MEDICIS PHARMACEUTICAL CORP
Form 10-K
September 13, 2005

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

FORM 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended June 30, 2005.

Or

o **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 0-18443
MEDICIS PHARMACEUTICAL CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	52-1574808
(State of other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
8125 North Hayden Road, Scottsdale, Arizona	85258-2463
(Address of principal executive office)	(Zip Code)

Registrant s telephone number, including area code: (602) 808-8800
Securities registered pursuant to Section 12(b) of the Act: Class A common stock, $0.014 par value

New York Stock Exchange	Preference Share Purchase Rights
(Name of each exchange on which registered)	(Title of each Class)

Securities registered pursuant to Section 12(g) of the Act: NONE

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 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 þ No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not 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 or any amendment to this Form 10-K o.
Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act) Yes þ No o
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ

The aggregate market value of the voting stock held on December 31, 2004 by non-affiliates of the registrant was $1,220,251,877, based on the closing price of $35.11 per share as reported on the New York Stock Exchange on December 31, 2004, the last business day of the registrant s most recently completed second fiscal quarter (calculated by excluding all shares held by executive officers, directors and holders known to the registrant of five percent or more of the voting power of the registrant s common stock, without conceding that such persons are affiliates of the registrant for purposes of the federal securities laws). As of September 7, 2005, there were 54,387,026 outstanding shares of Class A common stock.

Documents incorporated by reference:

Portions of the Proxy Statement for the registrant s 2005 Annual Meeting of Shareholders are incorporated herein by reference in Part III of this Form 10-K to the extent stated herein.

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PART I

ITEM 1: BUSINESS

Medicis Pharmaceutical Corporation, together with its wholly owned subsidiaries (Medicis , the Company , or as used in the context of we , us or our) is a leading specialty pharmaceutical company focusing primarily on helping patients attain a healthy and youthful appearance and self-image through the development and marketing of products in the United States for the treatment of dermatological, aesthetic and podiatric conditions. We also market products in Canada for the treatment of dermatological and aesthetic conditions. We believe that annual U.S. pharmaceutical sales in the dermatological market exceed $5 billion. According to the American Society for Aesthetic Plastic Surgery, a national not-for-profit organization for education and research in cosmetic plastic surgery, nearly 11.9 million surgical and non-surgical cosmetic procedures were performed in the United States during 2004. From 2003 to 2004, there was a 44% increase in the number of cosmetic procedures performed, including a 51% increase in non-surgical cosmetic procedures performed.

We have built our business by executing a four-part growth strategy. This strategy consists of promoting existing core brands, developing new products and important product line extensions, entering into strategic collaborations, and acquiring complementary products, technologies and businesses. We cultivate relationships of trust and confidence with the high prescribing dermatologists and podiatrists and the leading plastic surgeons in the United States.

We offer a broad range of products addressing various conditions including acne, fungal infections, rosacea, hyperpigmentation, photoaging, psoriasis, eczema, skin and skin-structure infections, seborrheic dermatitis and cosmesis (improvement in the texture and appearance of skin). We currently offer 15 branded products. Our core brands are DYNACIN® (minocycline HCI), LOPROX® (ciclopirox), OMNICEF® (cefdinir), PLEXION® (sodium sulfacetamide/sulfur), RESTYLANE® (hyaluronic acid), TRIAZ® (benzoyl peroxide), and VANOS (fluocinonide) Cream 0.1%. All of our core brands enjoy branded market leadership in the segments in which they compete. Because of the significance of these brands to our business, we concentrate our sales and marketing efforts in promoting them to physicians in our target markets. We also sell a number of other products that are considered less critical to our business.

OMNICEF® is a trademark of Fujisawa Pharmaceutical Co. Ltd. and is used under a license from Abbott Laboratories, Inc. (Abbott). On April 1, 2005, Fujisawa Pharmaceutical Co. Ltd. merged with Yamanouchi Pharmaceutical Co. Ltd., creating Astelles Pharma, Inc.

