

PROVECTUS PHARMACEUTICALS INC
Form 10KSB
March 22, 2007

**United States
Securities And Exchange Commission
Washington, DC 20549**

FORM 10-KSB

(Mark One)

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2006; OR

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission file number: 0-9410

Provectus Pharmaceuticals, Inc.

(Name of Small Business Issuer in Its Charter)

Nevada

(State or other jurisdiction of incorporation or
organization)

90-0031917

(I.R.S. Employer Identification Number)

**7327 Oak Ridge Highway, Suite A, Knoxville,
Tennessee**

(Address of Principal Executive Offices)

37931

(Zip Code)

865/769-4011

(Issuer's Telephone Number, Including Area Code)

Securities registered under Section 12(b) of the Exchange Act: **None**
(Title of Class)

Securities registered under Section 12(g) of the Exchange Act:

Common shares, par value \$.001 per share

(Title of Class)

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Note -
Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the
Exchange Act from their obligations under those Sections.

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during
the preceding 12 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 in response to Item 405 of Regulation S-B contained in this form,

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and no disclosure will be contained, to the best of 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. x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes o No x

The issuer's revenues for the most recent fiscal year were \$1,368

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of March 21, 2007, was \$23,318,557 (computed on the basis of \$1.29 per share).

The number of shares outstanding of the issuer's stock, \$0.001 par value per share, as of March 21, 2007 was 45,450,619.

Documents incorporated by reference in Part III hereof: Proxy Statement for 2007 Annual Meeting of Stockholders.

Transitional Small Business Disclosure Format (check one): Yes o No x

**Provectus Pharmaceuticals, Inc.
Annual Report on Form 10-KSB**

Table of Contents

	Page
Part I	
Item 1A.	
Risk Factors	3
Item 1B.	
Unresolved Staff Comments	8
Item 1. Description of Business	8
History	8
Description Of Business	9
Intellectual Property	15
Competition	16
Federal Regulation of Therapeutic Products	16
Personnel	18
Available Information	19
Item 2. Description of Property	19
Item 3. Legal Proceedings	20
Item 4. Submission of Matters to a Vote of Security Holders	20
Part II	
Item 5. Market for Common Equity and Related Stockholder Matters	21
Item 6. Management's Discussion and Analysis or Plan of Operation	22
Plan of Operation	23
Item 7. Financial Statements	26
Forward-Looking Statements	26
Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	26
Item 8A. Controls and Procedures	26
Item 8B. Other Information	26
Part III	
Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act	26
Item 10. Executive Compensation	27
Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	27
Item 12. Certain Relationships and Related Transactions	27
Item 13. Exhibits	27
Item 14. Principal Accountant Fees and Services	27
Signatures	28
Financial Statements	F-1
Exhibit Index	X-1

PART I

Item 1A. Risk Factors.

Risk Factors

Our business is subject to various risks, including those described below. You should carefully consider these risk factors, together with all of the other information included in this Annual Report on Form 10-KSB. Any of these risks could materially adversely affect our business, operating results and financial condition:

Our technologies are in early stages of development.

We have generated minimal initial revenues from sales and operations in 2006 and 2005, and we do not expect to generate revenues to enable us to be profitable for several calendar quarters unless we sell and/or license our technologies. We must raise substantial additional funds beyond 2008 in order to fully implement our integrated business plan, including execution of the next phases in clinical development of our pharmaceutical products. We estimate that our existing capital resources will be sufficient to fund our current and planned operations.

Ultimately, we must achieve profitable operations if we are to be a viable entity unless we are acquired by another company. We intend to proceed as rapidly as possible with the asset sale and licensure of OTC products that can be sold with a minimum of regulatory compliance and with the development of revenue sources through licensing of our existing intellectual property portfolio. We cannot assure you that we will be able to raise sufficient capital to sustain operations beyond 2008 before we can commence revenue generation or that we will be able to achieve, or maintain, a level of profitability sufficient to meet our operating expenses.

