercial sales, it has been necessary for us to prove our concepts, develop patent positions, engage in substantial clinical trials, develop appropriate manufacturing processes, obtain necessary regulatory approvals and establish a mutually beneficial marketing and distribution agreement with B. Braun. With all of this work effort and the attendant capital and operating expenditures, we still have not tested the market in a manner that can assure us or our investors that we will derive material revenues from LidoSite. If we are unable to derive material revenues from the sale of our LidoSite product, our liquidity will be materially and adversely impacted, we will require additional capital even sooner than we had

anticipated and we may find it more difficult to attract marketing partners for subsequent products that we may develop.

WE CANNOT EXPECT THAT WE WILL BE ABLE TO DERIVE MATERIAL REVENUES FROM THE SALE OF PRODUCTS OTHER THAN LIDOSITE IN THE NEAR FUTURE.

While we have commenced development of other products and believe that our technology can and should be pursued with respect to several applications that could result in commercially viable products, the process of developing drug delivery products to the point of commercial sales takes significant time and requires a substantial commitment of financial and other resources that may not be available to us. We cannot assure investors that we will have the financial resources necessary to bring future products to market or that developments in our industry will not preclude us from expanding our product line beyond LidoSite. If we are unable to bring additional products to market, we will be forced to rely on a single source of revenue and the future success of our company would be dependent entirely upon the continued demand for a single product. If we are forced to rely on a single product, our entire business would be at risk in the event that market or competitive conditions threatened the viability of that product, thereby increasing the risk of a dramatic decline in the market value of our capital stock.

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WE MAY NOT BE ABLE TO OBTAIN FDA OR FOREIGN REGULATORY APPROVAL FOR OUR PRODUCTS IN A TIMELY MANNER, OR AT ALL, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR ABILITY TO SELL AND MARKET OUR PRODUCTS.

Drug delivery systems that we may develop in the future cannot be sold in the United States until the FDA approves such products for medical use. Similar foreign regulatory approvals will be needed in order to sell any drug delivery system, including our LidoSite product, outside of the U.S. We may not be able to obtain FDA or foreign regulatory approval for our products in a timely manner, or at all. Delays in obtaining FDA or foreign approvals for our products could result in substantial additional costs to us, and, therefore, could adversely affect our ability to compete with other drug delivery companies. If we do not obtain such approvals at all, our revenues may be insufficient to support continuing operations.

IF OUR LIDOSITE PRODUCT IS NOT COMMERCIALY SUCCESSFUL, OUR BUSINESS, FINANCIAL CONDITION, OPERATING RESULTS AND FUTURE PROSPECTS WOULD LIKELY SUFFER SIGNIFICANTLY.

Although we have other products in various stages of early development, our primary focus at this time is the manufacture, sale and marketing in the United States of our LidoSite product in collaboration with B. Braun. Currently, our LidoSite product is our only product that could provide revenue for us. Our ability to achieve profitability in the foreseeable future is principally dependent on the manufacture and sale of our LidoSite product.

FOR THE FORESEEABLE FUTURE, WE WILL RELY ON A SINGLE CUSTOMER, B. BRAUN, TO GENERATE PRODUCT REVENUE. IF B. BRAUN IS UNABLE TO SELL OUR LIDOSITE PRODUCT EFFECTIVELY, IT WOULD MATERIALLY AND ADVERSELY AFFECT THE RESULTS OF OUR OPERATIONS.

We have granted B. Braun the right to be our exclusive, worldwide sales and marketing distributor for LidoSite. As a result, we are dependent on B. Braun and its ability to effectively market our only current product. If B. Braun is unable to sell our LidoSite product effectively, we will not have the ability to seek other customers for our LidoSite product at least until such time as satisfactory arrangements are made with B. Braun.

WE RELY ON SINGLE SUPPLIERS FOR CERTAIN KEY MATERIALS AND COMPONENTS USED IN OUR LIDOSITE PRODUCT, WHICH MAKES US DEPENDENT ON PERSONS THAT WE CANNOT CONTROL.

Certain raw materials and components used in the manufacture of our LidoSite product are available only from single suppliers. Some of those materials or components are custom-made for us and are the result of long periods of collaboration with our suppliers. The hydrogel that we use to hold lidocaine in the patch and the electrodes that we use to carry current through our lidocaine delivery system, for example, are both provided by single suppliers. Any curtailment of the availability of such raw materials or components could be accompanied by production or other delays and could result in a material loss of sales, with resulting adverse effects on our business and operating results. In addition, because raw material sources for pharmaceutical products must generally be approved by regulatory authorities, changes in raw material suppliers may eventually result in production delays, higher raw material costs and loss of sales, customers and market share.

We believe that, if necessary, alternative sources of raw materials and components could be located, alternate raw materials and components can be substituted for each single-sourced raw material or component, or we could redesign products to avoid the need for single-sourced raw materials or

components. However, the development or identification of alternative sources, or redesigning products, could be time-consuming and expensive. Although we have not experienced difficulty acquiring raw materials and components on commercially reasonable terms and in sufficient quantities to maintain required production levels for our clinical testing, we cannot assure you that price increases or interruptions in the supply of these materials will not occur in the future or that we will not have to seek alternate suppliers or obtain substitute raw materials or components, which may require additional product validations and regulatory approvals. Further, our suppliers could experience price increases or interruptions in the supply of materials from their suppliers, or could fail to meet our or governmental manufacturing standards. Any significant price increase, interruption of supply, our inability to secure an alternate source or our inability to qualify a substitute material could have a material adverse effect on our ability to manufacture our LidoSite product or maintain regulatory approval.

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WE HAVE NO EXPERIENCE IN MANUFACTURING DRUG DELIVERY SYSTEMS FOR COMMERCIAL RESALE AND MAY BE UNABLE TO MANUFACTURE OUR PRODUCTS FOR COMMERCIAL SALE ON A PROFITABLE OR RELIABLE BASIS.

Although some of our management personnel have manufacturing experience, as an organization we do not have any experience in manufacturing drug delivery systems for commercial sale. We must increase our production capabilities significantly beyond our present manufacturing capacity, which has been focused on producing small quantities of our LidoSite product for research and clinical testing, and incur significant capital expense in order to be able to sell our LidoSite product in commercial volumes in a cost effective manner. The equipment and machinery that we use to manufacture the drug and patches for our LidoSite product are expensive and custom-built, and have never been used in the large-scale production of pre-filled drug delivery patches.

We cannot assure investors that we can:

- o successfully increase our manufacturing capabilities and develop large-scale manufacturing processes on a profitable basis;
- o hire and retain skilled personnel to oversee our manufacturing operations;
- o avoid design and manufacturing defects; or
- o develop and maintain our manufacturing facility in compliance with governmental regulations, including the FDA's good manufacturing practices.

We may not be able to manufacture our LidoSite product, or any future products, in a manner that ensures that the systems provide reproducible dosages of stable formulations of drugs for sufficient periods after manufacture. If we cannot ensure that our products have sufficient post-production shelf-life, we may be unable to produce our products in sufficient quantities to develop an economical supply chain. Accordingly, we may not be able to successfully manage our inventory.

OUR NEED TO EXPAND OUR FACILITIES WILL EXPOSE US TO ADDITIONAL EXPENSES THAT MAY MATERIALLY ADVERSELY AFFECT OUR RESULTS OF OPERATIONS.

To date, all of our manufacturing, research and development and administrative functions have been operated out of a single facility that we sublease from Becton Dickinson. We recently entered into a lease for a second facility to be utilized as we expand our manufacturing capacity. We expect to incur substantial expenses in preparing this facility for production and recognize that in addition, we will incur ongoing redundancy costs in order to protect against the risks of having a single facility become disabled.

AT LEAST UNTIL WE OPERATE OUT OF MORE THAN ONE FACILITY, WE ARE SUBJECT TO SUBSTANTIAL BUSINESS DISRUPTION RISKS.

In the event that events outside of our control, such as a fire, adverse weather conditions or acts of terrorism, preclude us from operating in our existing facility, we will have no facility available us for our manufacturing processes until our second facility becomes operational. In the interim, we would likely experience substantial delays in our ability to manufacture products. In such instances, it could become necessary for us to incur substantial expenditures to assure that our customers' orders are fulfilled.

THE FAILURE OF ANY OF OUR PRODUCTS, INCLUDING OUR LIDOSITE PRODUCT, TO ACHIEVE MARKET ACCEPTANCE COULD MATERIALLY AND ADVERSELY IMPACT OUR FUTURE SUCCESS.

Our future success depends upon the acceptance of our LidoSite product and any of our potential future products by health care providers and patients. In addition, our future success may be dependent upon acceptance by third-party

payors, including, without limitation, health insurance companies, Medicaid and Medicare, of products that we may develop in the future. Such market acceptance may depend on numerous factors, many of which may not be under our control, including:

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- o the safety and efficacy of our products;
- o regulatory approval and product labeling;
- o the availability, safety, efficacy and ease of use of alternative technologies;
- o the price of our products relative to alternative technologies; and
- o for future products, the availability of third-party reimbursement.

Our LidoSite product is based upon a method of drug delivery through the skin that, to date, has not gained widespread market acceptance. We cannot assure you that LidoSite or any future product will ever gain broad market acceptance.

In addition, the adoption of new pharmaceutical products is greatly influenced by health care administrators, inclusion in hospital formularies, and reimbursement by third party payors. Because our existing and proposed drug delivery systems encompass both a device and a drug and may be used by many different departments within a hospital or health care facility, buying decisions in these settings require more departmental approvals than are required for either a stand-alone drug or a stand-alone device. As a result, it may be more difficult and more time consuming to achieve market penetration with our products. We cannot assure investors that health care administrators, hospitals or third party payors will accept our products on a large scale or on a timely basis, if at all, or that we will be able to obtain approvals for additional indications and labeling for our products which facilitate or expand their market acceptance or use. In addition, unanticipated side effects, patient discomfort, defects or unfavorable publicity concerning any of our products, or any other product incorporating technology similar to that used by our products, could have a material adverse effect on our ability to commercialize our products or achieve market acceptance.

WE MAY BE UNABLE TO SECURE STRATEGIC PARTNERING RELATIONSHIPS, WHICH COULD LIMIT OUR ABILITY TO EFFECTIVELY MARKET, SELL OR DISTRIBUTE OUR PRODUCTS.

In order for us to develop, market, sell and distribute future products, we will be dependant on entering into satisfactory arrangements with strategic partners. We cannot assure investors that we will be able to negotiate such agreements on terms that are acceptable to us, or at all. In addition, we cannot assure any investor that any strategic partner, including B. Braun, will not also engage in independent development of competitive delivery technologies.

IF WE ARE UNABLE TO PROTECT OUR PROPRIETARY TECHNOLOGY AND PRESERVE OUR TRADE SECRETS, WE WILL INCREASE OUR VULNERABILITY TO COMPETITORS WHICH COULD TAKE ACTIONS THAT COULD MATERIALLY ADVERSELY IMPACT OUR ABILITY TO REMAIN IN BUSINESS.

Our ability to successfully commercialize our LidoSite product and any other products that we develop will depend, in large measure, on our ability to protect those products and our technology with United States and foreign patents. We will also need to continue to preserve our trade secrets. The issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims of the patent. The patent positions of pharmaceutical, biotechnology and drug delivery companies, including our company, are uncertain and involve complex legal and factual issues.

We cannot assure you that our patents will prevent other companies from developing similar products or products which produce benefits substantially the same as our products, or that other companies will not be issued patents that may prevent the sale of our products or require us to pay significant licensing fees in order to market our products. Accordingly, if our patent applications are not approved or, even if approved, if such patents are circumvented or not upheld in a court of law, our ability to competitively exploit our patented products and technologies may be significantly reduced. Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued.

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From time to time, we may need to obtain licenses to patents and other

proprietary rights held by third parties in order to develop, manufacture and market our products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially exploit such products may be inhibited or prevented. Additionally, we cannot assure investors that any of our products or technology will be patentable or that any future patents we obtain will give us an exclusive position in the subject matter claimed by those patents. Furthermore, we cannot assure investors that our pending patent applications will result in issued patents, that patent protection will be secured for any particular technology, or that our issued patents will be valid, enforceable and provide us with meaningful protection.

IF WE ARE REQUIRED TO ENGAGE IN EXPENSIVE AND LENGTHY LITIGATION TO ENFORCE OUR INTELLECTUAL PROPERTY RIGHTS, THE COSTS OF SUCH LITIGATION COULD BE MATERIAL TO OUR RESULTS OF OPERATIONS, FINANCIAL CONDITION AND LIQUIDITY AND, IF WE ARE UNSUCCESSFUL, THE RESULTS OF SUCH LITIGATION COULD MATERIALLY ADVERSELY IMPACT OUR ENTIRE BUSINESS.

We may find it necessary to initiate litigation to enforce our patent rights, to protect our trade secrets or know-how or to determine the scope and validity of the proprietary rights of others. We plan to aggressively defend our proprietary technology and any issued patents. Litigation concerning patents, trademarks, copyrights and proprietary technologies can often be time-consuming and expensive and, as with litigation generally, the outcome is inherently uncertain.

Although we have entered into invention assignment agreements with our employees and with certain advisors, if those employees or advisors develop inventions or processes independently which may relate to products or technology under development by us, disputes may also arise about the ownership of those inventions or processes. Time-consuming and costly litigation could be necessary to enforce and determine the scope of our rights under these agreements.

We also rely on confidentiality agreements with our strategic partners, customers, suppliers, employees and consultants to protect our trade secrets and proprietary know-how. We may be required to commence litigation to enforce such agreements and it certainly possible that we will not have adequate remedies for breaches of our confidentiality agreements.

OTHER COMPANIES MAY CLAIM THAT OUR TECHNOLOGY INFRINGES ON THEIR INTELLECTUAL PROPERTY OR PROPRIETARY RIGHTS AND COMMENCE LEGAL PROCEEDINGS AGAINST US WHICH COULD BE TIME-CONSUMING AND EXPENSIVE AND COULD RESULT IN OUR BEING PROHIBITED FROM DEVELOPING, MARKETING, SELLING OR DISTRIBUTING OUR PRODUCTS.

Because of the complex and difficult legal and factual questions that relate to patent positions in our industry, we cannot assure you that our products or technology will not be found to infringe upon the intellectual property or proprietary rights of others. Third parties may claim that our products or technology infringe on their patents, copyrights, trademarks or other proprietary rights and demand that we cease development or marketing of those products or technology or pay license fees. We may not be able to avoid costly patent infringement litigation, which will divert the attention of management away from the development of new products and the operation of our business. We cannot assure you that we would prevail in any such litigation. If we are found to have infringed on a third party's intellectual property rights, we may be liable for money damages, encounter significant delays in bringing products to market or be precluded from manufacturing particular products or using particular technology.

Other parties have challenged certain of our foreign patent applications. If such parties are successful in opposing our foreign patent applications, we may not gain the protection afforded by those patent applications in particular jurisdictions and may face additional proceedings with respect to similar patents in other jurisdictions, as well as related patents. The loss of patent protection in one jurisdiction may influence our ability to maintain patent protection for the same technology in another jurisdiction.

IF WE DO NOT ACCURATELY PREDICT DEMAND FOR OUR PRODUCTS WHEN DECIDING TO INVEST IN NEW PRODUCTS, WE WILL LIKELY INCUR SUBSTANTIAL CAPITAL EXPENDITURES THAT WILL NOT BENEFIT OUR BUSINESS.

Research and development, clinical testing and obtaining regulatory approvals for new drug delivery systems takes a significant amount of time and requires significant investment in skilled engineering and scientific personnel and in expensive equipment. Furthermore, manufacturing our lidocaine delivery system requires expensive, custom-built machinery. We have made these investments, and intend to continue to make such investments, for our LidoSite product based on internal projections of the potential market for that system and of our potential profit margins on sales of that system. If those projections are inaccurate, we may not be able to obtain an acceptable return on our investment in the development of our LidoSite product. If our projections of the prospects of new products are inaccurate, we may make investments in the

development, testing and approval of those products that may result in unsatisfactory returns.

WE MAY BE UNABLE TO HIRE AND RETAIN SKILLED ENGINEERS AND SCIENTISTS IN A TIGHT LABOR MARKET, IN WHICH CASE WE WILL BE SEVERELY HAMPERED IN OUR PRODUCT DEVELOPMENT EFFORTS AND IN OUR ABILITY TO ATTRACT MARKETING AND DISTRIBUTION PARTNERS.

Skilled employees in our industry are in great demand. We are competing for employees against companies located near our headquarters that are more established than we are and have the ability to pay more cash compensation than we do. We require scientific and engineering personnel in many fields, some of which are addressed by relatively few companies. As a result, we may continue to experience difficulty in hiring and retaining highly skilled employees, particularly engineers and scientists. If we are unable to hire and retain skilled engineers and scientists, our business, financial condition, operating results and future prospects could be materially adversely affected.

IF WE ARE UNABLE TO RETAIN OUR KEY MANAGEMENT PERSONNEL, OUR BUSINESS, FINANCIAL CONDITION, OPERATING RESULTS AND FUTURE PROSPECTS COULD BE MATERIALLY ADVERSELY AFFECTED.

Our future success depends, to a significant degree, on the skills, experience and efforts of our key management personnel, principally Vincent De Caprio, Ph.D., our president and chief executive officer, Michael McGuinness, our chief financial officer, and James Garrison, our vice president of business development. If any of those individuals were unable or unwilling to continue in their present positions, it would be necessary for us to identify and hire replacements, which could be time-consuming and expensive and could divert our focus from our business objectives. Furthermore, such replacements may not be as successful in attracting and retaining marketing and distribution partners as our current management may be. Mr. McGuinness is not bound by an employment agreement with the Company. We do not maintain key person life insurance on any of our management personnel.

IF WE ARE UNABLE TO DEVELOP PRODUCTS OR TECHNOLOGIES THAT WILL BE MARKETABLE, WE WILL NOT BE ABLE TO REMAIN IN BUSINESS.

We may not be able to develop drug delivery products or technologies that will be marketable. Even if we are able to develop marketable drug delivery products or technologies, we may not be able to develop them or obtain patent protection, successful clinical trial results or regulatory approval for them. Our research and development efforts may be hampered by a variety of factors, many of which are outside of our control. Sustained development failures could materially adversely impact our business.

WE FACE SUBSTANTIAL COMPETITION FOR OUR LIDOSITE PRODUCT AND ANY FUTURE PRODUCTS THAT WE MAY DEVELOP, AS WELL AS FOR STRATEGIC PARTNERSHIP TRANSACTIONS. OUR FAILURE TO ADEQUATELY COMPETE COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR ABILITY TO DEVELOP, MARKET AND SELL OUR PRODUCTS AND MEET OUR FINANCIAL PROJECTIONS.

There is substantial competition to develop alternative drug delivery solutions from both drug delivery technology and pharmaceutical companies, most of which are much larger and have far greater resources than we do. Further, the drug delivery, pharmaceutical and biotechnology industries are highly competitive and rapidly evolving. We expect that significant developments in those industries will continue at a rapid pace. Our

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success will depend on our ability to establish and maintain a strong competitive position for our LidoSite product while developing new products that are effective and safe. We cannot assure you that any of our products will have advantages over alternative products and technologies that may be developed later and that may be significant enough to cause health care providers to prefer those products or technologies over ours.

In our drug delivery segment, focused on the process of actively delivering drugs through the skin, we are aware of several companies that are developing or marketing products based on this process. We also face competition from companies that are currently testing or already marketing delivery systems or products for lidocaine or similar topical anesthetics. We face indirect competition from companies that are actively involved in the development and commercialization of modified drug delivery technologies, including oral, pulmonary, buccal, nasal and needle-less injections, as well as companies working on processes that passively deliver drugs through the skin. We also expect to compete with other drug delivery companies and technologies in the establishment of strategic partnering arrangements with large pharmaceutical companies to assist in the development or marketing of products. Competition is expected to intensify as more companies enter the field.

Many of our competitors have substantially greater financial, technical,

research and other resources, are more experienced in research and development, manufacturing, pre-clinical and clinical testing, and obtaining regulatory approvals, and are larger, more established and have more collaborative partners than we do. In addition, those other entities may offer broader product lines and have greater name recognition than we do. Those other entities may succeed in developing competing technologies and obtaining regulatory approvals and market share more rapidly than we can. Some of those companies have competing products that have already been approved by the FDA and foreign authorities, or are further along in development than is our LidoSite product. We cannot assure you that those competitors will not succeed in developing or marketing products that are more effective or more commercially acceptable than our lidocaine delivery system or any future product. We cannot assure you that we will have the financial resources, technical or management expertise or manufacturing and sales capability to compete in the future.

Increased competition may result in price cuts, reduced gross margins and loss of market share, any of which could have a material adverse effect on our business, financial condition, results of operations and future prospects.

IF BECTON DICKINSON DEVELOPS COMPETING TECHNOLOGIES, OUR ABILITY TO MAINTAIN OUR CURRENT MARKET POSITION WILL BE PARTICULARLY VULNERABLE.