In March 2003, we expanded into the dermal aesthetic market through our acquisition of the exclusive United States and Canadian rights to market, distribute and commercialize the dermal restorative product lines known as RESTYLANE®, PERLANE and RESTYLANE FINE LINES from Q-Med AB, a Swedish biotechnology/medical device company and its affiliates, collectively Q-Med. RESTYLANE® has been approved by the Food and Drug Administration (the FDA) for use in the United States as a medical device for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. RESTYLANE®, PERLANE and RESTYLANE FINE LINES have been approved for use in Canada. Q-Med currently promotes these market-leading, patented non-animal stabilized hyaluronic acid brands in over 75 countries, where over 1.5 million procedures have been performed. RESTYLANE® is marketed and sold in over 75 countries outside the United States. Since 1996, dermatologists and plastic surgeons outside the U.S. have used it to contour and restore volume to skin and temporarily eliminate wrinkles and facial folds. Additionally, in certain countries other than the United States (such as Canada), RESTYLANE® also is approved to enhance the appearance and fullness of lips.

On March 20, 2005, we entered into an Agreement and Plan of Merger with Inamed Corporation (Inamed). Inamed is a global healthcare company with over 25 years of experience developing, manufacturing and marketing innovative, high-quality, science-based products. Current products include breast implants for aesthetic augmentation and for reconstructive surgery; a range of dermal products to treat facial wrinkles; and minimally invasive devices for obesity intervention, including the LAP-BAND® system for morbid obesity. Under the terms of the Agreement and Plan of Merger, Inamed will merge with us and each share of Inamed common stock will be converted into the right to receive 1.4205 shares of our common stock and $30.00 in cash. The completion of the

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transaction is subject to several customary conditions, including the receipt of applicable regulatory approvals, approvals from our stockholders and Inamed s stockholders, and the absence of any material adverse effect on either party s business. It is currently anticipated that the closing of the transaction would occur by the end of calendar 2005.

OUR PRODUCTS

We currently offer 15 branded products. Our sales and marketing efforts are currently focused on our core brands, which, during fiscal 2005, accounted for approximately 76% of our total net revenues. The following chart details certain important features of our core brands:

Brand	Treatment	U.S. Market Impact
DYNACIN®	Oral adjunctive treatment for moderate to severe acne	The number one branded minocycline product in the U.S., DYNACIN® tablets and capsules are available in a range of strengths for moderate to severe acne
LOPROX®	Topical treatment for certain fungal and yeast infections	A leading antifungal agent, including the number one branded shampoo for seborrheic dermatitis
OMNICEF®	A patented oral cephalosporin for skin and skin-structure infections	Superior kill rate compared to most frequently prescribed antibiotic for this indication
PLEXION®	Topical treatments for rosacea and acne-related conditions	Includes the leading branded prescription cleanser indicated for the treatment of rosacea, and the first prescription cleansing cloth for the treatment of acne and rosacea
RESTYLANE®	Injectable gel for treatment of fine lines and wrinkles, shaping facial contours and correcting deep facial folds	Launched on January 6, 2004, following approval by FDA on December 12, 2003
TRIAZ®	Topical patented gel and cleanser and patent-pending pad treatments for acne	The leading branded prescription benzoyl peroxide product
VANOS	Super-high potency topical corticosteroid for the treatment of plaque-type psoriasis in adult patients	Launched on April 19, 2005 following FDA approval on February 11, 2005

PRESCRIPTION PHARMACEUTICALS

Our principal branded pharmaceutical products are described below:

DYNACIN® is an oral antibiotic, available in 50-mg., 75-mg. and 100-mg. tablet and capsule dosage forms, and is prescribed as an adjunctive treatment for moderate to severe acne. The most commonly prescribed systemic acne treatments are tetracycline and its derivatives, minocycline and doxycycline. Minocycline, the active ingredient in DYNACIN®, is widely prescribed for the treatment of acne for several reasons. It has a more convenient dosing schedule, one or two doses per day, as compared to other forms of tetracycline, which can require up to four doses per day. Other forms of tetracycline, including doxycycline, require ingestion on an empty stomach and have been reported to often cause gastric irritation. Moreover, the other forms of tetracycline may increase patient sensitivity to sunlight, creating a greater risk of sunburn. In addition, resistance to several commonly used antibiotics, including erythromycin, clindamycin, doxycycline and tetracycline, by the primary bacterial organism responsible for acne has been documented. Studies suggest that bacterial resistance to erythromycin, doxycycline and tetracycline exceeds 50%, while the bacteria showed virtually no resistance to minocycline. DYNACIN® capsules were launched in fiscal 1993 with 50-mg. and 100-mg. dosage forms available. We launched DYNACIN® capsules in a 75-mg. dosage form in fiscal 1999. During fiscal 2003, we launched DYNACIN® in tablet form in 75-mg. and 100-mg. dosages, and we