We will need additional capital to conduct our operations and develop our products beyond 2008, and our ability to obtain the necessary funding is uncertain.

We estimate that our existing capital resources will be sufficient to fund our current and planned operations; however, we may need additional capital. We have based this estimate on assumptions that may prove to be wrong, and we cannot assure that estimates and assumptions will remain unchanged. For example, we are currently assuming that we will continue to operate without any significant staff or other resources expansion. We intend to acquire additional funding through public or private equity financings or other financing sources that may be available. Additional financing may not be available on acceptable terms, or at all. As discussed in more detail below, additional equity financing could result in significant dilution to shareholders. Further, in the event that additional funds are obtained through licensing or other arrangements, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise seek to develop and commercialize ourselves. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our programs, any of which could have a material adverse effect on our business, and may impair the value of our patents and other intangible assets.

Existing shareholders may face dilution from our financing efforts.

We must raise additional capital from external sources to execute our business plan beyond 2008. We plan to issue debt securities, capital stock, or a combination of these securities, if necessary depending on licensure and asset sale discussions. We may not be able to sell these securities, particularly under current market conditions. Even if we are successful in finding buyers for our securities, the buyers could demand high interest rates or require us to agree to onerous operating covenants, which could in turn harm our ability to operate our business by reducing our cash flow and restricting our operating activities. If we were to sell our capital stock, we might be forced to sell shares at a depressed market price, which could result in substantial dilution to our existing shareholders. In addition, any shares of capital stock we may issue may have rights, privileges, and preferences superior to those of our common

shareholders.

The prescription drug and medical device products in our internal pipeline are at an early stage of development, and they may fail in subsequent development or commercialization.

We are continuing to pursue clinical development of our most advanced pharmaceutical drug products, Xantryl and Provecta, for use as treatments for specific conditions. These products and other pharmaceutical drug and medical device products that we are currently developing will require significant additional research, formulation and manufacture development, and pre-clinical and extensive clinical testing prior to regulatory licensure and commercialization. Pre-clinical and clinical studies of our pharmaceutical drug and medical device products under development may not demonstrate the safety and efficacy necessary to obtain regulatory approvals. Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in earlier trials. Pharmaceutical drug and medical device products that appear to be promising at early stages of development may not reach the market or be marketed successfully for a number of reasons, including the following:

3

- a product may be found to be ineffective or have harmful side effects during subsequent pre-clinical testing or clinical trials;
 - a product may fail to receive necessary regulatory clearance;
 - a product may be too difficult to manufacture on a large scale;
 - a product may be too expensive to manufacture or market;
 - a product may not achieve broad market acceptance;
- others may hold proprietary rights that will prevent a product from being marketed; or
 - others may market equivalent or superior products.

We do not expect any pharmaceutical drug products we are developing to be commercially available for at least several years, if at all. Our research and product development efforts may not be successfully completed and may not result in any successfully commercialized products. Further, after commercial introduction of a new product, discovery of problems through adverse event reporting could result in restrictions on the product, including withdrawal from the market and, in certain cases, civil or criminal penalties.

Our OTC products are at an early stage of introduction, and we cannot be sure that they will be sold through a combination of asset sale and licensure in the marketplace or that we will have adequate capital to further develop these products, if necessary, which are an important factor in the future success of our business.

We recently have focused on marketing Pure-ific, one of our OTC products, on a limited basis to establish proof of concept. We have recognized minimal revenue from this product, as the sales of this product has not been material. In order for this product, and our other OTC products, to become commercially successful, unless we license and/or sell the underlying assets, we must increase significantly our distribution of them. Increasing distribution of our products requires, in turn, that we or distributors representing us increase marketing of these products. In view of our limited financial resources, we may be unable to afford increases in our marketing of our OTC products sufficient to improve our distribution of our products. Even if we can and do increase our marketing of our OTC products, we cannot assure you that we can successfully increase our distribution of our products.

If we do begin increasing our distribution of our OTC products, we must increase our production of these products in order to fill our distribution channels. Increased production will require additional financial resources that we do not plan to allocate at present. Additionally, we may succeed in increasing production without succeeding in increasing sales, which could leave us with excess, possibly unsaleable, inventory.