Becton Dickinson has substantial insight into the potential applications of our drug delivery technologies, and our business model, as we were operated as a division of Becton Dickinson for over ten years. Further, Becton Dickinson is in the business of developing alternative drug delivery technologies and we may compete in the future with alternative technologies developed or acquired by Becton Dickinson. Becton Dickinson has developed drug delivery technology employing "micro-needles", tiny needles that deliver compounds into the first few hundred microns of the skin. This technology, which has not yet been commercialized, may compete directly with our current technology. Given its size, access to capital and familiarity with our business, Becton Dickinson could make substantial inroads into our business prospects if it decides to compete directly with us.

WE MAY NOT BE ABLE TO LICENSE COMPLEMENTARY DRUG DELIVERY TECHNOLOGIES OR DRUG REFORMULATIONS TO EXPAND OUR PRODUCT OFFERINGS, IN WHICH CASE WE WILL BE SIGNIFICANTLY LIMITED IN OUR PRODUCT OFFERINGS.

In order to enhance our platform technology, strengthen our intellectual property portfolio and expand our overall market opportunity beyond that for our LidoSite product, we may seek to acquire or license rights to additional drug delivery technologies or reformulations of FDA-approved drugs that compliment our core drug delivery platform. We may not be able to acquire or license such other technologies or drug reformulations on terms that are acceptable to us, if at all. Further, efforts to identify such technologies and attempts to negotiate the terms of such acquisitions or licenses may divert the attention of our management away from the internal development of new applications for our existing technology and from the operation of our business.

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IF ANY OF OUR PRODUCTS INJURES A USER, WE COULD BE SUBJECT TO PRODUCT LIABILITY EXPOSURE IN EXCESS OF AMOUNTS FOR WHICH WE ARE INSURED, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS AND FUTURE PROSPECTS.

Clinical trials and subsequent sales of our LidoSite product or any other drug delivery system we may develop or manufacture in the future may result in injuries to persons using those products as a result of mislabeling, misuse or product failure. While we carry product liability insurance with respect to the now-completed clinical trials and for the commercial sale of our LidoSite product, there can be no assurance that our coverage will be adequate to protect us against future liability claims. Furthermore, we cannot assure you that that we can afford to maintain the insurance that we have obtained. Product liability insurance is expensive and there can be no assurance that this insurance will be available to us in the future for the commercial sale of our lidocaine delivery system or for any new products, on terms satisfactory to us, if at all. A successful product liability claim or series of claims brought against us in excess of our insurance coverage could have a material adverse effect on our business, financial condition, results of operations and future prospects.

IF WE DEFAULT UNDER OUR WORKING CAPITAL FACILITY, OUR LENDER WILL BE ABLE TO ENFORCE ITS LIEN AND TAKE TITLE TO OUR ASSETS, WHICH COULD LIMIT OUR ABILITY TO CONTINUE AS A GOING CONCERN.

Our working capital facility, if used, will be secured by a first priority lien on all of the assets of our operating subsidiary. In the past, we have defaulted on promissory notes due to our lack of liquidity. If we borrow under our working capital facility and are unable to raise sufficient capital to timely repay our obligations under the working capital facility, the lender, an affiliate of our principal stockholder, will be entitled to enforce its lien and take title to substantially all of our assets, which may be critical to our

continuing operations.

WE DO NOT INTEND TO PAY DIVIDENDS AND, CONSEQUENTLY, THE ONLY OPPORTUNITY FOR INVESTORS TO ACHIEVE A RETURN ON THEIR INVESTMENT IS IF A TRADING MARKET DEVELOPS AND INVESTORS ARE ABLE TO SELL THEIR SHARES AT A PROFIT OR IF OUR BUSINESS IS SOLD AT A PRICE THAT ENABLES INVESTORS TO RECOGNIZE A PROFIT.

We will need all of our cash resources to fund our operations, including the development of future products. Accordingly, we do not expect to pay cash dividends in the foreseeable future on our common stock. We cannot assure investors any return on their investment other than in connection with a sale of their shares or a sale of our business. At the present time there is no active trading market for our shares and we have no intention of selling our business. We cannot assure investors that an active trading market will develop or that any third party would offer to purchase our business on acceptable terms and at a price that would enable our investors to recognize a profit. There is no established public trading market or market maker for our securities. Therefore, if you purchase our securities, you may be unable to sell them. Accordingly, you should be able to bear the financial risk of losing your entire investment.

WE WILL BE REQUIRED TO MAKE LIQUIDATED DAMAGES PAYMENTS TO CERTAIN OF OUR STOCKHOLDERS WHICH COULD MATERIALLY AFFECT OUR FINANCIAL CONDITION.

We have filed a registration statement with the SEC relating to the resale of shares of the Company's common stock. Since that registration statement was not declared effective by the SEC by February 25, 2005, we are obligated to pay to certain stockholders an amount equal to 1% of the purchase price paid by such stockholders for the shares owned by such stockholders which are covered by the registration statement, and for each month, or portion of a month, in which such delay continues, an amount equal to 2% of such purchase price, until we have cured the delay, with an overall cap on such liquidated damages of 10% of the aggregate purchase price paid by such stockholders for such shares. The registration statement has not yet been declared effective. Such liquidated damages could amount to up to \$2.4 million, depending upon when the registration statement is ultimately declared effective by the SEC. Payments of substantial liquidated damages will adversely affect our financial condition.

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OUR COMPLIANCE WITH THE SARBANES-OXLEY ACT AND SEC RULES CONCERNING INTERNAL CONTROLS MAY BE TIME CONSUMING, DIFFICULT AND COSTLY FOR US.

Although individual members of our management have experience as officers of publicly-traded companies, that experience came prior to the adoption of the Sarbanes-Oxley Act of 2002. Vyteris had never operated as a publicly-traded company. It may be time consuming, difficult and costly for us to develop and implement the internal controls and reporting procedures required by the Sarbanes-Oxley Act. We may need to hire additional financial reporting, internal controls and other finance staff in order to develop and implement appropriate internal controls and reporting procedures. If we are unable to comply with the internal controls requirements of the Sarbanes-Oxley Act, we may not be able to obtain the independent accountant certifications that the Sarbanes-Oxley Act requires publicly-traded companies to obtain.

OUR CONTROLLING STOCKHOLDER MAY TAKE ACTIONS THAT CONFLICT WITH YOUR INTERESTS.

Kevin Kimberlin, through his ownership of Spencer Trask Specialty Group, LLC, or STSG, and related parties is our controlling stockholder. Mr. Kimberlin and related parties beneficially own over 60% of our voting stock. Accordingly, Mr. Kimberlin controls us and has the power to elect our directors and to generally approve all actions requiring the approval of the holders of our voting stock, including adopting amendments to our articles of incorporation and bylaws and approving mergers, certain acquisitions or sales of all or substantially all of our assets, which could delay or prevent someone from acquiring or merging with us or limiting the ability of our other stockholders to approve transactions that they may deem to be in their best interest.

THERE HAS BEEN NO ACTIVE PUBLIC MARKET FOR OUR COMMON STOCK, AND STOCKHOLDERS MAY NOT BE ABLE TO RESELL THEIR SHARES AT OR ABOVE THE PURCHASE PRICE PAID BY SUCH STOCKHOLDER, OR AT ALL.

There is no current active public market for the Company's common stock. An active public market for our common stock may not develop or be sustained in the future. The market price of our common stock may fluctuate significantly in response to factors, some of which are beyond our control, such as: the announcement of new products or product enhancements by us or our competitors; developments concerning intellectual property rights and regulatory approvals; quarterly variations in our competitors' results of operations; changes in earnings estimates or recommendations by securities analysts; developments in our industry; and general market conditions and other factors, including factors

unrelated to our own operating performance. The stock market in general has recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. Prospective investors should also be aware that price volatility might be worse if the trading volume of our common stock is low.

WE MAY NOT BE ABLE TO ATTRACT THE ATTENTION OF MAJOR BROKERAGE FIRMS, WHICH COULD HAVE A MATERIAL ADVERSE IMPACT ON THE MARKET VALUE OF OUR COMMON STOCK

Security analysts of major brokerage firms may not provide coverage of our common stock since there is no incentive to brokerage firms to recommend the purchase of our common stock. The absence of such coverage limits the likelihood that an active market will develop for our common stock. It also will likely make it more difficult to attract new investors at times when we require additional capital.

WE MAY BE UNABLE TO LIST OUR COMMON STOCK ON NASDAQ OR ANY OTHER SECURITIES EXCHANGE, IN WHICH CASE AN INVESTOR MAY FIND IT MORE DIFFICULT TO DISPOSE OF SHARES OR OBTAIN ACCURATE QUOTATIONS AS TO THE MARKET VALUE OF OUR COMMON STOCK.

Although we may apply to list our common stock on Nasdaq or the American Stock Exchange in the future, we cannot assure you that we will be able to meet the initial listing standards, including the minimum per share price and minimum capitalization requirements, of either of those or any other stock exchange, or that we will be able to maintain a listing of our common stock on either of those or any other stock exchange. If we are unable to list our common stock on Nasdaq, the American Stock Exchange or another stock exchange, or to

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maintain its listing, we expect that our common stock will trade on the OTC Bulletin Board maintained by Nasdaq, another over-the-counter quotation system, or on the "pink sheets," where an investor may find it more difficult to dispose of shares or obtain accurate quotations as to the market value of our common stock. In addition, we are subject to an SEC rule that, if we fail to meet the criteria set forth in such rule, imposes various practice requirements on broker-dealers who sell securities governed by the rule to persons other than established customers and accredited investors. Consequently, such rule may deter broker-dealers from recommending or selling our common stock, which may further affect the liquidity of our common stock. It would also make it more difficult for us to raise additional capital.

OUR COMMON STOCK MAY BE CONSIDERED A "PENNY STOCK" AND MAY BE DIFFICULT TO SELL.

The SEC has adopted regulations which generally define a "penny stock" to be an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to specific exemptions. Even though we have now implemented a one for ten reverse stock split, the market price of the Company's common stock, if a market develops, may be less than \$5.00 per share and therefore it may be designated as a "penny stock" according to SEC rules. This designation requires any broker or dealer selling these securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell our common stock and may affect the ability of investors to sell their shares.

WHEN AND IF THE SELLING STOCKHOLDERS UTILIZE OUR RECENTLY FILED PROSPECTUS TO SELL THEIR SHARES OF OUR COMMON STOCK, A SIGNIFICANT NUMBER OF SHARES WILL BE ELIGIBLE FOR SALE, AND SUCH SALES COULD DEPRESS THE MARKET PRICE OF OUR STOCK.

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock. As additional shares of our common stock become available for resale pursuant to our recently filed prospectus, the supply of our common stock will increase, which could decrease its market price. The prospectus is included in a registration statement that has not yet been declared effective by the SEC and thus may not be utilized at the present time.

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ITEM 7. FINANCIAL STATEMENTS.

VYTERIS HOLDINGS (NEVADA), INC.
(A DEVELOPMENT STAGE ENTERPRISE)

Report of Independent Registered Public Accounting Firm.....	52
Consolidated Balance Sheets as of December 31, 2004 and 2003.....	53
Consolidated Statements of Operations for the years ended December 31, 2004, 2003 and 2002 and for the period from November 10, 2000 (inception) to December 31, 2004.....	54
Consolidated Statements of Stockholders' Equity (Deficit) for the period from November 10, 2000 (inception) to December 31, 2004.....	55
Consolidated Statements of Cash Flows for the years ended December 31, 2004, 2003 and 2002 and for the period from November 10, 2000 (inception) to December 31, 2004.....	56
Notes to Consolidated Financial Statements.....	58

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Vyteris Holdings (Nevada), Inc.

We have audited the accompanying consolidated balance sheets of Vyteris Holdings (Nevada), Inc. and Subsidiary (a development stage enterprise) as of December 31, 2004 and 2003, and the related statements of operations, stockholders' equity (deficit), and cash flows for the years ended December 31, 2004, 2003, 2002 and the period from November 10, 2000 (inception) to December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Vyteris Holdings (Nevada), Inc. and Subsidiary at December 31, 2004 and 2003, and the results of their operations and their cash flows for the years ended December 31, 2004, 2003, 2002 and the period from November 10, 2000 (inception) to December 31, 2004 in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred recurring losses and is dependent upon obtaining sufficient financing to fund operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects of the recoverability of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ ERNST & YOUNG LLP

MetroPark, New Jersey
February 28, 2005 except for Note 20,
as to which the date is May 2, 2005

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VYTERIS HOLDINGS (NEVADA), INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED BALANCE SHEETS

	DECEMBER 31,	
	2004	2003
	-----	-----
<S>	<C>	<C>
ASSETS		
Current assets:		
Cash and cash equivalents.....	\$ 6,438,737	\$ 2,286,167
Accounts receivable.....	71,792	--
Prepaid expenses and other current assets.....	712,920	93,238
Deferred financing costs.....	956,250	--
	-----	-----
Total current assets.....	8,179,699	2,379,405
Property and equipment, net.....	3,015,448	2,934,902
Other assets.....	75,000	--
	-----	-----
TOTAL ASSETS.....	\$ 11,270,147	\$ 5,314,307
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable.....	\$ 953,459	\$ 887,858
Accrued expenses and other liabilities.....	1,011,833	721,720
Convertible, secured promissory notes payable to related parties.....	--	20,350,000
Secured promissory notes payable to related parties.....	--	2,900,000
Interest payable to related parties.....	--	2,056,495
Convertible promissory note payable to a related party.....	--	500,000
	-----	-----
Total current liabilities.....	1,965,292	27,416,073
Deferred revenue, less current portion.....	363,182	300,000
Capital lease obligation, less current portion.....	10,939	29,546
Vyteris preferred stock, 0 and 50,000,000 shares authorized, par value \$0.0001 per share; on December 31, 2004 and December 31, 2003, respectively:		
Vyteris Series A convertible, redeemable preferred stock; 0 and 333,333 shares issued and outstanding on December 31, 2004 and December 31, 2003, respectively; liquidation preference \$0 and \$9,999,990 at December 31, 2004 and December 31, 2003, respectively.....	--	333,333
Vyteris Series B convertible, redeemable preferred stock; 0 and 3,000,000 shares issued and outstanding on December 31, 2004 and December 31, 2003, respectively; liquidation preference \$0 and \$9,000,000 at December 31, 2004 and December 31, 2003, respectively.....	--	2,917,640
Vyteris Holdings preferred stock, 50,000,000 and 0 shares authorized, on December 31, 2004 and December 31, 2003, respectively:		
Vyteris Holdings Series B convertible, redeemable preferred stock; 7,500,000 and 0 shares outstanding on December 31, 2004 and December 31, 2003, respectively; liquidation preference \$7,650,000 and \$0 at December 31, 2004 and December 31, 2003, respectively.....	7,650,000	--
Stockholders' equity (deficit):		
Common stock, Vyteris par value \$0.0001 per share; 75,000,000 shares authorized, 1,812,479 shares issued and outstanding at December 31, 2003.....	--	181
Common stock, Vyteris Holdings par value \$.001 per share; 100,000,000 shares authorized, 19,293,858 shares outstanding at December 31, 2004.....	19,294	--
Additional paid-in capital.....	57,435,387	7,836,638
Deferred compensation	(131,546)	(43,347)
Deficit accumulated in development stage.....	(56,042,401)	(33,475,757)
	-----	-----
Total stockholders' equity (deficit).....	1,280,734	(25,682,285)
	-----	-----
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT).....	\$ 11,270,147	\$ 5,314,307
	=====	=====

The accompanying notes are an integral part of these consolidated financial statements.

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VYTERIS HOLDINGS (NEVADA), INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED STATEMENTS OF OPERATIONS

	YEARS ENDED DECEMBER 31,			PERIOD FROM
	-----			NOVEMBER 10, 2000
	2004	2003	2002	(INCEPTION) TO DECEMBER 31, 2004
<S>	<C>	<C>	<C>	<C>
Revenues.....	\$ 242,322	\$ 200,000	\$ 151,452	\$ 870,322
Operating expenses:				
Research and development.....	11,455,306	8,734,871	7,209,796	34,773,065
General and administrative.....	4,069,838	2,454,922	2,890,568	12,780,791
Total operating expenses.....	15,525,144	11,189,793	10,100,364	47,553,856
Interest income.....	(38,448)	(5,775)	(10,834)	(356,826)
Interest expense to related parties.....	1,256,047	1,782,930	824,986	3,878,763
Interest expense.....	6,404,256	4,213	4,630	6,413,547
Loss before benefit from state income taxes.....	(22,904,677)	(12,771,161)	(10,767,694)	(56,619,018)
Benefit from state income taxes.....	(338,033)	(238,584)	-	(576,617)
Net loss.....	\$ (22,566,644)	\$ (12,532,577)	\$ (10,767,694)	\$ (56,042,401)
Net loss per common share:				
Basic and diluted.....	\$ (2.19)	\$ (16.50)	\$ (14.92)	
Weighted average number of common shares:				
Basic and diluted.....	10,319,226	759,429	721,830	

The accompanying notes are an integral part of these consolidated financial statements.

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VYTERIS HOLDINGS (NEVADA), INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	DEFERRED COMPENSATION	DEFICIT ACCUMULATED IN DEVELOPMENT STAGE	TOTAL STOCKHOLDERS' EQUITY (DEFICIT)
	SHARES	AMOUNT				
<S>	<C>	<C>	<C>	<C>	<C>	<C>
Balance at November 10, 2000 (inception).....	-	\$ -	\$ -	\$ -	\$ -	\$ -
Issuance of common stock.....	698,333	698	6,501,329	-	-	6,502,027
Net loss.....	-	-	-	-	(716,621)	(716,621)
Balance at December 31, 2000.....	698,333	698	6,501,329	-	(716,621)	5,785,406
Compensation associated with stock option grants.....	-	-	-	260,810	(260,810)	-
Amortization of deferred compensation.....	-	-	-	48,177	-	48,177
Exercise of stock options.....	8,642	9	12,365	-	-	12,374
Issuance of warrants.....	-	-	64,000	-	-	64,000
Consultant compensation associated with stock options.....	-	-	8,799	-	-	8,799
Net loss.....	-	-	-	-	(9,458,865)	(9,458,865)
Balance at December 31, 2001.....	706,975	707	6,847,303	(212,633)	(10,175,486)	(3,540,109)
Issuance of common stock.....	52,375	52	499,948	-	-	500,000
Forfeited stock options.....	-	-	(25,161)	25,161	-	-
Amortization of deferred compensation.....	-	-	-	80,669	-	80,669
Exercise of stock options.....	78	1	111	-	-	112
Issuance of warrants.....	-	-	502,220	-	-	502,220
Net loss.....	-	-	-	-	(10,767,694)	(10,767,694)
Balance at December 31, 2002.....	759,428	760	7,824,421	(106,803)	(20,943,180)	(13,224,802)
Adjustment for cancelled-unamortized, stock option grants.....	-	-	(272)	2	-	-

Compensation associated with stock option grants.....	-	-	9,480	(9,480)	-	-
Amortization of deferred compensation.....	-	-	-	72,664	-	72,664
Consultant compensation associated with stock options.....	-	-	2,430	-	-	2,430
Net loss.....	-	-	-	-	(12,532,577)	(12,532,577)
<hr/>						
Balance at December 31, 2003.....	759,428	760	7,836,059	(43,347)	(33,475,757)	(25,682,285)
Adjustment for cancelled-unamortized, stock option grants.....	-	-	(6,461)	6,461	-	-
Compensation associated with stock option grants.....	-	-	333,122	(333,122)	-	-
Amortization of deferred compensation.....	-	-	-	238,462	-	238,462
Exercise of stock options.....	20,807	21	32,205	-	-	32,226
Issuance of common stock on conversion of debt and preferred stock.....	9,637,000	9,637	21,273,361	-	-	21,282,998
Issuance of warrants to convertible note holders.....	-	-	1,856,104	-	-	1,856,104
Beneficial conversion of convertible debt.....	-	-	2,401,057	-	-	2,401,057
Issuance of warrants associated with private placement.....	-	-	1,182,264	-	-	1,182,264
Issuance of common stock in exchange of debt....	69,833	70	249,930	-	-	250,000
Issuance of common stock on conversion of preferred stock.....	279,333	279	333,054	-	-	333,333
Issuance of common stock for capital raised, net.....	4,206,792	4,207	12,287,240	-	-	12,291,447
Issuance of common stock on conversion of debt and preferred stock.....	3,560,453	3,560	8,493,940	-	-	8,497,500
Reverse deferred financing costs upon conversion of debt.....	-	-	(462,863)	-	-	(462,863)
Issuance of common stock for working capital credit line.....	419,000	419	1,274,581	-	-	1,275,000
Merger with Vyteris Holdings.....	338,212	338	(7,977)	-	-	(7,639)
Issuance of warrants associated with merger....	-	-	347,255	-	-	347,255
Capital contribution by Vyteris Holdings officers.....	-	-	9,519	-	-	9,519
Issuance of common stock in exchange of services.....	3,000	3	2,997	-	-	3,000
Net loss.....	-	-	-	-	(22,566,644)	(22,566,644)
<hr/>						
Balance at December 31, 2004.....	19,293,858	\$19,294	\$57,435,387	\$ (131,546)	\$ (56,042,401)	\$ 1,280,734

The accompanying notes are an integral part of these consolidated financial statements.