launched the 50-mg. dosage in fiscal 2004.

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LOPROX® cream and topical suspension are both broad-spectrum prescription antifungal agents indicated for the topical treatment of tinea pedis, tinea corporis, tinea cruris, tinea versicolor and cutaneous candidiasis. LOPROX® works with a unique mode of action and has been shown to have fungistatic and fungicidal properties. The most frequently prescribed topical antifungal products in addition to LOPROX® include competitor products Spectazole®, Nizoral®, Oxistat® and Lotrisone® (steroid/antifungal combination). In addition to the cream and topical suspension formulations of LOPROX®, we market LOPROX® Gel for the treatment of seborrheic dermatitis and fungal infections. Currently, LOPROX® Gel is the only gel approved in the United States for seborrheic dermatitis. During fiscal 2003, we launched LOPROX® Shampoo, which is the first and only prescription antifungal shampoo approved in the United States for the treatment of seborrheic dermatitis of the scalp, a common fungal infection.

OMNICEF® is promoted to dermatologists and podiatrists pursuant to our exclusive co-promotion agreement with Abbott. OMNICEF® is indicated for the treatment of uncomplicated skin and skin-structure infections. Studies show that OMNICEF® has superior pathogen eradication rates versus Cephalexin, the most frequently prescribed antibiotic for uncomplicated skin and skin-structure infections. Since May 2001, we have promoted OMNICEF® capsules in the U.S. market to dermatologists and podiatrists. In return, we receive commission revenue from Abbott based on prescriptions generated in these categories. Our agreement with Abbott expires in 2013.

PLEXION® treats rosacea and acne-related conditions with internally developed cleanser and topical therapies. Rosacea is a chronic skin condition causing inflammation and redness of the face. The active ingredients in our PLEXION® products are sodium sulfacetamide and sulfur. PLEXION®, the leading branded prescription cleanser indicated for the treatment of rosacea, was launched in fiscal 2000. The topical acne rosacea market is comprised of products such as competitor products MetroGel®, MetroCream® and MetroLotion®. PLEXION TS®**,** a gentle topical suspension treatment for acne, was launched in fiscal 2001. In addition, during fiscal 2002 we launched PLEXION SCT®, a short contact therapy with a silica base that helps remove impurities from the skin pores. During fiscal 2005, we launched the first prescription cleansing cloth, PLEXION® Cleansing Cloths, for the treatment of acne and rosacea. Within its first three months on the market, PLEXION® Cleansing Cloths has become the leading branded sodium sulfacetamide and sulfur cleansing formulation in new prescriptions.

TRIAZ®, an internally developed topical therapy prescribed for the treatment of numerous forms and varying degrees of acne, is available as a patented gel or cleanser or in a patent-pending pad in three concentrations. TRIAZ® products are manufactured using the active ingredient benzoyl peroxide in a patented vehicle containing glycolic acid and zinc lactate. Studies conducted by third parties have shown that benzoyl peroxide is the most efficacious agent available for eradicating the bacteria that cause acne with no reported resistance. We introduced the TRIAZ® brand in fiscal 1996. In July 2003, we launched TRIAZ® Pads, the first and only benzoyl peroxide pad available in the U.S. indicated for the topical treatment of acne vulgaris.