If we are unable to successfully introduce, market and distribute these products, our business, financial condition, results of operations and cash flows would likely require additional capital beyond 2008 to continue as a going concern.

Competition in the prescription drug, medical device and OTC pharmaceuticals markets is intense, and we may be unable to succeed if our competitors have more funding or better marketing.

The pharmaceutical and biotechnology industries are intensely competitive. Other pharmaceutical and biotechnology companies and research organizations currently engage in or have in the past engaged in research efforts related to treatment of dermatological conditions or cancers of the skin, liver and breast, which could lead to the development of products or therapies that could compete directly with the prescription drug, medical device and OTC products that we

are seeking to develop and market.

Many companies are also developing alternative therapies to treat cancer and dermatological conditions and, in this regard, are our competitors. Many of the pharmaceutical companies developing and marketing these competing products have significantly greater financial resources and expertise than we do in:

4

- research and development;
- manufacturing;
- preclinical and clinical testing;
- obtaining regulatory approvals; and
- marketing.

Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Academic institutions, government agencies and other public and private research organizations also may conduct research, seek patent protection and establish collaborative arrangements for research, clinical development and marketing of products similar to ours. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our programs.

In addition to the above factors, we expect to face competition in the following areas:

- product efficacy and safety;
- the timing and scope of regulatory consents;
- availability of resources;
- reimbursement coverage;
- price; and
- patent position, including potentially dominant patent positions of others.

As a result of the foregoing, our competitors may develop more effective or more affordable products or achieve earlier product commercialization than we do.

Product Competition. Additionally, since our currently marketed products are generally established and commonly sold, they are subject to competition from products with similar qualities.

Our OTC product Pure-ific competes in the market with other hand sanitizing products, including in particular, the following hand sanitizers:

- Purell (owned by Johnson & Johnson),
- Avagard D (manufactured by 3M) and
- a large number of generic and private-label equivalents to these market leaders.

Our OTC product GloveAid represents a new product category that has no direct competitors; however, other types of products, such as AloeTouch(R) disposable gloves (manufactured by Medline Industries) target the same market niche.

Since our prescription products Provecta and Xantryl have not yet been approved by the FDA or introduced to the marketplace, we cannot estimate what competition these products might face when they are finally introduced, if at all. We cannot assure you that these products will not face significant competition for other prescription drugs and generic equivalents.

If we are unable to secure or enforce patent rights, trademarks, trade secrets or other intellectual property our business could be harmed.

We may not be successful in securing or maintaining proprietary patent protection for our products or products and technologies we develop or license. In addition, our competitors may develop products similar to ours using methods and technologies that are beyond the scope of our intellectual property protection, which could reduce our anticipated sales. While some of our products have proprietary patent protection, a challenge to these patents can be subject to expensive litigation. Litigation concerning patents, other forms of intellectual property and proprietary technology is becoming more widespread and can be protracted and expensive and can distract management and other personnel from performing their duties for us.

5

We also rely upon trade secrets, unpatented proprietary know-how and continuing technological innovation in order to develop a competitive position. We cannot assure you that others will not independently develop substantially equivalent proprietary technology and techniques or otherwise gain access to our trade secrets and technology, or that we can adequately protect our trade secrets and technology.

If we are unable to secure or enforce patent rights, trademarks, trade secrets or other intellectual property, our business, financial condition, results of operations and cash flows could be materially adversely affected. If we infringe on the intellectual property of others, our business could be harmed.

We could be sued for infringing patents or other intellectual property that purportedly cover products and/or methods of using such products held by persons other than us. Litigation arising from an alleged infringement could result in removal from the market, or a substantial delay in, or prevention of, the introduction of our products, any of which could have a material adverse effect on our business, financial condition, or results of operations and cash flows.

If we do not update and enhance our technologies, they will become obsolete.