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VYTERIS HOLDINGS (NEVADA), INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	YEARS ENDED DECEMBER 31,			PERIOD FROM
	2004	2003	2002	NOVEMBER 10, 2000 (INCEPTION) TO DECEMBER 31, 2004
	<C>	<C>	<C>	<C>
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	\$ (22,566,644)	\$ (12,532,577)	\$ (10,767,694)	\$ (56,042,401)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization.....	406,249	288,041	239,490	1,045,747
Amortization of notes payable discount.....	1,856,104	217,854	341,788	2,422,324
Amortization of deferred compensation.....	238,462	72,664	80,669	439,972
Amortization of financing costs.....	2,302,917	--	--	2,302,917
Amortization of beneficial conversion feature of warrants.....	2,401,057	--	--	2,401,057
Noncash compensation.....	--	2,430	--	11,229
Compensation for services paid with warrants and common stock..	350,255	--	--	350,255
Change in operating assets and liabilities:				
Prepaid expenses and other current assets.....	(766,474)	293,557	(232,302)	(859,712)
Accounts payable.....	65,601	(251,885)	484,790	953,459
Accrued expenses and other liabilities.....	357,306	37,964	83,835	1,284,829
Interest payable to related parties.....	708,873	1,565,984	482,311	2,765,368
Due to Spencer Trask.....	--	--	61,577	71,577
Net cash used in operating activities.....	14,646,294)	(10,305,968)	(9,225,536)	(42,853,379)

CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of equipment.....	(486,795)	(1,225,631)	(700,292)	(2,979,761)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Net proceeds from issuance of common stock.....	--	--	500,000	6,335,360
Net proceeds from private placement of common stock and warrants.....	12,291,447	--	--	12,291,447
Net proceeds from issuance of convertible redeemable preferred stock.....	--	--	--	2,917,640
Proceeds from exercise of options.....	32,226	--	112	44,712
Proceeds from issuance of convertible promissory notes to related parties.....	--	9,670,000	9,680,000	20,350,000
Proceeds from issuance of secured promissory notes to related parties, net.....	--	2,900,000	--	2,900,000
Proceeds from issuance of promissory note to related party....	--	500,000	--	500,000
Net proceeds from private placement of convertible debt and warrants.....	7,232,730	--	--	7,232,730
Repayment from issuance of promissory note to related party....	(250,000)	--	--	(250,000)
Repayment of capital lease obligations and other.....	(20,744)	(17,357)	(11,012)	(50,012)
Net cash provided by financing activities.....	19,285,659	13,052,643	10,169,100	52,271,877
Net increase in cash and cash equivalents.....	4,152,570	1,521,044	243,272	6,438,737
Cash and cash equivalents at beginning of the period.....	2,286,167	765,123	521,851	--
Cash and cash equivalents at end of the period.....	\$ 6,438,737	\$ 2,286,167	\$ 765,123	\$ 6,438,737

The accompanying notes are an integral part of these consolidated financial statements.

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VYTERIS HOLDINGS (NEVADA), INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED STATEMENTS OF CASH FLOWS
(CONTINUED)

	YEARS ENDED DECEMBER 31,			PERIOD FROM
	2004	2003	2002	NOVEMBER 10, 2000 (INCEPTION) TO DECEMBER 31, 2004
	<C>	<C>	<C>	<C>
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:				
Issuance of capital stock in exchange for equipment.....	\$ --	\$ --	\$ --	\$ 1,000,000
Equipment acquired under capital lease.....	--	25,216	43,043	81,434
Cancellation of warrants.....	--	--	502,220	(566,220)
Issuance of warrants in connection with issuance of convertible secured promissory notes payable.....	1,856,104	--	--	1,856,104
Issuance of warrants to placement agents.....	1,182,264	--	--	1,182,264
Beneficial conversion of convertible notes.....	2,401,057	--	--	2,401,057
Conversion of convertible secured promissory notes payable to related parties into convertible secured promissory notes payable.....	500,000	--	--	500,000
Conversion of convertible secured promissory notes payable into common stock.....	8,497,500	--	--	8,497,500
Conversion of convertible secured promissory notes payable to related parties into common stock.....	250,000	--	--	250,000
Conversion of convertible redeemable preferred stock into common stock.....	333,333	--	--	333,333
Issuance of common stock in exchange for working				

capital facility.....	1,275,000	--	--	1,275,000
Issuance of common stock in exchange for services.....	3,000	--	--	3,000
Interest paid.....	\$ 337,832	\$ 3,354	\$ 3,179	\$ 344,289
Recapitalization transaction:				
Exchanged:				
Interest payable to related parties.....	\$ (2,615,368)	\$ --	\$ --	\$ (2,615,368)
Convertible secured promissory notes payable to related parties.....	(20,350,000)	--	--	(20,350,000)
Warrants which were issued with convertible, secured promissory notes payable to related parties.....	(566,220)	--	--	(566,220)
Secured promissory notes payable to related parties.....	(2,900,000)	--	--	(2,900,000)
Convertible redeemable preferred stock.....	(2,917,640)	--	--	(2,917,640)
For:				
Due to Spencer Trask Specialty Group, LLC.....	10	--	--	10
Proceeds from issuance of convertible redeemable preferred stock.....	7,500,000	--	--	7,500,000
Common stock.....	2,300	--	--	2,300
Paid in capital.....	21,846,918	--	--	21,846,918
	\$ --	\$ --	\$ --	\$ --

The accompanying notes are an integral part of these consolidated financial statements.

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VYTERIS HOLDINGS (NEVADA), INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION AND BASIS OF PRESENTATION

MERGER

Vyteris Holdings (Nevada), Inc. (formerly Treasure Mountain Holdings, Inc.) was organized in Utah as Treasure Mountain Mining Company in 1954 to engage in the business of mining, milling, processing and marketing various minerals, primarily tungsten. The corporation engaged in the mining business for a period of time after inception and acquired various mineral leases, but became relatively inactive for several years until approximately 1997. In 1997, the corporation's name was changed to Treasure Mountain Holdings, Inc., it was re-domiciled as a Nevada corporation and the Utah corporation was subsequently dissolved. In May 2005 the corporation's name was changed to Vyteris Holdings (Nevada), Inc.

On September 29, 2004, Vyteris Holdings (Nevada), Inc. completed a business combination in which Vyteris, Inc. ("Vyteris"), a Delaware corporation, merged with a wholly-owned subsidiary of Vyteris Holdings (Nevada), Inc. (the "Merger"). As a result of the Merger, Vyteris became Vyteris Holdings (Nevada), Inc.'s wholly-owned subsidiary and the former stockholders of Vyteris became stockholders of Vyteris Holdings (Nevada), Inc. At the time of that business combination, Vyteris Holdings (Nevada), Inc. had no active business. As a result, Vyteris Holdings (Nevada), Inc.'s principal business after that business combination became the business in which Vyteris has been engaged since its formation in November 10, 2000. The terms "Treasure Mountain," "Vyteris Holdings" and the "Company" refer to each of Vyteris Holdings (Nevada), Inc., Vyteris, Inc. and the combined company.

After the Merger, the former stockholders of Vyteris owned 98.2% of the outstanding common stock and rights to receive common stock of Vyteris Holdings (Nevada), Inc. The former directors of Vyteris Holdings (Nevada), Inc. resigned immediately prior to the Merger and the directors of Vyteris immediately prior to the Merger became the sole directors of Vyteris Holdings (Nevada), Inc. Similarly, the former officers of Vyteris Holdings (Nevada), Inc. resigned immediately prior to the Merger and the executive officers of Vyteris immediately prior to the Merger became the sole officers of Vyteris Holdings (Nevada), Inc.

The accompanying consolidated balance sheet as of December 31, 2004 and the consolidated statements of operations for the year ended December 31, 2004, consolidate the historical financial statements of Vyteris Holdings with Vyteris after giving effect to the Merger where Vyteris is the accounting acquiror by

recording the transaction as the issuance of Vyteris stock for the net monetary assets of Vyteris Holdings, accompanied by a recapitalization with no goodwill or other intangibles recorded. As a result of the Merger, although Vyteris Holdings is the parent company, the information included in these financial statements relate to Vyteris as it is the accounting acquiror.

The Board of Directors authorized a one for ten reverse stock split effective May 2, 2005 (see Note 20). All share information with respect to the Company's common stock, options, and warrants have been adjusted to give retroactive effect to the reverse stock split for all periods presented.

The Vyteris/ Vyteris Holdings Merger Agreement (the "Merger Agreement") provided for the following:

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VYTERIS HOLDINGS (NEVADA), INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

- o Each outstanding share of Vyteris common stock was automatically converted into the right to receive 0.419 shares of the Company's common stock. Immediately prior to the consummation of the Merger, there were 45,233,047 shares of Vyteris, Inc. common stock outstanding. Accordingly, the shares of Vyteris, Inc. common stock outstanding immediately prior to the consummation of the Merger have been converted into 18,952,647 shares of the Company's common stock.
- o Each outstanding share of Vyteris, Inc. Series C convertible redeemable preferred stock was automatically converted into the right to receive one share of the Company's Series B convertible redeemable preferred stock. Each share of the Company's Series B convertible redeemable preferred stock is convertible into a number of shares of the Company's common stock equal to (i) 0.419 multiplied by (ii) the number of shares of Vyteris, Inc. common stock into which one share of Vyteris, Inc. Series C convertible redeemable preferred stock was convertible prior to the consummation of the Merger. The Vyteris, Inc. Series C convertible redeemable preferred stock was convertible into one quarter of a share of Vyteris, Inc. common stock if converted at any time within 18 months of March 31, 2004, one third of a share of Vyteris, Inc. common stock if converted at any time within the 18 months thereafter and two thirds of a share of Vyteris, Inc. common stock if converted at any time thereafter. Immediately prior to the consummation of the Merger, there were 7,500,000 shares of Vyteris, Inc. Series C convertible redeemable preferred stock outstanding. Accordingly, the shares of Vyteris, Inc. Series C convertible redeemable preferred stock outstanding immediately prior to the consummation of the Merger have been converted into 7,500,000 shares of the Company's Series B convertible redeemable preferred stock, which shares are currently convertible into the right to receive a total of 785,625 shares of the Company's common stock.
- o Each outstanding option and warrant to purchase one or more shares of Vyteris, Inc. common stock -- which we refer to as an existing option or an existing warrant - was automatically converted into an option or warrant to purchase one or more shares of the Company's common stock -- which we refer to as a new option or a new warrant. The number of shares of the Company's common stock covered by each new option or new warrant equals the number of shares of Vyteris, Inc. common stock covered by the corresponding existing option or existing warrant multiplied by 0.419. The exercise price of each new option or new warrant equals the exercise price of the corresponding existing option or existing warrant divided by 0.419. Immediately prior to the consummation of the Merger, there were existing options outstanding covering 3,766,911 shares of Vyteris, Inc. common stock and there were existing warrants outstanding covering 12,168,965 shares of Vyteris, Inc. common stock. Accordingly, upon consummation of the Merger, the existing options were converted into new options to purchase a total of 1,578,336 shares of the Company's common stock and the existing warrants were converted into new warrants to purchase a total of 5,098,796 shares of the Company's common stock.

By virtue of the Merger, warrants covering an additional 150,000 shares of the Company's common stock were granted to two former executive officers and directors of the Company.

ORGANIZATION

Vyteris, formerly Drug Delivery Technologies, Inc., was incorporated on July 19, 2000 in the State of Delaware. Vyteris had no operating activity prior to November 10, 2000. The Company has developed and produced the first electronically controlled transdermal drug delivery system that delivers drugs through the skin comfortably, without needles. This platform technology can be used to administer certain therapeutics either directly to the skin or into the bloodstream. The Company holds over 60 U.S. patents relating to the delivery of drugs across the skin using a mild electric current. The Company operates in one business segment.

Effective November 10, 2000, the Company, Becton Dickinson and Co. ("Becton Dickinson") and Spencer Trask entered into a stockholders' agreement (the "Stockholders' Agreement"), in conjunction with a transaction agreement (the "Transaction Agreement") also effective on November 10, 2000, whereby

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VYTERIS HOLDINGS (NEVADA), INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

Becton Dickinson agreed to transfer to the Company certain assets in exchange for common stock and Vyteris Series A convertible redeemable preferred stock and Spencer Trask agreed to contribute \$9.0 million in cash in exchange for common stock and Vyteris Series B convertible redeemable preferred stock. Becton Dickinson received 10% of the voting stock of the Company which was valued at \$1.0 million. The entire \$1.0 million was allocated to manufacturing equipment. The manufacturing equipment was carried at a net book value of greater than \$1.0 million by Becton Dickinson on November 10, 2000.

The Company paid certain Transaction Agreement expenses on behalf of Spencer Trask approximating \$0.3 million. The reimbursement was recorded as a reduction in additional paid-in capital associated with the common stock and Series B convertible redeemable preferred stock issued to Spencer Trask.

RECAPITALIZATION TRANSACTION

On March 31, 2004, Spencer Trask and a related party consummated a transaction with the Company wherein the Company issued to Spencer Trask and such related party a total, after giving effect to the Merger, of 9,637,000 shares of common stock, as well as shares of preferred stock which, pursuant to the Merger, were converted into 7.5 million shares of Vyteris Holdings Series B convertible redeemable preferred stock, and other nominal consideration in exchange for \$20.3 million principal amount of convertible, secured promissory notes payable to related parties and \$2.9 million of secured promissory notes payable to related parties (collectively the "Spencer Trask Notes"), \$2.6 million of accrued and unpaid interest on the Spencer Trask Notes, 3.0 million shares of Vyteris Series B convertible redeemable preferred stock and the cancellation of warrants to purchase 852,665 shares of Vyteris common stock with a paid-in capital value of \$0.6 million (the "Recapitalization Transaction") (see Note 9).

BASIS OF PRESENTATION

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern; however, at its current and planned rate of spending, the Company's cash and cash equivalents and the proceeds expected to be provided by the Working Capital Facility described in Note 10 are not sufficient to allow it to continue operations beyond July 30, 2005. No assurance can be given that the Company will be successful in arranging the additional planned financing needed to continue the execution of its business plan, which includes the development of new products. Failure to obtain such financing may require management to substantially curtail operations, which may result in a material adverse effect on the financial position or results of operations of the Company. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might occur if the Company is unable to continue in business as a going concern.

Intercompany balances and transactions have been eliminated in consolidation.

2. SIGNIFICANT ACCOUNTING POLICIES

CASH EQUIVALENTS

The Company considers all highly liquid instruments with maturities of three months or less at the date of purchase to be cash equivalents.

PROPERTY AND EQUIPMENT, NET

Property and equipment, net is stated at cost, except for certain equipment acquired in connection with the Transaction Agreement, which is recorded at the fair value of the equipment on the date of acquisition. Depreciation and amortization of property and equipment is provided on a straight-line basis over the asset's estimated useful life or related lease term as follows:

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VYTERIS HOLDINGS (NEVADA), INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

Leasehold improvements.....	2 - 10 years
Furniture, machinery and equipment.....	5 years
Computer software and hardware.....	3 years

Equipment held under capital leases is recorded at the present value of the minimum lease payments at the inception of the lease and is amortized on the straight-line method over the shorter of the lease term or the estimated useful life of the equipment. Amortization of equipment held under capital leases is included in depreciation and amortization expense in the accompanying consolidated financial statements. Leasehold improvements are amortized over the estimated useful life or over the term of the lease, whichever is shorter. Replacements, maintenance and repairs that do not improve or extend the life of the respective asset are expensed as incurred.

REVENUE

PRODUCT REVENUE. Through December 31, 2004, the Company has not had any product revenue. The Company will recognize product revenue, net of allowances for anticipated returns, provided that (1) persuasive evidence of an arrangement exists, (2) delivery to the customer has occurred, (3) the selling price is fixed or determinable and (4) collection is reasonably assured. Delivery is considered to have occurred when title and risk of loss have transferred to the customer. The price is considered fixed or determinable when it is not subject to refund or adjustments.

FEASIBILITY STUDIES. The Company conducts feasibility studies to demonstrate the viability of its technology to interest potential partners to enter into a development, marketing and supply partnership. Revenues on feasibility studies are measured using the proportional performance method of accounting. Such studies are typically completed within a one- to three-month period. Revenue producing feasibility studies do not occur regularly, are priced at what the Company anticipates the actual costs will be and are not expected to produce material revenues or a profit. When applying the proportional performance method, the Company relies on total expected input (contract) costs in order to determine the amount of revenue earned to date. The Company follows this method because reasonably dependable estimates of the revenue applicable to various contract milestones can be made. The Company monitors estimates of total contract revenues and cost on a routine basis throughout the contract period. The cumulative impact of any change in estimates of the contract revenues or costs is reflected in the period in which the changes become known. In the event that a loss is anticipated on a particular contract, provision is made for the estimated loss in the period in which the anticipated loss becomes known. The Company issues invoices related to fixed price contracts based on either the achievement of milestones during a project or other contractual terms. Differences between the timing of billings and the recognition of revenue based upon the proportional performance method of accounting are recorded as revenue earned in excess of billings or deferred revenue.

The cost of feasibility studies was approximately \$0.1 million, \$0.2 million, \$0.1 million, and \$0.5 million, for the years ended December 31, 2004, 2003, 2002 and for the period from November 10, 2000 (inception) to December 31, 2004, respectively, and is included in research and development expense in the accompanying consolidated statements of operations.

DEFERRED REVENUE. Non-refundable upfront fees are deferred and recognized as revenue on a straight-line basis in accordance with the contract terms and generally over the lives of the agreements.

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VYTERIS HOLDINGS (NEVADA), INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

REVENUES FROM REIMBURSEMENT OF DEVELOPMENT COSTS. In accordance with Emerging Issues Task Force, EITF, No. 01-14, Income Statement Characterization of Reimbursements Received for "Out-of-Pocket" Expenses Incurred, the Company recognizes revenues for the reimbursement of development costs when it bears all the risk for selection of and payment to vendors and employees.

STOCK-BASED COMPENSATION

As permitted by Statement of Financial Accounting Standards ("SFAS") No. 123, Accounting for Stock-Based Compensation ("SFAS No. 123"), the Company has elected to follow Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ("APB No. 25"), and related interpretations for its employee stock-based compensation. Under APB No. 25, no compensation expense is recognized at the time of option grant if the exercise price of the employee stock option is fixed and equals or exceeds the fair value of the underlying common stock on the date of grant and the number of shares to be issued pursuant to the exercise of such option are known and fixed at the date of grant. The Board of Directors determines the fair value of common stock.

The Company accounts for options issued to non-employees under SFAS No. 123 and EITF No. 96-18, Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Therefore, the fair value of options issued to non-employees is recorded as an expense and periodically re-measured over the vesting terms.

The following table illustrates the effect on net loss per common share as if the Company had applied the fair value recognition provisions for stock-based employee compensation of SFAS No. 123, as amended by SFAS No. 148, Accounting for Stock-Based Compensation -- Transition and Disclosure.

	DECEMBER 31,			PERIOD FROM
	2004	2003	2002	NOVEMBER 10, 2000 (INCEPTION) TO DECEMBER 31, 2004
<S>	<C>	<C>	<C>	<C>
Net loss, as reported.....	\$ (22,566,644)	\$ (12,532,577)	\$ (10,767,694)	\$ (56,042,401)
Add: stock-based employee compensation expense included in reported net loss.....	238,462	72,664	80,669	439,972
Deduct: stock-based employee compensation expense determined under fair value based method for all awards.....	(700,432)	(140,829)	(130,133)	(1,032,036)
SFAS No. 123 pro forma net loss.....	\$ (23,028,614)	\$ (12,600,742)	\$ (10,817,158)	\$ (56,634,465)
Net loss per common share, as reported:				
Basic and diluted.....	\$ (2.19)	\$ (16.50)	\$ (14.92)	
Basic and diluted, pro forma.....	\$ (2.23)	\$ (16.59)	\$ (14.99)	
Weighted average number of common shares:				
Basic and diluted.....	10,319,226	759,429	721,830	

For purposes of pro forma disclosures, the estimated fair value of the options granted is amortized to expense over the option vesting periods. The fair value of each option granted prior to the Merger was estimated using a minimum value option-pricing model and subsequent to the Merger using a Black-Scholes option-pricing model with the following weighted-average assumptions:

	DECEMBER 31,		
	2004	2003	2002
<S>	<C>	<C>	<C>
Expected holding period (years).....	6.0	6.0	6.0
Risk-free interest rate	3.97%	3.18%	4.75%
Dividend yield.....	0%	0%	0%
Fair value of options granted.....	\$ 1.80	\$ 1.80	\$ 1.80

</TABLE>

VYTERIS HOLDINGS (NEVADA), INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

Subsequent to the Merger, the Company issued options to purchase 178,075 shares of the Company's common stock at a price of \$1.90 per share to a key executive. Such options were issued in September 2004 using a Black-Scholes option-pricing model with an expected volatility of 97.0%. Currently there is no active trading market for the Company's common stock.

In addition, the option valuation models require input of highly subjective assumptions. Because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of employee stock options. The pro forma net loss per common share may not be representative of future disclosure since the estimated fair value of stock options is amortized to expense over the vesting period and additional options may be granted in future years.