VANOS™ cream, launched to dermatologists in April 2005 after approval by the FDA on February 11, 2005, is a super-high potency (Class I) topical corticosteroid indicated for the treatment of plaque-type psoriasis in adult patients. Plaque-type psoriasis is the most common form of psoriasis, a chronic, recurrent skin disorder affecting up to 2% of the United States population and characterized by scaling, often itching plaques in certain areas of the body that typically follow a course of exacerbation and remission. The active ingredient in VANOS™ is fluocinonide 0.1%, and is the only fluocinonide available in the Class I category of topical corticosteroids. Physicians may already be familiar with the fluocinonide 0.05%, the active ingredient in another of our products, the Class II corticosteroid LIDEX®. Two double blind clinical studies have demonstrated the efficacy, safety and tolerability of VANOS™. Its elegant base was formulated to have the cosmetic elegance of a cream, yet behave like an ointment on the skin. In addition, physicians have the flexibility of prescribing VANOS™ either once or twice daily. Considering that plaque-type psoriasis is recognized as a major challenge for physicians, and that VANOS™ is a new entry in its category, we believe VANOS™ will be an important treatment option for patients that suffer from plaque-type psoriasis.

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DERMAL RESTORATIVE PRODUCTS

Our principal branded dermal restorative products are described below:

RESTYLANE®, PERLANE™ and **RESTYLANE FINE LINES™** are injectable, transparent, Non-Animal-Stabilized-Hyaluronic Acid (NASHA™) gels, which require no patient sensitivity tests in advance of product administration. These tissue tailored, transparent, injectable products, which come in pre-packaged, glass syringes, have varying gel particle sizes which provide physicians with flexibility in treating fine lines and wrinkles and correcting deep facial folds. In the United States, the FDA regulates these products as medical devices. Medicis offers all three of these products in Canada, and began offering RESTYLANE® in the United States on January 6, 2004. PERLANE™ and RESTYLANE FINE LINES™ have not yet been approved by the FDA for use in the United States. We acquired the exclusive U.S. and Canadian rights to these dermal restorative products from Q-Med through a license agreement.

PRODUCTS IN DEVELOPMENT

We have developed and obtained rights to pharmaceutical agents in various stages of development. We have a variety of products under development, ranging from new products to existing product line extensions and reformulations of existing products. Our strategy involves the evaluation and formulation of new therapeutics by obtaining preclinical safety and efficacy data, when possible, followed by rapid safety and efficacy testing in humans. Over the next four years, our objective is to launch one new product annually through our research and development efforts. As a result of our increasing financial strength, we have begun adding long-term projects to our development pipeline and may add longer-term projects with inherently greater risk in the future. Historically, we have supplemented our research and development efforts by entering into research and development agreements with other pharmaceutical and biotechnology companies.

On July 15, 2004, we entered into an exclusive license agreement and other ancillary documents with Q-Med to market, distribute, sell and commercialize in the United States and Canada Q-Med s product currently known as SubQ™. Q-Med has the exclusive right to manufacture SubQ™ for Medicis. SubQ™ is currently not approved for use in the United States or Canada. Under the terms of the license agreement, Medicis Aesthetics Holdings Inc., a wholly owned subsidiary of Medicis, licenses SubQ™ for approximately $80.0 million, due as follows: approximately $30.0 million paid on July 15, 2004, which was recorded as research and development expense during the first quarter of fiscal 2005; approximately $10.0 million upon successful completion of certain clinical milestones; approximately $20.0 million upon the satisfaction of certain defined regulatory milestones; and approximately $20.0 million upon U.S. launch of SubQ™ . We also will make additional milestone payments to Q-Med upon the achievement of certain commercial milestones. SubQ™ is comprised of the same NASHA™ substance as RESTYLANE®, PERLANE™ and RESTYLANE FINE LINES™ with a larger gel particle size and has patent protection until at least 2015 in the United States.

On December 13, 2004, we entered into an exclusive development and license agreement and other ancillary agreements with Ansata Therapeutics, Inc. (Ansata). The development and license agreement grants us the exclusive, worldwide rights to Ansata s early stage, proprietary antimicrobial peptide technology. In accordance with the development and license agreement, we paid $5.0 million upon signing of the contract and will pay approximately $9.0 million upon the successful completion of certain developmental milestones. Should we continue with the development of this technology, we will incur additional milestone payments beyond the development and license agreement. The initial $5.0 million payment was recorded as a charge to research and development expense during the second quarter of fiscal 2005.