The pharmaceutical market is characterized by rapid technological change, and our future success will depend on our ability to conduct successful research in our fields of expertise, to discover new technologies as a result of that research, to develop products based on our technologies, and to commercialize those products. While we believe that current technology is adequate for our present needs, if we fail to stay at the forefront of technological development, we will be unable to compete effectively. Our competitors are using substantial resources to develop new pharmaceutical technologies and to commercialize products based on those technologies. Accordingly, our technologies may be rendered obsolete by advances in existing technologies or the development of different technologies by one or more of our current or future competitors.

If we lose any of our key personnel, we may be unable to successfully execute our business plan.

Our business is presently managed by four key employees:

- H. Craig Dees, Ph.D., our Chief Executive Officer;
- Timothy C. Scott, Ph.D., our President;
- Eric A. Wachter, Ph.D. our Vice President - Pharmaceuticals; and
- Peter R. Culpepper, CPA, our Chief Financial Officer.

In addition to their responsibilities for management of our overall business strategy, Drs. Dees, Scott and Wachter are our chief researchers in the fields in which we are developing and planning to develop prescription drug, medical device and OTC products. Also, as of December 31, 2006, we owe \$265,929 in accrued but unpaid compensation to our employees. The loss of any of these key employees could have a material adverse effect on our operations, and our ability to execute our business plan might be negatively impacted. Any of these key employees may leave their employment with us if they choose to do so, and we cannot assure you that we would be able to hire similarly qualified executives if any of our key employees should choose to leave.

Because we have only four employees in total, our management may be unable to successfully manage our business.

In order to successfully execute our business plan, our management must succeed in all of the following critical areas:

- Researching diseases and possible therapies in the areas of dermatology and skin care, oncology, and biotechnology;

- Developing prescription drug, medical device and OTC products based on our research;
 - Marketing and selling developed products;
- Obtaining additional capital to finance research, development, production and marketing of our products; and

6

- Managing our business as it grows.

As discussed above, we currently have only four employees, all of whom are full-time employees. The greatest burden of succeeding in the above areas therefore falls on Drs. Dees, Scott, Wachter, and Mr. Culpepper. Focusing on any one of these areas may divert their attention from our other areas of concern and could affect our ability to manage other aspects of our business. We cannot assure you that our management will be able to succeed in all of these areas or, even if we do so succeed, that our business will be successful as a result. We anticipate adding an additional regulatory affairs officer on a consulting basis within the next year. While we have not historically had difficulty in attracting employees, our small size and limited operating history may make it difficult for us to attract and retain employees in the future which could further divert management's attention from the operation of our business.

Our common stock price can be volatile because of several factors, including a limited public float which has increased significantly from 2005 to 2006.

During the year ended December 31, 2006, the sale price of our common stock fluctuated from \$1.97 to \$0.83 per share. We believe that our common stock is subject to wide price fluctuations because of several factors, including:

- absence of meaningful earnings and ongoing need for external financing,
- a relatively thin trading market for our common stock, which causes trades of small blocks of stock to have a significant impact on our stock price,
 - general volatility of the stock markets and the market prices of other publicly traded companies, and
- investor sentiment regarding equity markets generally, including public perception of corporate ethics and governance and the accuracy and transparency of financial reporting.

Financings that may be available to us under current market conditions frequently involve sales at prices below the prices at which our common stock trades on the Over the Counter Electronic Bulletin Board, as well as the issuance of warrants or convertible debt that require exercise or conversion prices that are calculated in the future at a discount to the then market price of our common stock.

Any agreement to sell, or convert debt or equity securities into, common stock at a future date and at a price based on the then current market price will provide an incentive to the investor or third parties to sell the common stock short to decrease the price and increase the number of shares they may receive in a future purchase, whether directly from us or in the market.

Financings that may be available to us frequently involve high selling costs.