INCOME TAXES

The Company records deferred tax assets and liabilities based on the differences between the financial statement and tax bases of assets and liabilities and on operating loss carryforwards using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

RESEARCH AND DEVELOPMENT

Research and development costs are charged to expense as incurred.

USE OF ESTIMATES

The Company's consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, which require management to make estimates and assumptions. These estimates and assumptions affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the revenues and expenses reported during the period. These estimates and assumptions are based on management's judgment and available information and, consequently, actual results could differ from these estimates.

NET LOSS PER SHARE

The Company computes net loss per share in accordance with SFAS No. 128, Earnings per Share. Under the provisions of SFAS No. 128, basic net loss per common share, or Basic EPS, is computed by dividing net loss by the weighted-average number of common shares outstanding. Diluted net loss per common share, or Diluted EPS, is computed by dividing net loss by the weighted average number of shares and dilutive common share equivalents then outstanding. Common equivalent shares consist of the incremental common shares issuable upon the exercise of stock options and warrants and the conversion of preferred stock. Diluted EPS is identical to Basic EPS since common equivalent shares are excluded from the calculation, as their effect is anti-dilutive. For the year ended December 31, 2004, Basic EPS and Diluted EPS on a pro forma basis gives effect to the conversion of rights certificates into common shares. The Company has calculated the weighted number of shares outstanding reflecting the 0.419:1 exchange ratio for all periods presented.

LONG-LIVED ASSETS

The Company reviews long-lived assets, including fixed assets, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when the estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is assessed using discounted cash flows. There were no impairment indicators during the year ended December 31, 2004.

FINANCIAL INSTRUMENTS

Cash and cash equivalents, accounts receivable, accounts payable, accrued expenses and other current liabilities reported in the consolidated balance sheets equal or approximate their fair value due to their short term to maturity.

SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity, specifies that instruments within its scope embody obligations of the issuer and that the issuer must classify them as liabilities. SFAS No. 150 requires issuers to classify as liabilities the following three types of freestanding financial instruments: (1) mandatorily redeemable financial instruments, (2) obligations to repurchase the issuer's equity shares by transferring assets and (3) certain obligations to issue a variable number of shares. SFAS No. 150 defines a "freestanding financial instrument" as a financial instrument that (1) is entered into separately and apart from any of the entity's other financial instruments or equity transactions or (2) is entered into in conjunction with some other transaction and can be legally detached and exercised on a separate basis. Accordingly, the Company has classified the Vyteris Series A convertible redeemable preferred stock, Vyteris Series B convertible redeemable preferred stock and Vyteris Holdings Series B convertible redeemable preferred stock as liabilities in the accompanying consolidated balance sheets.

CONCENTRATIONS OF CREDIT RISK

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash and cash equivalents and accounts receivable. The Company deposits its cash and cash equivalents with major financial institutions. At December 31, 2004, the Company had a cash balance in a financial institution that exceeded federal deposit insurance limits. Management believes that credit risk related to this deposit is minimal. The Company extends credit without collateral to companies that contract with it under contract research arrangements.

RISK AND UNCERTAINTIES

The Company relies on a single customer, B. Braun Medical, Inc., or B. Braun, to generate product revenue. The Company granted B. Braun the right to be its exclusive, worldwide sales and marketing distributor for its LidoSite product. As a result, the Company is dependent on B. Braun and its ability to effectively market the Company's only current product. If B. Braun is unable to sell the LidoSite product effectively, the Company does not have the ability to seek other customers for its LidoSite product at least until such time as satisfactory arrangements are made with B. Braun.

The Company also purchases raw materials and components from single-source suppliers. Some of those materials or components are custom-made and are the result of long periods of collaboration with suppliers. Although the Company has not experienced significant supply delays attributable to supply changes, the Company believes that, for integrated circuits and hydrogel in particular, alternative sources of supply would be difficult to develop over a short period of time. Because the Company has no direct control over its third-party suppliers, interruptions or delays in the products and services provided by these third parties may be difficult to remedy in a timely fashion. In addition, if such suppliers are unable or unwilling to deliver the necessary parts or products, the Company may be unable to redesign or adapt its technology to work without such parts or find alternative suppliers or manufacturers. In such events, the Company could experience interruptions, delays, increased costs, or quality control problems.

RECLASSIFICATIONS

Certain reclassifications have been made to prior-year amounts to conform to the current-year presentation.

RECENTLY ISSUED ACCOUNTING STANDARDS

As permitted by SFAS No. 123, the Company currently accounts for share-based payments to employees using APB No. 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options.

Accordingly, the adoption of Statement No. 123 (revised 2004), Share-Based Payment, an Amendment of Financial Accounting Standards Board (the "FASB") Statements No. 123 and 95, fair value method will have a significant impact on the Company's result of operations, although it will have no impact on its overall financial position. The impact of adoption of Statement No. 123 (revised 2004) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted Statement No. 123 (revised 2004) in prior periods, the impact of that standard would have approximated the impact of Statement No. 123 as described in the disclosure of pro forma net income and earnings per share to its consolidated financial statements. Statement No. 123 (revised 2004) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. The Company cannot estimate what those amounts will be in the future because they depend on, among other things, when employees exercise stock options.

In November of 2004, the FASB issued SFAS No. 151, Inventory Costs, an Amendment of ARB No. 43, Chapter 4 ("SFAS No. 151"). SFAS No. 151 clarifies that abnormal amounts of idle facility expense, freight, handling costs and spoilage should be expensed as incurred and not included in overhead. SFAS No. 151 also requires that allocation of fixed production overheads to conversion costs should be based on normal capacity of the production facilities. The provisions in SFAS No. 151 are effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Companies must apply the standard prospectively. The Company does not believe that the impact of this new standard will have a material effect on its prospective financial condition or results of operations.

In December 2004, the FASB issued SFAS No. 153, Exchanges of Non-Monetary Assets, an Amendment of APB No. 29 ("SFAS No. 153"). SFAS No. 153 amends APB Opinion No. 29, Accounting for Nonmonetary Transactions. Earlier guidance had been based on the principle that exchanges of nonmonetary assets should be based on the fair value of the assets exchanged and APB No. 29 included certain exceptions to this principle. However, SFAS No. 153 eliminated the specific exceptions for nonmonetary exchanges with a general exception for all exchanges of nonmonetary assets that do not have commercial and economic substance. A nonmonetary exchange has commercial substance only if the future cash flows of our company is expected to change significantly as a result of the exchange. SFAS No. 153 is effective for nonmonetary exchanges occurring in fiscal periods beginning after June 15, 2005. The Company does not believe that the impact of this new standard will have a material effect on its prospective financial condition or results of operations.

3. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consist of the following:

<TABLE>
<CAPTION>

	DECEMBER 31,	
	2004	2003
<S>	<C>	<C>
Manufacturing and laboratory equipment.....	\$ 1,557,083	\$ 1,235,815
Furniture and fixtures.....	96,306	32,743
Office equipment.....	150,081	104,516
Leasehold improvements.....	122,193	--
Software.....	102,542	82,200
	2,028,205	1,455,274
Less: Accumulated depreciation and amortization.....	(1,045,747)	(639,498)
	982,458	815,776
In-process equipment.....	1,763,921	1,888,396
Construction in progress.....	269,069	230,730
	\$ 3,015,448	\$ 2,934,902

</TABLE>

Depreciation and amortization expense, included in research and development expense and general and administrative expense in the accompanying consolidated statements of operations., was approximately \$0.4 million, \$0.3 million, \$0.2

million and \$1.0 million for the years ended December 31, 2004, 2003, 2002 and for the period from November 10, 2000 (inception) to December 31, 2004, respectively.

At December 31, 2004 and 2003, equipment held under capital lease included manufacturing and laboratory equipment and software of approximately \$81,000. At December 31, 2004 and 2003, in-process equipment included advances of approximately \$1.6 million for a continuous motion patch machine that is being custom manufactured for the Company. Additionally, at December 31, 2004 and 2003, in-process equipment included advances of approximately \$0.1 million for patch controller manufacturing equipment that is being custom manufactured for the Company.

Total open purchase commitments related to property and equipment were as follows at December 31, 2004:

	DECEMBER 31, 2004
Continuous motion patch machine.....	\$ 173,400
Laboratory equipment and other.....	9,757

	\$ 183,157
	=====

4. ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

<TABLE>
<CAPTION>

	DECEMBER 31, -----	
	2004	2003
<S>	<C>	<C>
Compensation and benefits.....	\$ 373,260	\$ 426,005
Accrued accounting fees.....	265,000	65,500
Deferred license fee revenue, current portion.....	75,455	--
Due to a related party.....	71,587	71,577
Current portion of capital lease obligation.....	18,609	22,620
Other.....	207,922	136,018
	-----	-----
	\$ 1,011,833	\$ 721,720
	=====	=====

</TABLE>

5. CONVERTIBLE SECURED PROMISSORY NOTES PAYABLE TO RELATED PARTIES

During 2003, 2002 and 2001, the Company issued convertible secured promissory notes (the "Convertible Notes") with an aggregate principal amount of \$20.3 million to the related parties listed below. Each of the Convertible Notes matured one year from its respective date of issuance and accrued interest at an annual rate of 8%, which was payable on maturity (the annual interest rate increases to 11% if payment of the principal is overdue).

VYTERIS HOLDINGS (NEVADA), INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

The following is a schedule of the Convertible Notes:

<TABLE>
<CAPTION>
<S>

PAYEE	ISSUANCE DATE	PRINCIPAL AMOUNT	BALANCE AT DECEMBER 31, 2003
-----	-----	-----	-----
Spencer Trask Specialty Group, LLC	November 21, 2001	\$ 750,000	\$ 750,000
Member of the Board of Directors	December 3, 2001	250,000	250,000
Spencer Trask Specialty Group, LLC	January 25, 2002	750,000	750,000
Spencer Trask Specialty Group, LLC	February 22, 2002	1,500,000	1,500,000
Spencer Trask Specialty Group, LLC	April 10, 2002	1,000,000	1,000,000
Spencer Trask Specialty Group, LLC	May 9, 2002	2,000,000	2,000,000

Spencer Trask Specialty Group, LLC	July 12, 2002	1,000,000	1,000,000
Spencer Trask Specialty Group, LLC	August 20, 2002	625,000	625,000
Spencer Trask Specialty Group, LLC	October 17, 2002	925,000	925,000
Spencer Trask Specialty Group, LLC	November 26, 2002	880,000	880,000
Spencer Trask Specialty Group, LLC	December 23, 2002	1,000,000	1,000,000
Spencer Trask Specialty Group, LLC	January 24, 2003	1,000,000	1,000,000
Spencer Trask Specialty Group, LLC	March 7, 2003	1,155,000	1,155,000
Spencer Trask Specialty Group, LLC	March 28, 2003	1,150,000	1,150,000
Spencer Trask Specialty Group, LLC	April 30, 2003	607,500	607,500
Spencer Trask Specialty Group, LLC	May 30, 2003	1,152,500	1,152,500
Spencer Trask Specialty Group, LLC	July 8, 2003	1,240,000	1,240,000
Spencer Trask Specialty Group, LLC	July 29, 2003	1,200,000	1,200,000
Spencer Trask Specialty Group, LLC	August 28, 2003	1,165,000	1,165,000
Spencer Trask Specialty Group, LLC	October 3, 2003	1,000,000	1,000,000

			20,350,000
Less discount from issuance of warrants			-

			\$ 20,350,000
			=====

</TABLE>

The Company defaulted on payment of the entire principal and accrued interest due on the Convertible Notes dated November 21, 2001, December 3, 2001, January 25, 2002, February 22, 2002, April 10, 2002, May 9, 2002, July 12, 2002, August 20, 2002, October 17, 2002, November 26, 2002, December 23, 2002, January 24, 2003, March 7, 2003 and March 28, 2003. Therefore, the Company accrued interest at an annual rate of 11% for each of the Convertible Notes in default starting on their respective maturity dates. At December 31, 2003, approximately \$2.0 million of accrued interest on the Convertible Notes was recorded in interest payable to related parties in the accompanying consolidated balance sheet.

In connection with the issuance of the Convertible Notes, warrants were issued to purchase a total, after giving effect to the Merger, of approximately 853,000 shares (405,000 during 2003, 406,000 during 2002 and 42,000 during 2001) of common stock at an exercise price of \$9.55 per share. Management estimated that the warrants had an aggregate fair value of approximately \$0.6 million (none for 2003 issues, \$0.5 million for 2002 issues, and \$0.1 million for 2001 issues) based on a valuation on each of the respective dates of issue. Therefore, the Company recorded an aggregate discount on the Convertible Notes of approximately \$0.6 million and paid-in capital of approximately \$0.5 million and \$0.1 million in the accompanying consolidated statements of changes in stockholders' equity (deficit) for the years ended December 31, 2002 and 2001, respectively (none in 2003). The discount was amortized over each of the Convertible Notes' respective one-year lives. The warrants had an expiration date of the earlier of seven years from the date of issuance or three years from the date of a qualified initial public offering, or IPO. A qualified IPO is defined as one in which the minimum gross proceeds of \$10.0 million and the minimum price per common share is \$12.00.

As discussed in Note 1 and Note 9, the Convertible Notes were exchanged for common stock and preferred stock in March 2004.

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VYTERIS HOLDINGS (NEVADA), INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

6. SECURED PROMISSORY NOTES PAYABLE TO RELATED PARTIES

During 2003, the Company issued secured promissory notes (the "Notes") with an aggregate principal amount of \$3.0 million to the related parties listed below. Each of the secured promissory notes to related parties matured one year from its respective date of issuance and accrued interest at an annual rate of 8%, which was payable on maturity (the annual interest rate increases to 11% if payment of the principal is overdue).

The following is a schedule of the secured promissory notes:

<TABLE>
<CAPTION>

PAYEE	ISSUANCE DATE	PRINCIPAL AMOUNT	BALANCE AT DECEMBER 31, 2003
-----	-----	-----	-----
<S>	<C>	<C>	<C>

Spencer Trask Specialty Group, LLC	November 6, 2003	\$ 800,000	\$ 800,000
Spencer Trask Specialty Group, LLC	December 12, 2003	1,000,000	1,000,000
Spencer Trask Specialty Group, LLC	December 30, 2003	1,100,000	1,100,000

			\$ 2,900,000
			=====

</TABLE>

As discussed in Note 9, the Notes were exchanged for common stock and preferred stock in 2004. At December 31, 2003, approximately \$13,000 of accrued interest was recorded in interest payable to related parties in the accompanying consolidated balance sheet.

7. CONVERTIBLE PROMISSORY NOTE PAYABLE TO RELATED PARTY

On July 1, 2003, the Company issued a convertible promissory note to Becton Dickinson (the "BD Convertible Note") with an aggregate principal amount of \$0.5 million. The BD Convertible Note matured one year from its date of issuance and accrued interest at an annual rate of 8%, which was payable on maturity (the annual interest rate increases to 11% if payment of the principal is overdue). At any time prior to maturity, all interest and principal on the BD Convertible Note was, at the option of the holder, convertible into common stock. At December 31, 2003, accrued and unpaid interest on the BD Convertible Note was approximately \$20,000 and is reflected in the accompanying consolidated balance sheets as interest payable to related parties.

In connection with the issuance of the BD Convertible Note, warrants were issued (the "Becton Warrants") which represents the right to purchase a total, after giving effect to the Merger, of 20,950 shares of common stock at an exercise price of \$9.55 per share. Management estimated that the BD Warrants had no fair value on the date of issue. The BD Warrants expire at the earlier of seven years from the date of issuance or three years from the date of a qualified initial public offering with minimum gross proceeds are \$10.0 million.

On July 2004, the terms of the BD Convertible Note were changed. The BD Convertible Note was originally due to be repaid on July 1, 2004. Becton Dickinson and the Company agreed to change the repayment date to the earlier of September 30, 2004 or the closing of a private placement and the Merger with Vyteris Holdings. The BD Convertible Note continued to accrue interest at a rate of 8%. In September 2004, Becton Dickinson agreed to the redemption of \$0.25 million of the principal amount of the BD Convertible Note in exchange for a total, after giving effect to the Merger, of 69,833 shares of common stock and warrants to purchase a total, after giving effect to the Merger, of 17,458 shares of common stock at an exercise price of \$4.47 per share. The remaining \$0.25 million in principal amount and all interest accrued to date on the BD Convertible Note was paid on October 1, 2004.

8. PRIVATE PLACEMENT TRANSACTIONS AND PROMISSORY NOTES ISSUED IN 2004

\$15.1 MILLION PRIVATE PLACEMENT

Immediately prior to the consummation of the Merger, the Company consummated a \$15.1 million private placement transaction (the "September Private Placement"). After giving effect to the Merger, the Company

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VYTERIS HOLDINGS (NEVADA), INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

issued units (the "Units") covering a total of 4,206,792 shares of common stock and warrants to purchase a total of 1,051,698 shares of common stock (the "Recent Warrants"). Net proceeds to the Company from the September Private Placement were approximately \$12.3 million. The Recent Warrants have an initial exercise price equal to \$4.47 per share. The Recent Warrants are exercisable immediately upon issuance and have a term of five years. In addition, as part of the September Private Placement, the Company agreed to sell to each of the placement agents or their respective designees, for nominal consideration, warrants to purchase the number of shares of common stock equal to 20% of (i) the aggregate number of shares of common stock included in the Units placed by such placement agent, plus (ii) the aggregate number of shares of common stock underlying the Recent Warrants included in the Units placed by such placement agent, at an exercise price of \$3.58 per share. The placement agents' warrants are exercisable for a period of five years from issuance. The September Private Placement included the conversion of \$1.6 million of loans made to the Company during the month of September 2004 by Spencer Trask Specialty Group, LLC

("Spencer Trask") and certain of its related parties (the "September Notes").

PRIVATE PLACEMENT OF \$8.5 MILLION CONVERTIBLE SECURED PROMISSORY NOTES

During March, April and May of 2004, the Company issued \$8.5 million of 8% convertible secured promissory notes, maturing December 31, 2004 (the "December Notes") in a private placement transaction. In connection with the issuance of the December Notes, warrants were issued to purchase a total, after giving effect to the Merger, of 1,708,226 shares of common stock at an exercise price of \$2.39 per share. The warrants have an expiration date of five years from the date of issuance. Management estimated that the warrants had an aggregate fair value of approximately \$1.9 million. In addition, the Company estimated that the December Notes contained a beneficial conversion feature valued at approximately \$2.4 million. Therefore, the Company initially recorded a discount on the December Notes and increased additional paid-in capital by approximately \$4.3 million. The discount and beneficial conversion feature were being amortized over the life of the December Notes and are included in interest expense in the accompanying consolidated statements of operations.

Simultaneously with the closing of the September Private Placement, the \$8.5 million principal amount of the December Notes converted into a total, after giving effect to the Merger, of 3,560,453 shares of common stock. Upon the conversion of the December Notes, the Company recorded the unamortized portion of the discount and beneficial conversion feature in interest expense in the accompanying consolidated statements of operations.

Costs relating to the private placement transaction were initially capitalized and amortized over the term of the December Notes. Total deferred financing costs of approximately \$2.4 million included placement agent fees and non-accountable expenses of approximately \$1.1 million, legal and other expenses of \$0.1 million and warrants issued to the placement agent valued at approximately \$1.2 million. Amortization expense was included in interest expense in the accompanying consolidated statements of operations. Upon the conversion of the December Notes, the Company recorded \$0.5 million of non-cash financing costs in additional paid-in capital.

The resultant charges to interest expense in 2004 were as follows:

<TABLE>
<CAPTION>

	FAIR VALUE DISCOUNT	BENEFICIAL CONVERSION FEATURE	DEFERRED FINANCING COSTS	TOTAL
<S>	<C>	<C>	<C>	<C>
Interest expense amortization.....	\$ 1,172,602	\$ 1,516,879	\$ 1,548,659	\$ 4,238,140
Interest expense recorded upon conversion of the December Notes on September 29, 2004	683,502	884,178	435,508	2,003,188
Total noncash interest expense.....	\$ 1,856,104	\$ 2,401,057	\$ 1,984,167	\$ 6,241,328

</TABLE>

VYTERIS HOLDINGS (NEVADA), INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

In addition, \$0.5 million was charged to additional paid-in capital upon conversion of the December Notes on September 29, 2004.

Interest expense, including interest expense to related parties, on the consolidated statement of operations for 2004 consists of the following:

	TWELVE MONTHS ENDED DECEMBER 31, 2004
Noncash interest expense:	
Interest expense amortization	\$ 4,238,140
Interest expense recorded upon conversion.....	2,003,188
Coupon and other interest.....	1,418,975
Total interest expense.....	\$ 7,660,303

Included in the December Notes are convertible secured promissory notes payable with principal of \$0.2 million and warrants to purchase a total, after giving effect to the Merger, of 38,758 shares of common stock at \$2.39 per share

issued to members of the Company's Board of Directors and senior management, who purchased the December Notes on the same terms and conditions as all other purchasers of the December Notes.

Spencer Trask Ventures, Inc., a related party to the Company's principal stockholder, acted as placement agent in this transaction. Spencer Trask Ventures, Inc. received a 10% placement fee, a 3% non-accountable expense allowance and warrants to purchase a total, after giving effect to the Merger, of 1,068,136 shares of common stock at an exercise price of \$2.39 per share as compensation for acting as placement agent. These warrants also provide for a cashless exercise right and certain customary anti-dilution and price protection provisions. In addition, the Company granted Spencer Trask Ventures, Inc. an irrevocable right of first refusal for a period of two years following the closing of the aforementioned offering to either purchase for its own account or act as agent for any proposed private offering of our securities by the Company, other than notes or convertible notes to be issued to STSG.

SECURED PROMISSORY NOTES

During February 2004, the Company issued secured promissory notes payable (the "Promissory Notes") with principal of \$1.0 million to Spencer Trask and related parties. Each of the Promissory Notes matured 120 days from its respective date of issuance and bore an annual interest rate of 12%, which was payable on maturity, and were convertible into common stock, at the option of the holders under certain circumstances at \$1 per share.

During May 2004, the holders of \$0.5 million principal amount of the Promissory Notes issued to related parties converted their notes into convertible secured promissory notes (the "December Notes") and warrants in a private placement transaction.

Holders of the remaining \$0.5 million principal amount of the Promissory Notes issued to related parties elected not to convert. On July 2004, \$0.5 million of the Promissory Notes issued to related parties was repaid together with interest of \$20,000.

9. RECAPITALIZATION TRANSACTION

On March 31, 2004 Spencer Trask and a related party consummated a transaction with the Company wherein the Company issued to Spencer Trask and such related party a total, after giving effect to the Merger, of 9,637,000 shares of common stock, shares of preferred stock which converted in the Merger into 7.5 million shares of Vyteris Holdings Series B convertible redeemable preferred stock, and other nominal consideration in exchange for \$20.3 million principal amount of convertible, secured promissory notes payable to related parties and \$2.9 million of secured promissory notes payable to related parties (collectively, the "Spencer Trask Notes"), \$2.6 million of accrued and unpaid interest on the Spencer Trask Notes, 3.0 million shares of Vyteris

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Series B convertible redeemable preferred stock and the cancellation of warrants to purchase 852,665 shares of Vyteris common stock with a paid-in capital value of \$0.6 million, (the "Recapitalization Transaction").

Each holder of Vyteris Series C convertible redeemable preferred stock was entitled to receive dividends when, and if declared by the Board of Directors as long as any shares of the Vyteris Series A preferred stock remained outstanding. Effective upon cancellation of all outstanding shares of the Vyteris Series A convertible redeemable preferred stock, the holders of the Vyteris Series C convertible redeemable preferred stock were entitled to receive, ratably, an annual cash dividend of 8% of the then applicable redemption price, as defined, out of funds legally available, payable quarterly. Subject to the prior rights of the Vyteris Series A convertible redeemable preferred stock, the dividends on the Vyteris Series C convertible redeemable preferred stock were cumulative, whether or not earned or declared and were to be paid quarterly in arrears. Additionally, the holders of Vyteris Series A convertible preferred stock were entitled to receive ratably, dividends if declared by the Board of Directors out of funds legally available, before any dividends were received by holders of common stock. In the event of liquidation, holders of Vyteris Series C convertible redeemable preferred stock were entitled to receive a liquidation preference of \$1.00 per share (adjusted for stock splits or combinations of such stock, recapitalizations, or other similar transactions that have the effect of

increasing or decreasing the number of shares represented by each outstanding share of such stock), plus an amount equal to all declared but unpaid dividends on the Vyteris Series C convertible redeemable preferred stock.

The terms of the Merger called for each share of Vyteris Series C convertible redeemable preferred stock to be exchanged for one share of Vyteris Holdings Series B convertible redeemable preferred stock. All of the outstanding shares of Vyteris Series A convertible redeemable preferred stock were cancelled on September 29, 2004. Therefore, the Company accrued interest of \$0.15 million in the fourth quarter of 2004 on the shares of Vyteris Holdings Series B convertible redeemable preferred stock issuable pursuant to the Merger.

With respect to the distribution of assets, Vyteris Holdings Series B convertible redeemable preferred stock ranks senior to the Company's common stock. Each share of Vyteris Holdings Series B convertible redeemable preferred stock is convertible at any time, at the option of the holder, into common stock at a price per share if converted within 18 months from March 31, 2004, of \$9.50; if converted within the next 18 months, \$7.20; or if converted any time thereafter, \$3.60. The holders of Vyteris Holdings Series B convertible redeemable preferred stock (and the holders of any other series of preferred stock with similar voting rights as the Vyteris Holdings Series B convertible redeemable preferred stock) vote together with the holders of shares of common stock as a single class in all matters to be voted on by shareholders of the Company, except that the vote or consent of the holders of a majority of the shares of Vyteris Holdings Series B convertible redeemable preferred stock is necessary to authorize or issue an equity security having any preference over or being on a parity with the Vyteris Holdings Series B convertible redeemable preferred stock with respect to dividend or liquidation preference; increase the number of authorized shares of Vyteris Holdings Series B convertible redeemable preferred stock; or amend, alter or repeal any provision of the Company's Certificate of Incorporation, Certificate of Designations or By-laws, if such action would alter, in any material respect, the rights of the Vyteris Holdings Series B convertible redeemable preferred stock. Commencing on the first anniversary date of the first commercial sale of LidoSite, and continuing for one year thereafter, the Company is required to redeem (on a quarterly basis) an amount of Vyteris Holdings Series B convertible redeemable preferred stock equal to 5% of the gross profits derived from the sale of LidoSite. During the following years, the Company is required to redeem (on a quarterly basis) an amount of Vyteris Holdings Series B convertible redeemable preferred stock equal to 10% of the gross profits derived from the sale of LidoSite. The redemption price of the Vyteris Holdings Series B convertible redeemable preferred stock is \$1.00 per share (adjusted for splits, etc.) plus any accrued but unpaid dividends.

In accordance with EITF Issue No. 00-27, Application of EITF Issue No. 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios to Certain Convertible Instruments, EITF No. 00-27, the Company utilized the most favorable conversion price that would be in effect at the conversion date to determine if there would be a beneficial conversion feature in connection with the Vyteris Series C convertible redeemable preferred stock. The Vyteris Series C convertible redeemable preferred stock did not have a beneficial conversion feature at the commitment date since even though the

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conversion has three different conversion prices depending upon how long the shares were held, the most favorable conversion price was \$3.60 per share, which was still in excess of the fair value of a common share at the date of the issuance of the Vyteris Series C convertible redeemable preferred stock of \$2.20. If there had been any intrinsic value at the commitment date, it would not be recognized until and unless the triggering event occurred.

Since these transactions were between the Company and its majority shareholder, the transactions were treated as capital transactions and no gain or loss has been reflected in the accompanying consolidated financial statements.

10. WORKING CAPITAL FACILITY

Immediately prior to the closing of the September Private Placement, Spencer Trask agreed to provide the Company (or, at its option, cause a related party to provide the Company) with up to \$5.0 million in working capital loans

in the form of 11.5% secured demand promissory notes (the "Working Capital Facility"). Pursuant to the current terms of the Working Capital Facility, amounts drawn under the facility must be repaid on or before November 15, 2005. As consideration for the commitment of the Working Capital Facility, the Company issued a total, after giving effect to the Merger, of 419,000 shares of common stock to Spencer Trask and recorded the fair value of these shares as deferred financing costs of \$1.3 million. Each time funds are loaned to the Company under the Working Capital Facility, the Company shall issue to the lender a common stock purchase warrant to purchase such number of shares equal to the quotient obtained by dividing (i) 40% of the amount loaned by (ii) 3.58. The warrants are exercisable for five years from the date of issuance and have an initial exercise price of \$3.58 per share. The Working Capital Facility, if used, will be secured by a first priority lien on all of the Company's assets. Management estimates that it will borrow funds under this Working Capital Facility in the second quarter of 2005. As of December 31, 2004 no amounts have been loaned to the Company under the Working Capital Facility.

11. RELATED PARTY TRANSACTIONS

In addition to the September Private Placement described in Notes 1 and 8, the convertible secured promissory notes payable to related parties described in Note 5, the secured promissory notes payable to related parties described in Note 6, the convertible promissory note payable to related party described in Note 7, the secured promissory notes payable transactions in 2004 described in Note 8, the Recapitalization Transaction described in Note 9, the working capital facility described in Note 10 and the non-cancelable operating sublease with Becton Dickinson described in Note 13, the Company had the following related party transactions:

- o At December 31, 2004 and 2003, approximately \$61,000 is included in due to related party in the accompanying consolidated balance sheets for amounts owed to Spencer Trask and Spencer Trask Ventures, Inc. for certain expenses paid on behalf of the Company.
- o During December 2001, \$10,000 of Spencer Trask's funds were deposited in the Company's bank account in error by the Company's bank. Therefore, at December 31, 2004 and 2003, \$10,000 is included in due to related party in the accompanying balance sheets.
- o At December 31, 2004 and 2003, approximately \$30,000 is included in accounts payable in the accompanying consolidated balance sheets for amounts owed to a related party for operating facility expenses.

12. INCOME TAXES

The Company has available for federal income tax purposes net operating loss carryforwards, subject to review by the Internal Revenue Service, aggregating approximately \$48.9 million and expiring from 2020 to 2024. The difference between the deficit accumulated during the development stage for financial reporting purposes and the net operating loss carryforwards for income tax purposes is primarily due to differences in accounting and tax bases of certain assets resulting from the Transaction Agreement.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

Utilization of net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The Company has not performed a detailed analysis to determine whether an ownership change under Section 382 of the Internal Revenue Code occurred as a result of the Merger. The effect of the ownership change could create an imposition of an annual limitation on the use of net operating loss carryforwards attributable to periods before the change.

Except as described below, the Company has not recorded a provision for or benefit from income taxes in the accompanying consolidated financial statements due to recurring losses and the uncertainty of the future recoverability of its deferred tax assets. Accordingly, the Company has provided a full valuation allowance against its federal deferred tax assets of approximately \$24.4 million and \$12.7 million at December 31, 2004 and 2003, respectively. The deferred tax assets are principally due to net operating loss carryforwards.

Significant components of the Company's deferred tax assets at December 31, 2004 and 2003 are as follows:

<TABLE>
<CAPTION>

	DECEMBER 31,	
	2004	2003
<S>	<C>	<C>
Deferred tax assets:		
Net operating tax loss carryforwards.....	\$ 19,042,500	\$ 11,505,000
Research and development tax credits.....	1,213,000	441,000
Amortization of loan discount and accrued interest, related party.....	1,846,000	-
Beneficial warrant conversion.....	959,000	-
Fixed asset depreciation.....	859,800	796,000
Other.....	436,200	-
	-----	-----
Total deferred tax asset.....	24,356,500	12,742,000
Less valuation allowance.....	(24,356,500)	(12,742,000)
	-----	-----
Net deferred tax asset.....	\$ -	\$ -
	=====	=====

</TABLE>

During 2004 and 2003, the Company recognized a benefit from state income taxes of approximately \$0.3 million and \$0.2 million, respectively, related to the sale of approximately \$4.2 million and \$3.0 million, respectively, of state net operating loss carryforwards.

A reconciliation of the statutory tax rates for the years ended December 31, 2004 and 2003 is as follows:

<TABLE>
<CAPTION>

	DECEMBER 31,	
	2004	2003
<S>	<C>	<C>
Statutory rate.....	(34)%	(34)%
State income tax.....	(7)%	(8)%
Research and development credits.....	(2)%	(2)%
Change in valuation allowance and other items.....	42%	42%
	-----	-----
Benefit for income tax.....	(1)%	(2)%
	=====	=====

</TABLE>

13. COMMITMENTS AND CONTINGENCIES

LEGAL

The Company is involved in pending opposition proceedings involving its patents. The ultimate outcome cannot be predicted at this time. Management does not believe that the pending opposition proceedings will have a material adverse effect on the financial position, results of operations or cash flows of the Company.

EMPLOYMENT CONTRACT

In June 2004 the Company entered into a two-year employment contract with a key executive. The contract calls for the issuance of options to purchase a total, after giving effect to the Merger, of 178,075 shares of the Company's common stock at a price of \$1.90 per share upon execution of the contract. Such options were

issued in September 2004. The contract also calls for the issuance of additional options to this key executive upon the closing of a financing or series of financings (including the September Private Placement and the offering of convertible secured promissory notes and warrants) aggregating up to \$27 million, such that executive's total potential ownership of the Company is equal to 4% of the shares outstanding after such financing or series of financing.

During 2003, the Company funded two separate University research programs. The first aimed to advance the iontophoretic delivery of drugs through the skin. The second targeted the delivery of therapeutic drugs for a specific condition. The cost of the research programs was approximately \$0.2 million in 2004 and 2003, and is included in research and development expense in the accompanying consolidated financial statements. The agreements provide for future funding of approximately \$84,000 in 2005 and \$5,000 in 2006.

LEASES

At December 31, 2004, the minimum lease payments under capital lease obligations and non-cancelable operating subleases for office and facility space are as follows:

<TABLE>

<CAPTION>

	CAPITAL LEASE OBLIGATIONS	OPERATING LEASE (1)
<S>	<C>	<C>
Years ended December 31,		
2005.....	\$ 20,288	\$ 442,843
2006.....	11,332	471,355
2007.....	-	272,391
2008.....	-	277,367
2009.....	-	290,178
Thereafter.....	-	1,813,105
	-----	-----
Total minimum lease payments.....	31,620	\$ 3,567,239
		=====
Less amounts representing interest (interest imputed using rates from 7.4%-13.8%).....	2,073	

Present value of minimum capital lease payments.....	29,547	
Less current portion of capital lease obligation.....	18,609	

Capital least obligation, less current portion.....	\$ 10,938	
	=====	

</TABLE>

- (1) Includes minimum lease payments of \$0.3 million and \$0.2 million in 2005 and 2006, respectively, under a non-cancelable operating sublease with Becton Dickinson for office and facility space.

Rent expense recorded in the accompanying consolidated statements of operations was approximately \$0.3 million, for the years ended December 31, 2004, 2003 and 2002 and \$1.2 million for the period from November 10, 2000 (inception) to December 31, 2004, respectively.

14. STOCK COMPENSATION PLAN

In March 2001, the Board of Directors and stockholders of the Company approved the adoption of the Vyteris, Inc. 2001 Stock Option Plan (the "Option Plan"). The Option Plan provides for the granting of both incentive and nonqualified stock options to employees, officers, directors, and consultants of the Company to purchase up to a total, after giving effect to the Merger, of 2,933,000 shares of common stock, in the aggregate. Only employees of the Company may be granted incentive stock options under the Option Plan.

Options granted under the Option Plan vest as determined by the Compensation Committee of the Board of Directors (the "Compensation Committee") and terminate after the earliest of the following events: expiration of the option as provided in the option agreement, termination of the employee, or ten years from the date of

grant (five years from the date of grant for incentive options granted to an employee who owns more than 10% of the total combined voting power of all classes of the Company stock at the date of grant). Granted stock options are immediately exercisable into restricted shares of common stock, which vest in accordance with the original terms of the related options. If an optionee's

status as an employee or consultant changes due to termination, the Company has the right to purchase from the optionee all unvested shares at the original option exercise price. In general, the vesting period is 33% per annum over a three-year period.

The option price of each share of common stock shall be determined by the Compensation Committee, provided that with respect to incentive stock options, the option price per share shall in all cases be equal to or greater than 100% of the fair value of a share of common stock on the date of the grant, except an incentive option granted under the Option Plan to a shareholder that at any time an option is granted owns more than 10% of the total combined voting power of all classes of the Company stock, shall have an exercise price of not less than 110% of the fair value of a share of common stock on the date of grant. No participant may be granted incentive stock options, which would result in shares with an aggregate fair value of more than \$100,000 first becoming exercisable in one calendar year.

Stock option transactions for the years ended December 31, 2004, 2003 and 2002 under all plans are as follows (after giving effect to the Merger):

<TABLE>
<CAPTION>

	NUMBER OF SHARES	EXERCISE PRICE PER SHARE	WEIGHTED AVERAGE EXERCISE PRICE
<S>	<C>	<C>	<C>
Outstanding at December 31, 2001.....	31,783	\$ 1.40 - \$1.40	\$ 1.40
Granted.....	56,373	9.50 - 9.50	9.50
Exercised.....	(78)	1.40 - 1.40	1.40
Cancelled.....	(7,228)	1.40 - 9.50	3.30
Outstanding at December 31, 2002.....	80,850	1.40 - 9.50	7.00
Granted.....	109,935	1.90 - 1.90	1.90
Exercised	-	-	-
Cancelled.....	(2,776)	1.40 - 9.50	3.20
Outstanding at December 31, 2003.....	188,009	1.40 - 9.50	4.10
Granted.....	636,348	1.90 - 1.90	1.90
Exercised	(20,807)	1.40 - 1.90	1.60
Cancelled.....	(89,273)	1.40 - 9.50	7.00
Outstanding at December 31, 2004.....	714,277	\$1.40 - \$1.90	\$ 1.90

</TABLE>

During 2004, a total, after giving effect to the Merger, of 53,598 of the cancelled stock options were reissued with an exercise price of \$1.90. In accordance with APB No. 25 and FASB Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB Opinion No. 25, the reissued options are accounted for as a direct re-pricing, which requires the Company to re-measure the option value until the option is exercised, expired or forfeited. During 2004, the Company re-measured the option value of the re-priced stock options and recognized compensation expense of approximately \$18,600 in the consolidated statement of operations.

The following table summarizes information about stock options outstanding at December 31, 2004 (after giving effect to the Merger):

<TABLE>
<CAPTION>

EXERCISE PRICE	OPTIONS OUTSTANDING AT DECEMBER 31, 2004			OPTIONS EXERCISABLE AT DECEMBER 31, 2004	
	NUMBER OF SHARES	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (YEARS)	NUMBER OF SHARES	WEIGHTED AVERAGE EXERCISE PRICE
<S>	<C>	<C>	<C>	<C>	<C>
\$ 0.14.....	10,021	\$ 1.40	6.1	10,021	\$ 1.40
\$ 0.19.....	704,256	1.90	9.3	383,241	1.90
Total.....	714,277	\$ 1.90	9.3	393,262	\$ 1.90

</TABLE>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

Stock options available for grant under the Option Plan covered a total, after giving effect to the Merger, of 2,189,196 shares of common stock at December 31, 2004.

15. EMPLOYMENT BENEFIT PLAN

During December 2000, the Company's Board of Directors adopted a 401(k) plan (the "Plan"), effective January 1, 2001 that covers substantially all employees. The Company expensed approximately \$115,000, \$80,000, \$55,000 and \$294,000 in contributions to the Plan for the years ended December 31, 2004, 2003, 2002 and for the period from November 10, 2000 (inception) to December 31, 2004, respectively; no contributions were made to the Plan prior to 2001.

16. MATERIAL AGREEMENTS

In September 2004, the Company entered into a license and development agreement for an infertility product with Ferring Pharmaceuticals, Inc. ("Ferring"), a leading pharmaceutical company in women's health. The Company and Ferring will jointly develop the infertility product, the Company will be responsible for manufacturing the product, and Ferring will be responsible for the marketing and sales of the product. The agreement provides for Ferring and the Company to share development costs, for Ferring to fund the clinical trials and regulatory filings, for Ferring to make payments to the Company upon the Company's reaching certain milestones, for Ferring to pay a royalty on sales of this infertility product, and for the payment of a transfer price by Ferring to the Company upon shipments of the infertility product by the Company to Ferring. The current projected development timeline is that a New Drug Application for the product will be submitted to the Federal Drug Administration in 2008 or 2009. The revenues to be earned by the Company from sales of this product are a function of the selling price, the gross sales made in each year by Ferring, the number of units sold, and the contract year.

The Company is required to pay Becton Dickinson a royalty in respect of sales of each iontophoresis product stemming from intellectual property received by the Company from Becton Dickinson as part of the formation of the Company. For each such product, on a country-by-country basis, that obligation continues for the later of 10 years after the date of the first commercial sale of such product in a country and the date of the original expiration of the last-to-expire patent related to such product granted in such country. The royalty, which is to be calculated semi-annually, will be equal to the greater of 5% of all direct revenues, as defined below, or 20% of all royalty revenues, with respect to the worldwide sales on a product-by-product basis. No royalties will be earned by Becton Dickinson prior to November 10, 2005. "Direct revenues" are the gross revenues actually received by the Company from the commercial sale of any iontophoresis product, including upfront payments, less amounts paid for taxes, duties, discounts, rebates, freight, shipping and handling charges or certain other expenses. "Royalty revenues" are the gross revenues actually received by the Company from any licensing or other fees directly relating to the licensing of any iontophoresis product, including upfront payments, less amounts paid for taxes, duties, discounts, rebates, freight, shipping and handling charges and certain other expenses.