Because of our limited operating history, low market capitalization, thin trading volume and other factors, we have historically had to pay high costs to obtain financing and expect to continue to be required to pay high costs for any future financings in which we may participate. For example, our past sales of shares and our sale of the debentures have involved the payment of finder's fees or placement agent's fees. These types of fees are typically higher for small companies like us. Payment of fees of this type reduces the amount of cash that we receive from a financing transaction and makes it more difficult for us to obtain the amount of financing that we need to maintain and expand our operations.

It is our general policy to retain any earnings for use in our operation.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, for use in our business and therefore do not anticipate paying any cash dividends on our common

stock in the foreseeable future.

Our stock price is below \$5.00 per share and is treated as a "penny stock" which places restrictions on broker-dealers recommending the stock for purchase.

7

Our common stock is defined as "penny stock" under the Exchange Act and its rules. The SEC has adopted regulations that define "penny stock" to include common stock that has a market price of less than \$5.00 per share, subject to certain exceptions. These rules include the following requirements:

- broker-dealers must deliver, prior to the transaction a disclosure schedule prepared by the SEC relating to the penny stock market;
 - broker-dealers must disclose the commissions payable to the broker-dealer and its registered representative;
 - broker-dealers must disclose current quotations for the securities;
- if a broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealers presumed control over the market; and
- a broker-dealer must furnish its customers with monthly statements disclosing recent price information for all pennies stocks held in the customer's account and information on the limited market in penny stocks.

Additional sales practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. If our common stock remains subject to these penny stock rules these disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result, fewer broker-dealers may be willing to make a market in our stock, which could affect a shareholder's ability to sell their shares.

Item 1B. Unresolved Staff Comments.

None.

Item 1. Description of Business.

History

Provectus Pharmaceuticals, Inc., formerly known as "Provectus Pharmaceutical, Inc." and "SPM Group, Inc.," was incorporated under Colorado law on May 1, 1978. SPM Group ceased operations in 1991, and became a development-stage company effective January 1, 1992, with the new corporate purpose of seeking out acquisitions of properties, businesses, or merger candidates, without limitation as to the nature of the business operations or geographic location of the acquisition candidate.

On April 1, 2002, SPM Group changed its name to "Provectus Pharmaceutical, Inc." and reincorporated in Nevada in preparation for a transaction with Provectus Pharmaceuticals, Inc., a privately-held Tennessee corporation, which we refer to as "PPI." On April 23, 2002, an Agreement and Plan of Reorganization between Provectus Pharmaceutical and PPI was approved by the written consent of a majority of the outstanding shares of Provectus Pharmaceutical. As a result, holders of 6,680,000 shares of common stock of Provectus Pharmaceutical exchanged their shares for all of the issued and outstanding shares of PPI. As part of the acquisition, Provectus Pharmaceutical changed its name to "Provectus Pharmaceuticals, Inc." and PPI became a wholly owned subsidiary of Provectus. For accounting purposes, we treat this transaction as a recapitalization of PPI.

On November 19, 2002, we acquired Valley Pharmaceuticals, Inc., a privately-held Tennessee corporation formerly known as Photogen, Inc., by merging our subsidiary PPI with and into Valley and naming the surviving corporation "Xantech Pharmaceuticals, Inc." Valley had minimal operations and had no revenues prior to the transaction with the

Company. By acquiring Valley, we acquired our most important intellectual property, including issued U.S. patents and patentable inventions, with which we intend to develop:

- prescription drugs, medical and other devices (including laser devices) and over-the-counter pharmaceutical products in the fields of dermatology and oncology; and
- technologies for the preparation of human and animal vaccines, diagnosis of infectious diseases and enhanced production of genetically engineered drugs.

Prior to the acquisition of Valley, we were considered to be, and continue to be, in the development stage and had not generated any revenues from the assets we acquired.

On December 5, 2002, we acquired the assets of Pure-ific L.L.C., a Utah limited liability company, and created a wholly owned subsidiary, Pure-ific Corporation, to operate that business. We acquired the product formulations for Pure-ific personal sanitizing sprays, along with the "Pure-ific" trademarks. We intend to continue product development and begin to market a line of personal sanitizing sprays and related products to be sold over the counter under the "Pure-ific" brand name.