17. STOCKHOLDER'S EQUITY

At December 31, 2003, there were 759,428 shares of common stock outstanding. The following is a summary of transactions in Vyteris' common stock from January 1, to September 29, 2004 resulting in 18,952,646 shares of Vyteris common stock issued and outstanding prior to consummation of the Merger on September 29, 2004 with Vyteris Holdings:

- o issued 20,807 shares of common stock on the exercise of stock options (see Note 14);
- o issued 9,637,000 shares of common stock in the Recapitalization Transaction (see Note 9);
- o issued 69,833 shares of common stock upon redemption of the Becton Dickinson Convertible Note (see Note 7);

- o issued 279,333 shares of common stock to Becton Dickinson in exchange for its 333,333 shares of Vyteris Series A convertible redeemable preferred stock;
- o issued 3,560,453 shares of common stock upon conversion of the December Notes (see Note 8);
- o issued 4,206,792 shares of common stock upon consummation of the September Private Placement (see Note 8); and
- o issued 419,000 shares of common stock as consideration for the Working Capital Commitment (see Note 12).

The terms of the Merger called for each share of common stock to be exchanged for 0.419 shares of common stock; as a result, the holders of common stock were entitled to receive 18,952,647 shares of common stock (see Note 1).

At the Merger date, September 29, 2004, there were 341,212 shares of Treasure Mountain Holdings, Inc. common stock outstanding.

18. LOSS PER SHARE

The following table sets forth the computation of basic and diluted net loss attributable to common stockholders per share after giving effect to the Merger.

<TABLE>
<CAPTION>

	YEARS ENDED DECEMBER 31,		
	2004	2003	2002
<S>	<C>	<C>	<C>
Numerator:			
Net loss.....	\$ (22,566,644)	\$ (12,532,577)	\$ (10,767,694)
Denominator:			
Weighted average shares.....	10,319,226	759,429	721,830
Basic and diluted net loss per share.....	\$ (2.19)	\$ (16.50)	\$ (14.92)

</TABLE>

The following table shows dilutive common share equivalents outstanding, which are not included in the above historical calculations, as the effect of their inclusion is anti-dilutive during each period.

<TABLE>
<CAPTION>

	DECEMBER 31,		
	2004	2003	2002
<S>	<C>	<C>	<C>
Convertible preferred stock.....	785,625	349,167	349,167
Convertible debt.....	-	2,184,038	1,118,730
Warrants.....	5,210,000	873,615	447,492
Options.....	714,277	188,009	80,850
B. Braun purchase right.....	38,797	38,797	38,797
Total.....	3,633,626	2,035,036	6,748,699

</TABLE>

VYTERIS HOLDINGS (NEVADA), INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

19. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

<TABLE>
<CAPTION>

	QUARTERS ENDED			
	DEC. 31, 2004	SEPT. 30, 2004	JUNE 30, 2004	MARCH. 31 2004
<S>	<C>	<C>	<C>	<C>
Revenue.....	\$ 149,822	\$ 32,500	\$ 60,000	\$ -

Research and development	2,910,760	3,310,850	2,841,571	2,392,125
General and administrative.....	1,090,216	1,492,087	714,168	773,367
	-----	-----	-----	-----
Total operating expenses.....	4,000,976	4,802,937	3,555,739	3,165,492
Interest income	(30,693)	(1,992)	(4,667)	(1,096)
Interest expense to related parties.....	468,749	111,106	75,958	600,234
Interest expense.....	745	4,431,554	1,970,705	1,252
	-----	-----	-----	-----
Loss before benefit from state taxes.....	(4,289,955)	(9,311,105)	(5,537,735)	(3,765,882)
Benefit from state taxes.....	(338,033)	-	-	-
	-----	-----	-----	-----
Net loss.....	\$(3,951,922)	\$(9,311,105)	\$(5,537,735)	\$(3,765,882)
	=====	=====	=====	=====
Net loss per common share:				
Basic and diluted.....	\$ (0.20)	\$ (0.88)	\$ (0.53)	\$ (4.35)
	=====	=====	=====	=====
Weighted average number of shares:				
Basic and diluted.....	19,293,858	10,607,658	10,401,781	865,330

	QUARTERS ENDED			
	DEC. 31, 2003	SEPT. 30, 2003	JUNE 30, 2003	MARCH. 31 2003
	-----	-----	-----	-----
Revenue.....	\$ -	\$ 55,000	\$ 40,000	\$ 105,000
Research and development	2,262,828	2,286,664	2,345,305	1,840,074
General and administrative.....	674,434	601,679	577,059	601,750
	-----	-----	-----	-----
Total operating expenses.....	2,937,262	2,888,343	2,922,364	2,441,824
Interest income	(1,293)	(1,153)	(1,636)	(1,693)
Interest expense to related parties.....	533,963	477,044	407,860	364,063
Interest expense.....	501	949	1,630	1,133
	-----	-----	-----	-----
Loss before benefit from state taxes.....	(3,470,433)	(3,310,183)	(3,290,218)	(2,700,327)
Benefit from state taxes.....	(238,584)	-	-	-
	-----	-----	-----	-----
Net loss.....	\$(3,231,849)	\$(3,310,183)	\$(3,290,218)	\$(2,700,327)
	=====	=====	=====	=====
Net loss per common share:				
Basic and diluted.....	\$ (4.26)	\$ (4.36)	\$ (4.33)	\$ (3.56)
	=====	=====	=====	=====
Weighted average number of shares:				
Basic and diluted.....	759,429	759,429	759,429	759,429

</TABLE>

20. SUBSEQUENT EVENTS

In February 2005, the Company received correspondence from Dr. George Nascaris, who the Company believes to be the principal of Greystone Healthcare Group, Inc., and Dr. Nascaris' counsel, threatening to bring a lawsuit or mediation proceeding against the Company in connection with a dispute over fees which Greystone alleges should have been paid pursuant to an agreement between the Company and Greystone with respect to an alternative financing transaction which neither Vyteris Inc. nor Vyteris Holdings (Nevada), Inc. has consummated, nor is currently pursuing. The Company believes that Greystone's claims are without merit and that, if such a suit or proceeding is actually commenced, Vyteris Holdings (Nevada), Inc. and Vyteris Inc. will have substantial defenses and counterclaims against Greystone. If such a suit or proceeding is actually commenced against either Vyteris Holdings (Nevada), Inc. or Vyteris Inc., Vyteris Holdings (Nevada), Inc. and Vyteris Inc. intend to defend it vigorously. The Company does not believe that an adverse outcome of this matter will be material to the Company's consolidated financial position, results of operations or cash flows.

The Company filed a registration statement with the SEC relating to the resale of shares of its common stock. Since that registration statement was not declared effective by the SEC by February 25, 2005, the Company is obligated to pay to certain stockholders an amount equal to 1% of the purchase price paid by such stockholders for the shares owned by such stockholders which are covered by the registration statement, and for each month, or portion of a month, in which such delay continues, an amount equal to 2% of such purchase price, until the Company has cured the delay, with an overall cap on such liquidated damages of 10% of the aggregate purchase price paid by such stockholders for such shares. The registration statement has not yet been declared effective. Such liquidated damages could amount to up to \$2.4 million, depending upon when the registration statement is ultimately declared effective by the SEC. Payments of substantial liquidated damages will adversely affect the Company's financial condition.

On May 2, 2005, the Company amended its Articles of Incorporation to change its name from Treasure Mountain Holdings, Inc. to Vyteris Holdings (Nevada), Inc. The Company also filed amendments to its Articles of Incorporation which, among other things, increased the number of shares of common stock that the Company is authorized to issue to 100,000,000 shares, authorized the issuance of 7,500,000 shares of Series B Preferred Stock, authorized the issuance of an additional 42,750,000 shares of preferred stock which may be issued, from time to time, pursuant to terms established by the Company's Board of Directors and authorized a ten for one reverse stock split effective May 2, 2005. All share information with respect to the Company's common stock, options, and warrants have been adjusted to give retroactive effect to the reverse stock split for all periods presented.

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VYTERIS HOLDINGS HOLDINGS, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Ernst & Young LLP was the independent auditor for Vyteris, Inc. and has been since Vyteris, Inc. was incorporated in 2000. By virtue of the Merger of Vyteris, Inc. with a wholly-owned subsidiary of Vyteris Holdings (Nevada) on September 29, 2004, there was deemed to have been a change in Vyteris Holdings (Nevada)'s certifying accountants. On November 10, 2004 the audit committee of Vyteris Holdings (Nevada)'s Board of Directors approved the engagement of Ernst & Young LLP as its independent auditors for the fiscal year ended December 31, 2004 to replace Madsen & Associates. Such action effected the dismissal of Madsen & Associates as Vyteris Holdings (Nevada)'s certifying accountants.

Madsen & Associates served as Vyteris Holdings (Nevada)'s certifying accountants with respect to the financial statements for the year ended December 31, 2003. As noted in Vyteris Holdings (Nevada)'s Annual Report on Form 10-KSB for the year ended December 31, 2003, the firm of Sellers and Andersen, LLC served as Vyteris Holdings (Nevada)'s independent certifying accountants for the year ended December 31, 2002. As reported in Vyteris Holdings (Nevada)'s Annual Report on Form 10-KSB for the year ended December 31, 2003, there were no disagreements with Sellers & Andersen on any matters of accounting principles and practices, financial statement disclosure, or auditing scope or procedures which, if not resolved to the satisfaction of Sellers & Andersen, would have caused them to make reference to the subject matter of the disagreement in connection with its report on Vyteris Holdings (Nevada)'s financial statements. Further, during the year ended December 31, 2003 and during the period from January 1, 2004 through November 10, 2004, there were no disagreements with Madsen & Associates on any matters of accounting principles and practices, financial statement disclosure, or auditing scope or procedures which, if not resolved to the satisfaction of Madsen & Associates, would have caused them to make reference to the subject matter of the disagreement in connection with its report on Vyteris Holdings (Nevada)'s financial statements. Further, for 2002 and 2003 and through November 10, 2004, none of the events described in Item 304(a)(1)(iv)(B) of the SEC's Regulation S-B occurred.

Inasmuch as Ernst & Young LLP was the independent auditor for Vyteris, Inc. throughout the period during which Vyteris, Inc. planned for the Vyteris Holdings/Vyteris merger, Ernst & Young was consulted and provided oral advice during 2004 with respect to the principles applicable to the accounting treatment for such merger. Such advice was an important factor considered by the registrant in reaching a decision with respect to such accounting treatment. Ernst & Young LLP orally advised the registrant that the appropriate accounting treatment is to combine the historical financial statements of Vyteris, Inc. and

Vyteris Holdings (Nevada) after giving effect to the merger by recording the merger as the issuance of Vyteris, Inc. stock for the net monetary assets of Vyteris Holdings (Nevada), accompanied by a recapitalization with no goodwill or other intangibles recorded. Vyteris Holdings (Nevada)'s former accountants were not consulted with respect to the accounting treatment for the merger.

Audit reports of Sellers & Andersen and of Madsen & Associates for Vyteris Holdings (Nevada)'s 2003 and 2002 year-end financial statements contained a modification expressing substantial doubt as to Vyteris Holdings (Nevada)'s ability to continue as a going concern.

We requested that Ernst & Young LLP review the disclosures set forth above. We also provided Ernst & Young LLP with the opportunity to furnish us with a letter, addressed to the SEC, containing any new information, clarification of our expression of our views or the respects, if any, in which it does not agree with the statements made by us above. Ernst & Young LLP has determined that no such letter is necessary.

We also provided Madsen & Associates with a copy of the disclosures set forth above and requested Madsen & Associates to furnish us with a letter addressed to the SEC stating whether it agrees with our statements and, if not, stating the respects in which it does not agree. We have previously filed with the SEC a copy of a letter received from Madsen & Associates in response to that request.

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VYTERIS HOLDINGS HOLDINGS, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

ITEM 8A. CONTROLS AND PROCEDURES.

We carried out an evaluation required by the Securities Exchange Act of 1934, under the supervision and with the participation of our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our chief executive officer and chief financial officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective in timely alerting them to material information required to be included in our periodic Securities and Exchange Commission reports.

During the most recent fiscal quarter, there has been no change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 8B. OTHER INFORMATION.

None.

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PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT.

EXECUTIVE OFFICERS

The following table identifies our executive officers, their ages as of March 31, 2005 and their current positions. Each listed person has the same positions with Vyteris Holdings (Nevada) and Vyteris.

NAME	AGE	POSITION
----	---	-----
Vincent De Caprio, Ph.D.	54	Chief Executive Officer, President and Vice Chairman of the Board of Directors
Michael McGuinness	51	Chief Financial Officer
James Garrison	44	Vice President of Business Development
C. Gregory Arnold	57	Vice President of Manufacturing and Process Development

The following biographical histories describe our executive officers' history with Vyteris. Each of our executive officers became executive officers of Vyteris Holdings (Nevada) upon consummation of the Merger.

VINCENT DE CAPRIO, PH.D., Chief Executive Officer (June 2004 to present), President (November 2000 to present) and Vice Chairman of the Board of Directors (November 2000 to present), joined Vyteris in November 2000 after spending 23 years at Becton Dickinson, a diversified medical products company, including serving as Senior Vice President and General Manager (1999-2000), Senior Vice President and Chief Technology Officer (1996-1999) and Senior Vice President, Planning and Technology (1995-1996) of Becton Dickinson. Prior to that time, he served as sector president of the Becton Dickinson Technique Products Group (1994-1995), where he operated as the chief executive officer of four divisions with over 3,000 employees, multiple manufacturing locations and numerous worldwide sales offices. He was also President of the Becton Dickinson Vascular Access Business. Dr. De Caprio received a B.S.E.E. from the Newark College of Engineering (New Jersey Institute of Technology) and an MS and Ph.D. in bioengineering from the Polytechnic Institute of New York (Polytechnic University).

MICHAEL MCGUINNESS joined Vyteris in September 2001 and has served as Chief Financial Officer since that time. Mr. McGuinness has 27 years of finance and accounting experience with large multinational operations, medium sized public companies and small, early stage companies. From 1998 to 2001, he was the Chief Financial Officer and a member of the board of directors of EpiGenesis Pharmaceuticals, Inc., a privately-held biotechnology company, where he was a member of the negotiating team on two licensing and development agreements and was instrumental in managing the growth from six to 40 employees. Prior to that time, he was the Chief Financial Officer of BlueStone Capital Partners, an investment bank and broker/dealer, and was the principal accounting officer of Health-Chem Corporation, an American Stock Exchange listed company. Mr. McGuinness received a BBA in public accounting from Hofstra University and became certified as a public accountant in New York State in 1984. Mr. McGuinness' CPA license is currently inactive.

JAMES GARRISON joined Vyteris at its inception in November 2000 and has served as Vice President of Business Development since that time. From 1996 to November 2000 Mr. Garrison was Director of Business Development for the Becton Dickinson Transdermal Systems Group. Prior to that time, he served as Manager of Business Development for the U.S. operations of Zambon Group SpA (a pharmaceutical company). Prior to working for Zambon, he held a variety of positions in research and marketing at American Cyanamid, Citicorp, NA, and JP Morgan. Mr. Garrison received a BA in English from Rhode Island College, a Masters of Information Services from Rutgers University and a Masters of Business Administration from Seton Hall University.

C. GREGORY ARNOLD, Vice President of Manufacturing and Process Development, joined Vyteris in November 2002. From 1993 to 2002 he was the executive director of Transdermal Development for Watson Pharmaceuticals (Theratech), and was responsible for managing manufacturing scale-up and facility validation for the commercial launch of two transdermal products. Prior to his employment with Watson, he was the Vice President of Operations for Cygnus Therapeutic Systems, where he managed manufacturing scale-up and facilities validation for the commercial introduction of a transdermal product. Previously, he was Manager of Product Development for Ciba-Geigy Corporation where he managed manufacturing scale-up and facilities validation for commercial launches of two transdermal products. Mr. Arnold received a BS in Industrial Engineering from The Pennsylvania State University.

BOARD OF DIRECTORS

The following table identifies Vyteris Holdings (Nevada)'s directors and their ages as of March 31, 2005. Each listed person serves on the Boards of both Vyteris Holdings (Nevada) and Vyteris and has a term of one year on each Board. Biographical information is presented below the table for all of the directors other than Dr. De Caprio, whose biographical information is presented above.

With the exception of Mr. LePore, who joined the Vyteris Holdings (Nevada) Board on February 1, 2005, and Dr. Potts, who joined the Vyteris Holdings (Nevada) Board on April 25, 2005, the terms on the Vyteris Holdings (Nevada) Board of the persons named below commenced on September 29, 2004, the date on which the Merger was consummated. The terms of all members of the Vyteris Holdings (Nevada) Board will expire at the 2005 annual meeting of stockholders.

NAME	AGE
-----	---
Donald F. Farley	62
Vincent De Caprio, Ph.D.	54

David DiGiacinto	51
Patrick G. LePore	50
Russell O. Potts, Ph.D	58
Solomon Steiner, Ph.D.	67

DONALD F. FARLEY, chairman of the board of Vyteris Holdings (Nevada) and Vyteris has served as a member of the Vyteris Board since its inception in November 2000. He is the chief executive officer of Spencer Trask Specialty Group, LLC, or STSG, an investment firm which is affiliated with our controlling stockholder and which is focused on investing in emerging and development companies in specialty chemicals, food ingredients and health care. Prior to joining STSG in 1998, Mr. Farley spent more than 30 years at Pfizer (a diversified health care company), most recently serving as President of Pfizer Consumer Health Care (from 1996 to 1998) and President of Pfizer Food Science Group (from 1993 to 1996). Mr. Farley received a BS in Chemical Engineering from the University of Rhode Island and a Masters of Business Administration from the University of Hartford. Mr. Farley is also a director of Minrad, Inc.

DAVID DIGIACINTO has served as the Secretary of Vyteris and a member of the Vyteris Board of Directors since its inception in November 2000. He has been a Senior Managing Director of STSG since April 2000. From December 1982 to March 2000, he worked at Pfizer in various positions including sales, marketing, business development and general management in the Chemical/Food Science and Consumer Health Care Groups. He holds a BS in Engineering from the U.S. Military Academy at West Point. Mr. DiGiacinto is also a director of Minrad, Inc.

PATRICK G. LEPORE was elected as a member of the Vyteris Holdings (Nevada) Board of Directors on February 1, 2005. Mr. LePore is a consultant to Cardinal Health, a health care products and services company, where he has provided such services since June 2003. From June 2002 to June 2003, Mr. LePore served as an Executive Vice President of Cardinal Health. In 1991, Mr. LePore co-founded Boron, LePore & Associates, a full service medical education company, doing business as BLP Group Companies. Mr. LePore served as the Chairman and Chief Executive Officer of BLP Group Companies until June of 2002 when it was acquired by Cardinal Health.

Mr. LePore serves on the board of directors of Saturn Pharmaceuticals, a pharmaceutical company; Douglas Laboratories, a vitamin manufacturer; Zargis Medical Corporation and the New Jersey Junior Achievement Association. He is also a trustee and member of the board of directors of Montclair State University.

RUSSELL O. POTTS, PH.D joined the Vyteris Holdings (Nevada) Board on April 25, 2005. Dr. Potts is an independent consultant in drug delivery, glucose monitoring, and medical devices. He previously served (from 2001 to 2002) as Vice President of Research and Development at Cygnus, Inc., a Company which develops and manufactures diagnostic and drug delivery systems, where he helped develop the first FDA-approved continuous glucose-monitoring device for patient use, the GlucoWatch(R) Biographer. Prior to joining Cygnus, he led a Research and Development group at Pfizer to develop topically-applied drugs. Russell Potts received a MS degree in physical chemistry from Cornell University, and a Ph.D. in biochemistry from the University of Massachusetts, followed by a postdoctoral position in the Chemistry Department at Yale University.

SOLOMON STEINER, PH.D. has served as a member of the Vyteris Board of Directors since December 2002. Dr. Steiner is founder, Chairman of the Board and Chief Executive Officer of Biodel Inc., a pharmaceutical consulting company, where he has served since October 2002. Dr. Steiner founded Pharmaceutical Development Corporation, or PDC, a company developing novel drug delivery technology, in 1991, and is an inventor of its Technosphere(TM) drug delivery system and MedTone(TM) dry powder inhaler. Dr. Steiner served as PDC's chief executive officer and chairman of the board of directors from 1991 until October of 2002 when it merged with MannKind Corporation. Prior to his employment with PDC, he was a founder and the Chief Executive Officer of Emisphere Technologies, Inc., a publicly-traded drug delivery company (1985-1990). Dr. Steiner received a BA and a Ph.D. from New York University.

BOARD COMMITTEES

The Board of Directors of Vyteris Holdings (Nevada) has three standing committees: an audit committee, a compensation committee and a nominating committee. Each such committee is governed by a written charter.

Doctor Steiner is a member of the Vyteris Holdings (Nevada) audit committee, which committee has been established in accordance with Section 3(a)(58)(A) of the Exchange Act. Two other members of the Audit Committee, including the former chairman of the Audit Committee, have resigned from the Board and hence from the Audit Committee. Replacements have not yet been identified. The audit committee is responsible for the hiring and dismissal of the outside auditors. By virtue of the change in the composition of the audit

committee, the Board presently has not designated anyone as an "audit committee financial expert", pending re-establishment of the full committee and a review of the credentials of the individuals members of the committee.

Messrs. DiGiacinto, Farley and Steiner serve on the compensation committee, with Mr. Dr. Steiner serving as chairman. The Vyteris Holdings (Nevada) compensation committee reviews, recommends and approves compensation for executive officers and other senior level employees, and administers benefit and compensation plans.

Messrs. DiGiacinto and Farley serve on the recently established nominating committee. A third member, who served as the Chairman, recently resigned from the Board and hence from the nominating committee. A replacement has not yet been identified. The nominating committee will be responsible for proposing to the Board candidates for election to the Board.

During 2004 and prior to the consummation of the Merger, the Board of Directors of Vyteris conducted ten Board meetings, one Audit Committee meeting and three Compensation Committee meetings. During 2004 but subsequent to the Merger, the members of the Board of Directors of Vyteris Holdings (Nevada) conducted three Board meetings, one Audit Committee meeting, one Compensation Committee meeting and two Nominating Committee meetings. None of the current Board members attended less than 75% of the Board and committee meetings that he was required to attend during 2004 as a Vyteris director or a Vyteris Holdings (Nevada) director.

The Company has adopted a code of ethics entitled "Code of Ethics for the Senior Financial Officers, Executive Officers and Directors of Vyteris Holdings (Nevada), Inc." A copy is available to any person without charge upon written request to:

Vyteris, Inc.
 Attention: Investor Relations
 13-01 Pollitt Drive
 Fair Lawn, New Jersey 07430

ITEM 10. EXECUTIVE COMPENSATION.

CASH COMPENSATION

The following table sets forth the total cash and non-cash compensation that we paid or accrued during the years ended December 31, 2004, 2003 and 2002 with respect to Vincent De Caprio, and the other executive officers who, during 2004, received salary and bonus in excess of \$100,000. The principal components of these individuals' current cash compensation are the annual base salary and bonus included in the Summary Compensation Table. We have also described below other compensation these individuals received under employment agreements and Vyteris' stock option plan. We refer to the persons identified in the table below as the "named executive officers". The number of securities covered by stock options have been adjusted to give effect to the Vyteris Holdings/Vyteris Merger and the one-for-ten reverse stock split effected on May 2, 2005.

<TABLE>
 <CAPTION>

SUMMARY COMPENSATION TABLE

NAME AND PRINCIPAL POSITION <S>	YEAR <C>	ANNUAL COMPENSATION SALARY (\$) <C>	ANNUAL BONUS (\$) (1) <C>	LONG TERM COMPENSATION	ALL OTHER COMPENSATION
				SECURITIES UNDERLYING OPTIONS/SARS (#) (2) <C>	\$ (3) <C>
Vincent De Caprio, Ph.D., President and Chief Executive Officer	2004 2003 2002	280,000 250,000 250,000	105,000 122,500 125,000	178,075 -- 15,713	7,000 7,000 5,500
Michael McGuinness, Chief Financial Officer	2004 2003 2002	186,000 167,193 152,500	59,400 69,190 (4) 23,000	101,083 8,904 10,475	5,400 4,845 4,791
James Garrison, Vice President of Business Development	2004 2003 2002	160,000 150,000 128,000	50,000 45,000 25,600	93,314 4,452 13,094	4,400 4,500 4,326
C. Gregory Arnold, Vice President, Manufacturing and Process Development (5)	2004 2003 2002	185,000 175,000 20,200	7,000 10,000 --	20,950 13,094 --	5,545 5,250 --

- (1) Bonuses for 2004 include certain bonuses that were earned in 2004 but were not paid until 2005. Bonuses for 2003 include certain bonuses that were earned in 2003 but were not paid until 2004. Bonuses for 2002 include certain bonuses that were earned in 2002 but were not paid until 2003.
- (2) Options granted to Messrs. De Caprio, McGuinness and Garrison during 2002 were canceled by Vyteris prior to the Vyteris Holdings/Vyteris Merger.
- (3) Represents matching payments by Vyteris under our 401(k) plan.
- (4) Mr. McGuinness received a retention bonus for 2003 of \$36,890, consisting of a non-cash credit of \$22,500 which was used for the exercise of stock options and a \$14,390 cash payment to cover taxes due on such non-cash credit.
- (5) Mr. Arnold joined Vyteris in November 2002.

STOCK OPTIONS

The following table presents certain information regarding stock options granted to the named executive officers during 2004 under the Vyteris stock option plan. The number of securities covered by stock options and the exercise prices have been adjusted to give effect to the Vyteris Holdings/Vyteris Merger and the one-for-ten reverse stock split. INDIVIDUAL GRANTS

NAME	NUMBER OF SECURITIES UNDERLYING OPTIONS GRANTED (#)	PERCENTAGE OF TOTAL OPTIONS GRANTED TO EMPLOYEES	EXERCISE PRICE (\$)	EXPIRATION DATE
V. De Caprio	178,075	28.0%	\$1.90	12/31/14
M. McGuinness	101,083	15.9%	\$1.90	12/31/14
J. Garrison	93,314	14.7%	\$1.90	12/31/14
C. Arnold	20,950	3.3%	\$1.90	(1)

- (1) Options to purchase 2,619 shares of common stock expire 2/1/14;
options to purchase 18,331 shares of common stock expire 12/31/14.

The following table presents information regarding the number of stock options held by the named executive officers at December 31, 2004. None of the stock options listed in the table were in-the-money at December 31, 2004. The number of securities covered by stock options have been adjusted to give effect to the Vyteris Holdings /Vyteris Merger and the one-for-ten reverse stock split.

<TABLE>
<CAPTION>

NAME	NUMBER OF SHARES UNDERLYING UNEXERCISED OPTIONS AT FISCAL YEAR-END (#)		VALUE OF UNEXERCISED IN-THE-MONEY OPTIONS AT FISCAL YEAR-END (\$)	
	EXERCISABLE	UNEXERCISABLE	EXERCISABLE	UNEXERCISABLE
<S>	<C>	<C>	<C>	<C>
V. De Caprio	89,037	89,038	N/A	N/A
M. McGuinness	63,618	46,369	N/A	N/A
J. Garrison	57,472	40,294	N/A	N/A
C. Arnold	17,895	16,149	N/A	N/A

Mr. McGuinness exercised 15,712 stock options with an exercise price of \$1.43 during 2004. He did not realize a gain from such exercise as the fair market value of the acquired shares was equal to the exercise price on the date of exercise. None of the other named executive officers exercised stock options during 2004.

EMPLOYMENT AGREEMENTS AND MANAGEMENT COMPENSATION

VINCENT DE CAPRIO, PH.D. In June 2004 Vyteris entered into an employment agreement with Vincent De Caprio, Ph.D., its Chief Executive Officer, President and Vice-Chairman. The agreement expires on December 31, 2005 and may be automatically extended for successive one year periods until either Dr. De Caprio or Vyteris provides written notice of termination at least 180 days prior to the end of the initial term or any renewal term. Under the terms of the agreement, Dr. De Caprio is entitled to receive a minimum base salary of

\$280,000 and annual cash bonuses of up to 60% of base salary, subject to the achievement of certain revenue objectives and strategic milestones. In September 2004, Vyteris granted Dr. De Caprio options to purchase 178,075 shares of common stock after giving effect to the one-for-ten reverse stock split. Dr. De Caprio's employment agreement requires Vyteris to grant him additional options from time to time to maintain his ownership of Vyteris stock at 4% of Vyteris' stock, on a fully-diluted, as-converted basis, after each financing transaction effected by Vyteris since March 31, 2004, up to and including a total of \$27 million, and in which Vyteris receives cash proceeds in exchange for the issuance of its common stock or a security convertible into, exchangeable for or exercisable for shares of common stock. The agreement contains provisions prohibiting the non-solicitation of employees and clients, a confidentiality provision and a non-competition provision.

JAMES GARRISON. In December 2003 Vyteris entered into an employment agreement with James Garrison, its Vice President of Business Development. The agreement expires on December 31, 2005, and may be automatically extended for successive one-year terms until either Mr. Garrison or Vyteris provides written notice of termination at least 180 days prior to the end of the initial term or any renewal term. Under the terms of the agreement, Mr. Garrison is entitled to receive a minimum base salary of \$150,000 and annual cash bonuses of up to 30% of base salary. Mr. Garrison's qualification for receiving bonuses is based on achievement of Vyteris' operating plan, budgets and strategic development milestones, as established by our Board of Directors.

If Mr. Garrison's employment with Vyteris is terminated by Vyteris without cause, or by Mr. Garrison for good reason, Mr. Garrison is entitled to receive his base salary for a period of six months from the date of termination, as well as all earned but unpaid salary and bonus for the period prior to termination. If Mr. Garrison's employment with Vyteris is terminated by Vyteris for cause, or by Mr. Garrison without good reason, Vyteris has no obligation to pay any further compensation, other than accrued but unpaid salary and bonus through the date of termination. Mr. Garrison's employment agreement also prohibits him from competing with Vyteris or interfering with Vyteris' relationships with its customers, vendors or employees for a period of six months after his employment is terminated for any reason. Under his employment agreement, Mr. Garrison is also bound to keep certain information confidential and to assign to Vyteris any intellectual property developed by him during the term of his employment.

C. GREGORY ARNOLD. In September 2002 Vyteris entered into an employment agreement with C. Gregory Arnold, its Vice President of Manufacturing and Process Development. Under the terms of the agreement, Mr. Arnold is entitled to receive a minimum base salary of \$175,000 and annual cash bonuses of up to 20% of base salary. Mr. Arnold's qualification for receiving bonuses is based on achievement of certain goals and objectives determined at the beginning of each calendar year. The agreement expires on October 31, 2005.

If Mr. Arnold's employment with Vyteris is terminated by Vyteris without cause, or by Mr. Arnold for good reason, Mr. Arnold is entitled to receive the shorter of his base salary for a period of six months from the date of termination or until the expiration of the employee agreement, as well as all earned but unpaid salary and bonus for the period prior to termination. If Mr. Arnold's employment with Vyteris is terminated by Vyteris for cause, or by Mr. Arnold without good reason, Vyteris has no obligation to pay any further compensation, other than accrued but unpaid salary and bonus through the date of termination. Mr. Arnold's employment agreement also prohibits him from competing with Vyteris or interfering with Vyteris' relationships with its customers, vendors or employees for a period of twelve months after his employment is terminated for any reason. Under his employment agreement, Mr. Arnold is also bound to keep certain information confidential and to assign to Vyteris any intellectual property developed by him during the term of his employment.

LIMITATION OF LIABILITY AND INDEMNIFICATION OBLIGATIONS

The Nevada Corporation Code grants to Vyteris Holdings the power to indemnify the officers and directors of Vyteris Holdings, under certain circumstances and subject to certain conditions and limitations as stated therein, against all expenses and liabilities incurred by or imposed upon them as a result of suits brought against them as such officers and directors if they act in good faith and in a manner they reasonably believe to be in or not opposed to the best interests of Vyteris Holdings and, with respect to any criminal action or proceeding, have no reasonable cause to believe their conduct was unlawful.

Article IX of the Vyteris Holdings articles of incorporation provides as follows: "To the fullest extent allowed by law, the directors and executive officers of the Corporation shall be entitled to indemnification from the Corporation for acts and omissions taking place in connection with their activities in such capacities."

Under Nevada law, a director or officer is not individually liable to the corporation or its stockholders or creditors for any damages as a result of any act or failure to act in his capacity as a director or officer unless it is proven that his or her act or failure to act constituted a breach of fiduciary duty as a director or officer and his or her breach of those duties involved intentional misconduct, fraud or a knowing violation of law. One of the amendments to the articles of incorporation adopted at the April 25, 2005 meeting of Vyteris Holdings' stockholders confirmed that, in the event that Nevada law were no longer automatically applied to all Nevada corporations, then, to the maximum extent permitted under Nevada law, no director or officer of Vyteris Holdings would be personally liable to the corporation or its stockholders for damages as a result of any act or failure to act in his or her capacity as a director or officer.

The registration rights agreement entered into by Vyteris Holdings immediately after the consummation of the Vyteris Holdings/Vyteris Merger contains provisions pursuant to which each selling stockholder severally agrees to indemnify Vyteris Holdings, any person controlling Vyteris Holdings within the meaning of Section 15 of the Securities Act of 1933, or Section 20 of the Securities Exchange Act of 1934, each of Vyteris Holdings' directors, and each officer of Vyteris Holdings who signs this registration statement with respect to information relating to such selling stockholder furnished in writing to Vyteris Holdings by or on behalf of such selling stockholder specifically for inclusion in this registration statement.

We also maintains directors' and officers' liability insurance to cover such individuals. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of Vyteris Holdings pursuant to the foregoing provisions, or otherwise, Vyteris Holdings has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

See Item 5 for certain information regarding the registrant's equity compensation plans.

The following table sets forth certain information regarding the beneficial ownership of our common stock as of March 31, 2005, by (i) each person who is known by us to be the beneficial owner of more than 5% of our outstanding common stock; (ii) each of our directors and executive officers; and (iii) all of our directors and executive officers as a group. Unless otherwise specified, the address of each of the persons set forth below is in care of Vyteris, Inc., 13-01 Pollitt Drive, Fair Lawn, New Jersey 07410. In determining the number and percentage of shares beneficially owned by each person, shares that may be acquired by such person under options or warrants exercisable within 60 days of March 31, 2005 are deemed beneficially owned by such person and are deemed outstanding for purposes of determining the total number of outstanding shares for such person and are not deemed outstanding for such purpose for all other stockholders. All share numbers in the following table give effect to our one for ten reverse stock split and the issuance of our Series B Convertible Preferred Stock.

<TABLE>
<CAPTION>

NAME OF BENEFICIAL OWNER -----	AMOUNT -----	PERCENTAGE OF OUTSTANDING -----
<S>	<C>	<C>
Kevin Kimberlin (1)	14,332,894	64.3% (2)
Vincent De Caprio (2)	177,376	*
Michael McGuinness (3)	79,331	*
James Garrison (4)	64,455	*
C. Gregory Arnold (5)	17,895	*
Donald Farley (6)	233,774	1.2
David DiGiacinto (7)	14,455	*
Patrick LePore	-	*
Russell O. Potts (8)	524	*
Solomon Steiner (9)	41,725	*
Directors and Officers as a group (9 persons) (10)	629,535	3.3

* Represents less than one percent.

(1) Represents (i) 10,247,648 shares of common stock that were acquired upon consummation of the Vyteris Holdings/Vyteris, Inc. merger by Spencer Trask Specialty Group or STSG, of which Mr. Kimberlin is the non-member manager; (ii) 419,000 shares of common stock that were acquired by STSG in exchange for its

extending to us a line of credit through November 15, 2005; (iii) 278,164 shares of common stock owned by Scimitar Holdings, LLC, or Scimitar, a New York limited liability company and wholly-owned subsidiary of Spencer Trask & Co., a Delaware corporation of which Mr. Kimberlin is the controlling stockholder and chairman; (iv) 776,199 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock covered by rights certificates held by STSG; (v) 2,039,249 shares of common stock issuable upon exercise of warrants issued to Spencer Trask Ventures, Inc., a wholly-owned subsidiary of Spencer Trask & Co.; (vi) 34,917 shares of common stock issuable upon exercise of warrants issued to STSG; (vii) an aggregate of 388,273 shares of common stock that were acquired in the Vyteris Holdings/Vyteris, Inc. merger by Spencer Trask Private Equity Fund I LP, Spencer Trask Private Equity Fund II LP, Spencer Trask Private Equity Accredited Fund III LLC and Spencer Trask Illumination Fund LLC, which we refer to as the "Funds"; and (viii) 149,443 shares of common stock issuable upon exercise of warrants issued to the Funds. Spencer Trask & Co. is the 100% owner of the manager of each of the Funds. Does not include (x) 758,156 shares of common stock that were acquired in the Vyteris Holdings /Vyteris, Inc. merger by Qubit Holdings, LLC, a Delaware limited liability company owned by certain trusts formed for the benefit of Mr. Kimberlin's children, or (y) warrants to purchase an aggregate of 189,539 shares of common stock held by Qubit Holdings, LLC, as to all of which securities Mr. Kimberlin disclaims beneficial ownership on the basis that Mr. Kimberlin has no voting power as to or any power to dispose, or direct the disposition, of any of the securities held by Qubit Holdings, LLC or such trusts. The information provided in this proxy statement with respect to Mr. Kimberlin is derived, in part, from a Form 4 report and Schedule 13D submitted by Mr. Kimberlin to the SEC.

(2) Includes 17,808 shares of common stock which are issuable upon the exercise of warrants and 89,037 shares of common stock which are issuable upon the exercise of stock options. Dr. De Caprio also owns options to purchase shares of common stock which will not be exercisable on or before May 30, 2005.

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(3) Includes 63,618 shares of common stock which are issuable upon the exercise of stock options. Mr. McGuinness also owns options to purchase shares of common stock which will not be exercisable on or before May 30, 2005.

(4) Includes 57,472 shares of common stock which are issuable upon the exercise of stock options. Mr. Garrison also owns options to purchase shares of common stock which will not be exercisable on or before May 30, 2005.

(5) Represents shares of common stock which are issuable upon the exercise of stock options. Mr. Arnold also owns options to purchase shares of common stock which will not be exercisable on or before May 30, 2005.

(6) Includes (i) 115,619 shares of common stock owned by a trust for which Mr. Farley serves as a trustee, (ii) 9,425 shares of common stock issuable upon conversion of our Series B convertible preferred stock, (iii) 23,045 shares of common stock issuable upon exercise of warrants and (iv) 14,455 shares of common stock which are issuable upon the exercise of stock options. Mr. Farley also owns options to purchase shares of common stock which will not be exercisable on or before May 30, 2005. Mr. Farley, an employee of an affiliate of STSG, disclaims beneficial ownership with respect to securities owned by STSG and its affiliates, as he has no power to vote or dispose of those securities.

(7) Represents shares of common stock which are issuable upon the exercise of stock options. Mr. DiGiacinto also owns options to purchase shares of common stock which will not be exercisable on or before May 30, 2005. Mr. DiGiacinto, an employee of an affiliate of STSG, disclaims beneficial ownership with respect to securities owned by STSG and its affiliates, as he has no power to vote or dispose of those securities.

(8) Represents shares of common stock which are issuable upon the exercise of stock options.

(9) Includes (i) 10,475 shares of common stock issuable upon the exercise of warrants, and (ii) 10,300 shares of common stock which are issuable upon the exercise of stock options. Dr. Steiner also owns options to purchase shares of common stock which will not be exercisable on or before May 30, 2005.

(10) Includes (i) 115,619 shares of common stock owned by a trust for which Mr. Farley serves as a trustee, (ii) 9,425 shares of common stock issuable upon conversion of our Series B convertible preferred stock owned by a trust for which Mr. Farley serves as a trustee, (y) 51,327 shares of common stock issuable upon the exercise of warrants and (iv) 267,756 shares of common stock which are issuable upon the exercise of stock options. The directors and executive officers also own options to purchase additional shares of common stock which will not be exercisable on or before May 30, 2005.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

Vyteris was incorporated in Delaware in July 2000. In November 2000, Vyteris purchased assets from Becton Dickinson comprising Becton Dickinson's iontophoresis drug delivery products and related research and development program, as well as related patents, patent applications and other intellectual property using funds contributed to it by Spencer Trask Specialty Group, LLC, or STSG. We refer to that transaction as the "Acquisition". Kevin Kimberlin, though his ownership of STSG, is, and has been since our inception, Vyteris' controlling stockholder and has voting and dispositive control over STSG.

Scimitar Holdings, LLC, a New York limited liability company and an affiliate of STSG, acquired an 82% interest in Vyteris Holdings in February 2004, resulting in a change in control of Vyteris Holdings.

Throughout the corporate history of Vyteris, Vyteris has had material relationships with STSG, its related parties and Becton Dickinson and has been controlled by Kevin Kimberlin, STSG and its affiliates. Since February 2004, Vyteris Holdings has also been controlled by Kevin Kimberlin, STSG and its affiliates.

CERTAIN RELATIONSHIPS BETWEEN VYTERIS AND STSG AND ITS RELATED PARTIES

All references under this caption to the number of shares of common stock have been adjusted to give effect to the Vyteris Holdings /Vyteris Merger and the one-for-ten reverse stock split.

As noted above, Kevin Kimberlin has voting and dispositive control over STSG and its affiliated entities.

THE ACQUISITION

STSG, our controlling stockholder, provided the financing to Vyteris for the Acquisition. In consideration of its initial capital contribution of \$9,000,000 made at the time of the Acquisition in November 2000, STSG acquired 628,500 shares of common stock and 3,000,000 shares of Vyteris' Series B Convertible Preferred Stock, all of which shares of preferred stock were subsequently sold back to Vyteris for nominal consideration and cancelled pursuant to a transaction referred to below as the "Recapitalization." In connection with the Acquisition, STSG transferred 34,917 and 6,984 shares of common stock held by it to Dr. De Caprio and Mr. Garrison, respectively.