Description Of Business

Overview

Provectus, and its five wholly owned subsidiaries:

- Xantech Pharmaceuticals, Inc.
- Pure-ific Corporation
- Provectus Biotech, Inc.
- Provectus Devicetech, Inc.
- Provectus Pharmatech, Inc.

(which we refer to as our subsidiaries) develop, license and market and plan to sell products in three sectors of the healthcare industry:

- Over-the-counter products, which we refer to in this report as "OTC products;"
- Prescription drugs; and
- Medical device systems

We manage Provectus and our subsidiaries on an integrated basis and when we refer to "we" or "us" or "the company" in this Annual Report on Form 10-KSB, we refer to all six corporations considered as a single unit. Our principal executive offices are located at 7327 Oak Ridge Highway, Suite A, Knoxville, Tennessee 37931, telephone 865/769-4011.

Through discovery and use of state-of-the-art scientific and medical technologies, the founders of our pharmaceutical business have developed a portfolio of patented, patentable, and proprietary technologies that support multiple products in the prescription drug, medical device and OTC products categories. These patented technologies are for:

- (a) treatment of cancer;
- (b) novel therapeutic medical devices;
- (c) enhancing contrast in medical imaging;
- (d) improving signal processing during biomedical imaging; and
- (e) enhancing production of biotechnology products.

Our prescription drug products encompass the areas of dermatology and oncology and involve several types of small molecule-based drugs. Our medical device systems include therapeutic and cosmetic lasers, while our OTC products address markets primarily involving skincare applications. Because our prescription drug candidates and medical device systems are in the early stages of development, they are not yet on the market and there is no assurance that they will advance to the point of commercialization.

Our first commercially available products are directed into the OTC market, as these products pose minimal or no regulatory compliance barriers to market introduction. For example, the active pharmaceutical ingredient (API) in our ethical products is already approved for other medical uses by the FDA and has a long history of safety for use in humans. This use of known APIs for novel uses and in novel formulations minimizes potential adverse concerns from the FDA, since considerable safety data on the API is available (either in the public domain or via license or other agreements with third parties holding such information). In similar fashion, our OTC products are based on established APIs and, when possible, utilize formulations (such as aerosol or cream formulations) that have an established precedent. (For more information on compliance issues, see "Federal Regulation of Therapeutic Products" below.) In this fashion, we believe that we can diminish the risk of regulatory bars to the introduction of safe, consumer-friendly products and minimize the time required to begin generating revenues from product sales. At the same time, we continue to develop higher-margin prescription pharmaceuticals and medical devices, which have longer development and regulatory approval cycles.

Over-the-Counter Pharmaceuticals

Our OTC products are designed to be safer and more specific than competing products. Our technologies offer practical solutions for a number of intractable maladies, using ingredients that have limited or no side effects compared with existing products. To develop our OTC products, we typically use compounds with potent antibacterial and antifungal activity as building blocks and combine these building blocks with anti-inflammatory and moisture-absorbing agents. Products with these properties can be used for treatment of a large number of skin afflictions, including:

- hand irritation associated with use of disposable gloves
 - eczema
 - mild to moderate acne

Where appropriate, we have filed or will file patent applications and will seek other intellectual property protection to protect our unique formulations for relevant applications.

GloveAid

Personnel in many occupations and industries now use disposable gloves daily in the performance of their jobs, including:

- Airport security personnel;
- Food handling and preparation personnel;
 - Sanitation workers;
- Postal and package delivery handlers and sorters;
 - Laboratory researchers;
- Health care workers such as hospital and blood bank personnel; and
 - Police, fire and emergency response personnel.

Accompanying the increased use of disposable gloves is a mounting incidence of chronic skin irritation. To address this market, we have developed GloveAid, a hand cream with both antiperspirant and antibacterial properties, to increase the comfort of users' hands during and after the wearing of disposable gloves. During 2003, we ran a pilot scale run at the manufacturer of GloveAid. We now intend to license this product to a third party with experience in the institutional sales market.