DEBT FINANCINGS

After Vyteris utilized the capital contributed by STSG, our controlling stockholder, in the Acquisition, Vyteris was largely dependent upon STSG for its financing. Between November 2001 and December 2003, STSG and a trust beneficially owned by Donald Farley, the Chairman of the Board of Vyteris and, since September 29, 2004, Vyteris Holdings, provided Vyteris with an aggregate amount of debt financing equal to \$25,900,000, representing principal and accrued and unpaid interest calculated through March 31, 2004. On March 31, 2004, Vyteris consummated a recapitalization in which it issued to STSG, and to a trust beneficially owned by Donald Farley, in the aggregate, 9,637,000 shares of Vyteris common stock, 7,500,000 shares of a newly-designated Vyteris Series C convertible preferred stock and other nominal consideration, in exchange for \$20,350,000 in aggregate principal amount of 8% convertible secured promissory notes, \$2,900,000 principal amount of 8% secured promissory notes -- which we refer to collectively as the "STSG Notes" -- \$2,615,000 of accrued and unpaid interest as of March 31, 2004 on the STSG Notes, 3,000,000 shares of Vyteris' Series B Convertible Preferred Stock and the cancellation of warrants held by STSG to purchase 852,665 shares of Vyteris common stock. We refer to this transaction as the "Recapitalization." .

During February 2004, Vyteris issued secured promissory notes in the aggregate principal amount of \$1,000,000 to STSG and the following related parties of STSG: Spencer Trask Private Equity Fund I, Spencer Trask Private Equity Fund II, Spencer Trask Private Equity Accredited Fund III, LLC and Spencer Trask Illumination Fund. Each of these notes was scheduled to mature 120 days from its respective date of issuance and bore an annual interest rate of 12%, which was payable on maturity, and was convertible into common stock, at the option of the holders under certain circumstances. During May 2004, \$500,000 in principal amount of these notes was converted into the Bridge Notes described below. The remaining \$500,000 of principal amount of such notes was due on June 26, 2004 and has been paid in full.

THE BRIDGE FINANCING

In March, April and May of 2004, Vyteris issued \$8,497,500 in 8% secured convertible notes, which were scheduled to mature on December 31, 2004, in a private placement managed by Spencer Trask Ventures, an affiliate of STSG, which

is also controlled by Kevin Kimberlin. We refer to this issuance as the "Bridge Financing" and to the notes issued in the Bridge Financing as the "Bridge Notes" or the "December Notes". In the Bridge Financing, Spencer Trask Ventures received placement fees and non-accountable expense allowances of \$1,039,675 and warrants to purchase 1,068,136 shares of common stock, at an exercise price of \$2.387 per share, as compensation for acting as placement agent for the Bridge Financing.

As part of the Bridge Financing, Vyteris agreed that in the event that Spencer Trask Ventures introduces Vyteris to a third party which may be interested in engaging in a business combination or financing arrangement with Vyteris, which may include a merger or purchase of some or all of the stock or assets of Vyteris, an investment in

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the securities of Vyteris or a loan to Vyteris, Spencer Trask Ventures will be paid a finder's fee of 7% of the first \$1,000,000 or portion thereof of the consideration paid in such transaction; plus; 6% of the next \$1,000,000 or portion thereof of the consideration paid in such transaction; plus 5% of the next \$5,000,000 or portion thereof of the consideration paid in such transaction; plus 4% of the next \$1,000,000 or portion thereof of the consideration paid in such transaction; plus 3% of the next \$1,000,000 or portion thereof of the consideration paid in such transaction; plus 2.5% of any consideration paid in such transaction in excess of \$9,000,000. Such finder's fee will not be applicable to an investment by STSG and/or its related parties. To date, no such business combinations or financing arrangements have been consummated. Accordingly, no such finder's fee has been paid to Spencer Trask Ventures.

SEPTEMBER 2004 FINANCING

In September 2004, Vyteris consummated a private placement of units consisting of common stock and warrants. Spencer Trask Ventures served as one of two placement agents in that offering. In connection with this transaction, Spencer Trask Ventures received placement fees and non-accountable expense allowances of \$1,807,801 and warrants to purchase 971,114 shares of common stock, at an exercise price of \$3.58 per share, as compensation for acting as placement agent. Vyteris also agreed to pay Spencer Trask Ventures, as well as an unrelated placement agent, similar cash and warrant compensation with respect to, and based on, any investment by any investor in the September 2004 transaction who subsequently invests in us at any time on or before September 29, 2006: provided, however, neither placement agent will be entitled to any such compensation for investments made as part of an underwritten public offering, investments made by STSG or investments made by any of our employees. In addition, Vyteris entered into a right of first refusal agreement with Spencer Trask Ventures which grants to Spencer Trask Ventures the irrevocable preferential right of first refusal to purchase for its account or to act as agent for any proposed private offering of our securities.

During September 2004, STSG and a trust beneficially owned by Donald Farley, our Chairman of the Board, advanced certain sums to Vyteris which were converted into units as part of the September 2004 financing.

CREDIT FACILITY.

In September 2004, Spencer Trask agreed to provide us (or, at its option, cause a related party to provide us) with up to \$5.0 million in working capital loans in the form of 11.5% secured demand promissory notes. We refer to this arrangement as our Working Capital Facility. Pursuant to the terms of the Working Capital Facility, amounts drawn under the facility must be repaid on or before November 15, 2005. As consideration for the commitment of the Working Capital Facility, we issued 419,000 shares of common stock to Spencer Trask and recorded the fair value of these shares as deferred financing costs of \$1.3 million. Each time funds are loaned to us under the Working Capital Facility, we will be required to issue to the lender a common stock purchase warrant to purchase such number of shares equal to the quotient obtained by dividing (i) 40% of the amount loaned by (ii) 3.58. The warrants are exercisable for five years from the date of issuance and have an initial exercise price of \$3.58 per share. The Working Capital Facility enables us to borrow up to the lesser of \$5.0 million or the sum of qualifying accounts receivable and inventory. At present, our qualifying accounts receivable and inventory are de minimus, pending commencement of the commercialization of our first product. Management estimates that it will borrow funds under this Working Capital Facility in the second quarter of 2005. As of December 31, 2004, no amounts have been loaned to us under the Working Capital Facility. If used, the Working Capital Facility will be secured by a first priority lien on all of our assets.

RELATIONSHIP BETWEEN VYTERIS AND BECTON DICKINSON

In connection with the formation of Vyteris, Becton Dickinson agreed to treat and hold as confidential for five years all information relating to the

operations and affairs of the business that Vyteris purchased in the Acquisition. Becton Dickinson's obligation of confidentiality will expire in November 2005. Additionally, for a five year period expiring in November 2005, Becton Dickinson agreed not to sell, manufacture, develop, license or lease any iontophoresis system anywhere in the world, or create, develop or implement a business plan or strategy for a business that would, directly or indirectly, sell, manufacture, develop, license or lease any iontophoresis system anywhere in the world.

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We are required to pay Becton Dickinson a royalty in respect of sales of each iontophoresis product stemming from intellectual property received by Vyteris from Becton Dickinson as part of the formation of Vyteris. For each such product, on a country-by-country basis, that obligation continues for the later of 10 years after the date of the first commercial sale of such product in a country and the date of the original expiration of the last-to-expire patent related to such product granted in such country. The royalty, which is to be calculated semi-annually, will be equal to the greater of 5% of all direct revenues, as defined below, or 20% of all royalty revenues, with respect to the worldwide sales on a product-by-product basis. No royalties will be earned by Becton Dickinson prior to November 10, 2005. "Direct revenues" are the gross revenues actually received by us from the commercial sale of any iontophoresis product, including upfront payments, less amounts paid for taxes, duties, discounts, rebates, freight, shipping and handling charges or certain other expenses. "Royalty revenues" are the gross revenues actually received by Vyteris from any licensing or other fees directly relating to the licensing of any iontophoresis product, including upfront payments, less amounts paid for taxes, duties, discounts, rebates, freight, shipping and handling charges and certain other expenses.

In connection with the formation of Vyteris, Vyteris agreed to hold Becton Dickinson harmless against damages arising from any breach of the representations, warranties, agreements and covenants made by Vyteris in the definitive agreement relating to the Acquisition, and Vyteris assumed certain liabilities, including liabilities under environmental laws. Vyteris' indemnification obligations generally lasted until November 2002, although indemnification obligations with respect to certain representations and warranties made by Vyteris in that agreement will last for the applicable statute of limitations period, which extends beyond November 2002.

At the time that Vyteris was formed, Vyteris entered into a sublease agreement with Becton, Dickinson with respect to our 27,000 square-foot, Fair Lawn, New Jersey, facility. We pay to Becton Dickinson \$23,500 per month in base and additional rent. For the years ended December 31, 2002, 2003 and 2004, we paid Becton Dickinson \$292,000, \$301,300 and \$297,200 respectively, under the sublease. The sublease expires in September 2006.

In July 2003, Becton Dickinson purchased a \$500,000 principal amount 8% convertible promissory note from Vyteris. The note matured on July 1, 2004. Warrants to purchase 20,950 shares of common stock at an exercise price of \$9.55 per share were issued to Becton Dickinson in connection with its purchase of that note. In September 2004, Vyteris entered into an exchange agreement with Becton Dickinson. Pursuant to that agreement, we issued 117,041 shares of common stock and warrants to purchase an additional 29,260 shares of common stock and cancelled all of the Series A convertible preferred stock issued to Becton Dickinson in connection with the Acquisition. At the same time, we converted \$250,000 of debt into 29,260 shares of common stock and warrants to purchase 7,315 shares of common stock and paid Becton Dickinson approximately \$300,000 in payment of the balance of our indebtedness to Becton Dickinson.

We are unaware of who controls Becton Dickinson. A review of Becton Dickinson's most recent proxy statement indicates that Eugene J. Ludwig is the Chairman, Chief Executive Officer and President of Becton Dickinson and that Mr. Ludwig owns less than one percent of the outstanding common stock of Becton Dickinson. As of September 30, 2004, Becton Dickinson disclosed that its largest single shareholder was Barclays Global Investors NA, which owned less than 11% of Becton's Dickinson's outstanding common stock on that date.

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ITEM 13. EXHIBITS

- 2.1 Merger Agreement and Plan of Reorganization, dated as of July 8, 2004, by and among Treasure Mountain Holdings, Inc. ("Treasure Mountain Holdings"), TMH Acquisition Corp. and Vyteris ("Vyteris") is incorporated by reference to Exhibit 2.1 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.

- 2.2 Amendment No. 1, dated as of September 29, 2004, to the Merger Agreement and Plan of Reorganization, dated as of July 8, 2004, by and among Treasure Mountain Holdings, TMH Acquisition Corp. and Vyteris is incorporated by reference to Exhibit 2.2 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 3.1 Articles of Incorporation, as amended, of Treasure Mountain Holdings is incorporated by reference to Exhibit 3.1 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 3.2 By-laws, as amended, of Treasure Mountain Holdings is incorporated by reference to Exhibit 3.2 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 3.3 Proposed amendments to the articles of incorporation of Treasure Mountain Holdings are incorporated by reference to Exhibit 3.3 of Amendment No. 2 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed January 3, 2005.
- 10.1 Employment Agreement between Vyteris and Vincent De Caprio is incorporated by reference to Exhibit 10.1 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 10.2 Employment Agreement between Vyteris and James Garrison is incorporated by reference to Exhibit 10.2 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 10.3 Treasure Mountain Holdings Proposed 2005 Stock Option Plan is incorporated by reference to Exhibit 10.3 of Amendment No. 2 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed January 3, 2005.
- 10.4 Sublease Agreement between Vyteris and Becton Dickinson, dated November 10, 2000 is incorporated by reference to Exhibit 10.4 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 10.5 License, Development and Distribution Agreement, dated as of September 20, 2002 is incorporated by reference to Exhibit 10.5 to Amendment No. 1 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed April 15, 2005. (Y)
- 10.6 License and Development Agreement, dated as of September 27, 2004 is incorporated by reference to Exhibit 10.6 to Amendment No. 1 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed April 15, 2005. (Y)
- 10.7 Supply Agreement, dated as of September 27, 2004 is incorporated by reference to Exhibit 10.7 to Amendment No. 1 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed April 15, 2005. (Y)
- 10.8 Registration Rights Agreement, dated as of September 29, 2004 is incorporated by reference to Exhibit 10.8 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 10.9 Securities Purchase Agreement, dated as of September 28, 2004, between Vyteris and Spencer Trask Specialty Group, LLC is incorporated by reference to Exhibit 10.9 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 10.10 Security Agreement, dated as of September 28, 2004 is incorporated by reference to Exhibit 10.10 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 10.11 Finder's Agreement, dated as of March 31, 2004, between Vyteris and Spencer Trask Ventures, Inc. is incorporated by reference to Exhibit 10.11 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 10.12 Right of First Refusal Agreement, dated as of March 31, 2004, between Vyteris and Spencer Trask Ventures, Inc. is incorporated by reference to Exhibit 10.12 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.

- 10.13 Placement Agency Agreement, dated as of March 19, 2004, between Vyteris and Spencer Trask Ventures, Inc. is incorporated by reference to Exhibit 10.13 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 10.14 Placement Agency Agreement, dated as of June 18, 2004, among Vyteris, Inc, Spencer Trask Ventures, Inc. and Rodman & Renshaw, LLC is incorporated by reference to Exhibit 10.14 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 10.15 Amendment No. 1, dated July 8, 2004, to Placement Agency Agreement, dated as of June 18, 2004, among Vyteris, Inc, Spencer Trask Ventures, Inc. and Rodman & Renshaw, LLC is incorporated by reference to Exhibit 10.15 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 10.16 Amendment No. 2, dated September 13, 2004, to Placement Agency Agreement, dated as of June 18, 2004, among Vyteris, Inc, Spencer Trask Ventures, Inc. and Rodman & Renshaw, LLC is incorporated by reference to Exhibit 10.16 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 10.17 Lease, dated December 14, 2004, between CK Bergen Holdings, L.L.C. and Vyteris, Inc. is incorporated by reference to Exhibit 10.17 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed April 15, 2005.
- 10.18 Employment Agreement between Vyteris and C. Gregory Arnold is incorporated by reference to Exhibit 10.18 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed April 15, 2005.
- 10.19 Vyteris Holdings (Nevada), Inc. 2005 Stock Option Plan is incorporated by reference to Exhibit 10.1 to Vyteris Holdings (Nevada), Inc.'s Current Report on Form 8-K filed April 26, 2005.
- 16.1 Letter from Madsen & Associates, CPA's, Inc. dated November 5, 2004 is incorporated by reference to Exhibit 16.1 to Treasure Mountain Holdings' Current Report on Form 8-K filed November 5, 2004.
- 21.1 Subsidiaries of Treasure Mountain is incorporated by reference to Exhibit 21.1 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 31.1 Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- 32.2 Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- (Y) Portions of this document have been omitted and filed separately with the SEC pursuant to a request for confidential treatment in accordance with Rule 406 of the Securities Act.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The following table presents fees for professional audit services rendered by Ernst & Young LLP ("E&Y") for the audit of the Company's annual consolidated financial statements for the years ended December 31, 2004, and December 31, 2003, and fees billed for other services rendered by E&Y during those periods:

	DECEMBER 31,	

	2004	2003
	-----	-----
Audit fees.....	\$ 277,750	\$ 60,420
Audit-related fees.....	407,284	--
Tax fees.....	15,000	6,955
All other fees.....	--	--

-----	-----
\$ 700,034	\$ 67,375
=====	=====

- 1) Audit Fees -- These are fees for professional services performed by E&Y for the audit of the Company's annual consolidated financial statements and review of consolidated financial statements included in the Company's 10-QSB filing.
- 2) Audit-Related Fees -- These are fees for assurance and related services performed by E&Y that are reasonably related to the performance of the audit or review of the Company's financial statements. This includes: the issuance of comfort letters and consents, reviews of and assistance with documents filed with the SEC, due diligence related to mergers and acquisitions and consulting on financial accounting/reporting standards before the Company became a public company on September 29, 2004.
- 3) Tax Fees -- These are fees for professional services performed by E&Y with respect to tax compliance, tax advice and tax planning. This includes preparation of original and amended tax returns for the Company; refund claims; tax audit assistance; and tax work stemming from "Audit-Related" items.
- 4) All Other Fees -- These are fees for other permissible work performed by E&Y that does not meet the above category descriptions.

These services are actively monitored (both spending level and work content) by the Audit Committee to maintain the appropriate objectivity and independence in E&Y's core work, which is the audit of the Company's consolidated financial statements. In accordance with the requirements of the Sarbanes-Oxley Act of 2002 and the Audit Committee's charter, all audit and audit-related work and all non-audit work performed by E&Y is approved in advance by the Audit Committee, including the proposed fees for such work. The Audit Committee is informed of each service actually rendered. Applicable law and regulations provide an exemption that permits certain services to be provided by Vyteris Holdings' outside auditors even if they are not pre-approved. Vyteris Holdings has not relied on this exemption at any time since the Sarbanes-Oxley Act was enacted.

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SIGNATURE

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Vyteris Holdings (Nevada), Inc.

May 2, 2005

By: /s/ Michael McGuinness

Michael McGuinness
Vice President and
Chief Financial Officer

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EXHIBIT INDEX

- 2.1 Merger Agreement and Plan of Reorganization, dated as of July 8, 2004, by and among Treasure Mountain Holdings, Inc. ("Treasure Mountain Holdings"), TMH Acquisition Corp. and Vyteris ("Vyteris") is incorporated by reference to Exhibit 2.1 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 2.2 Amendment No. 1, dated as of September 29, 2004, to the Merger Agreement and Plan of Reorganization, dated as of July 8, 2004, by and among Treasure Mountain Holdings, TMH Acquisition Corp. and Vyteris is incorporated by reference to Exhibit 2.2 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 3.1 Articles of Incorporation, as amended, of Treasure Mountain Holdings is incorporated by reference to Exhibit 3.1 to Treasure Mountain

- 3.2 By-laws, as amended, of Treasure Mountain Holdings is incorporated by reference to Exhibit 3.2 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 3.3 Proposed amendments to the articles of incorporation of Treasure Mountain Holdings are incorporated by reference to Exhibit 3.3 of Amendment No. 2 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed January 3, 2005.
- 10.1 Employment Agreement between Vyteris and Vincent De Caprio is incorporated by reference to Exhibit 10.1 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 10.2 Employment Agreement between Vyteris and James Garrison is incorporated by reference to Exhibit 10.2 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 10.3 Treasure Mountain Holdings Proposed 2005 Stock Option Plan is incorporated by reference to Exhibit 10.3 of Amendment No. 2 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed January 3, 2005.
- 10.4 Sublease Agreement between Vyteris and Becton Dickinson, dated November 10, 2000 is incorporated by reference to Exhibit 10.4 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed November 12, 2004.
- 10.5 License, Development and Distribution Agreement, dated as of September 20, 2002 is incorporated by reference to Exhibit 10.5 to Amendment No. 1 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed April 15, 2005. (Y)
- 10.6 License and Development Agreement, dated as of September 27, 2004 is incorporated by reference to Exhibit 10.6 to Amendment No. 1 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed April 15, 2005. (Y)
- 10.7 Supply Agreement, dated as of September 27, 2004 is incorporated by reference to Exhibit 10.7 to Amendment No. 1 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed April 15, 2005. (Y)
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- 10.20 Lease, dated December 14, 2004, between CK Bergen Holdings, L.L.C. and Vyteris, Inc. is incorporated by reference to Exhibit 10.17 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed April 15, 2005.
- 10.21 Employment Agreement between Vyteris and C. Gregory Arnold is incorporated by reference to Exhibit 10.18 to Treasure Mountain Holdings' Registration Statement on Form SB-2 (333-120411) filed April 15, 2005.
- 10.22 Vyteris Holdings (Nevada), Inc. 2005 Stock Option Plan is incorporated by reference to Exhibit 10.1 to Vyteris Holdings (Nevada), Inc.'s Current Report on Form 8-K filed April 26, 2005.
- 16.1 Letter from Madsen & Associates, CPA's, Inc. dated November 5, 2004 is incorporated by reference to Exhibit 16.1 to Treasure Mountain Holdings' Current Report on Form 8-K filed November 5, 2004.
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- 31.1 Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- (Y) Portions of this document have been omitted and filed separately with the SEC pursuant to a request for confidential treatment in accordance with Rule 406 of the Securities Act.

CERTIFICATION PURSUANT TO RULE 13A-14 OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Vincent De Caprio, Chief Executive Officer, certify that:

1. I have reviewed this annual report on Form 10-KSB/A of Vyteris Holdings (Nevada), Inc.:
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal

control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 2, 2005

/s/ Vincent De Caprio

Vincent De Caprio
Chief Executive Officer

CERTIFICATION PURSUANT TO RULE 13A-14 OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael McGuinness, Chief Financial Officer, certify that:

1. I have reviewed this annual report on Form 10-KSB/A of Vyteris Holdings (Nevada), Inc.:
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal

control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 2, 2005

/s/ Michael McGuinness

Michael McGuinness
Chief Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Vyteris Holdings (Nevada), Inc. (the "Company") on Form 10-KSB/A for the year ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Form"), I, Vincent De Caprio, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Form fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Form fairly presents, in all material respects, the financial condition and result of operations of the Company.

May 2, 2005

/s/ Vincent De Caprio

Vincent De Caprio
Chief Executive Officer

This certification has been furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Vyteris Holdings (Nevada), Inc. (the "Company") on Form 10-KSB/A for the year ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Form"), I, Michael McGuinness, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Form fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Form fairly presents, in all material respects, the financial condition and result of operations of the Company.

May 2, 2005

/s/ Michael McGuinness

Michael McGuinness
Chief Financial Officer

This certification has been furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.