On January 28, 2005, we amended our strategic alliance with aaiPharma, Inc. (aaiPharma) previously initiated in June 2002 for the development, commercialization and license of a dermatologic product. The consummation of the amendment has not affected the timing of the development project. The amendment allowed for the immediate transfer of the work product as defined under the agreement, as well as the product s management and development, to us, and provides that aaiPharma will continue to assist us with the development of the product on a fee for services basis. We will have no future financial obligations to pay aaiPharma on the attainment of

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clinical milestones, but incurred approximately $8.3 million as a charge to research and development expense during the third quarter of fiscal 2005, as part of the amendment and the assumption of all liabilities associated with the project.

We incurred total research and development costs for all of our sponsored and unreimbursed co-sponsored pharmaceutical projects for fiscal 2005, 2004 and 2003 of $65.7 million, $16.5 million and $29.6 million, respectively. Research and development costs for fiscal 2005 include $30.0 million related to the license agreement with Q-Med related to the SubQ™ product, $5.0 million related to the Ansata development and license agreement and $8.3 million related to the aaiPharma research and development collaboration. Research and development costs for fiscal 2004 include $2.4 million paid to Dow Pharmaceutical Services, Inc. (Dow) for the development and commercialization of a patented dermatologic product, under an agreement that we entered into in September 2002. Research and development costs for fiscal 2003 include $14.2 million paid to Dow under this agreement and $6.0 million related to the aaiPharma research and development collaboration. In addition to the payments made during fiscal 2004 and 2003, the Dow agreement includes potential future payments due to Dow upon the successful completion of various development milestones.

SALES AND MARKETING

Our combined dedicated sales force, consisting of 162 employees as of June 30, 2005, focuses on high prescribing dermatologists, plastic surgeons and podiatrists. Since a relatively small number of physicians are responsible for writing a majority of prescriptions and performing dermal aesthetic procedures, we believe that the size of our sales force is appropriate to reach our target physicians. Our dermatology and podiatric sales force consists of 110 employees who regularly call on approximately 8,800 dermatologists and 3,200 podiatrists. Our dermal aesthetic sales force consists of 52 employees who regularly call on leading plastic surgeons, facial plastic surgeons, dermatologists and dermatologic surgeons. We also have seven national account managers who regularly call on managed care organizations, large retail chains, formularies and related organizations.

We cultivate relationships of trust and confidence with the high prescribing dermatologists and podiatrists and the leading plastic surgeons in the United States. We use a variety of marketing techniques to promote our products including sampling, journal advertising, promotional materials, specialty publications, coupons, money-back or product replacement guarantees, educational conferences and informational websites.

We believe we have created an attractive incentive program for our sales force that is based upon goals in prescription growth and market share achievement.

WAREHOUSING AND DISTRIBUTION

We utilize an independent national warehousing corporation to store and distribute our products from primarily two regional warehouses in Nevada and Georgia, as well as additional warehouses in Maryland and North Carolina. Upon the receipt of a purchase order through electronic data input (EDI), phone, mail or facsimile, the order is processed into our inventory systems. The order is transmitted electronically to the appropriate warehouse for picking and packing. Upon shipment, the warehouse sends back to us via EDI the necessary information to automatically process the invoice in a timely manner.

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CUSTOMERS

Our customers include certain of the nation s leading wholesale pharmaceutical distributors, such as AmerisourceBergen Corporation (AmerisourceBergen), Cardinal Health, Inc. (Cardinal), McKesson Corporation (McKesson) and other major drug chains. During the last three fiscal years, these customers accounted for the following portions of our net revenues:

	Fiscal 2005	Fiscal 2004	Fiscal 2003
McKesson	51.2%	36.9%	20.2%
Cardinal	21.8%	23.8%	25.4%
Quality King	*	*	17.0%
AmerisourceBergen	*	*	15.5%

* less than 10%

McKesson is our sole distributor of our RESTYLANE® product, which was launched in January 2004.

MANUFACTURING

We currently outsource all of our manufacturing needs, and we are required by the FDA to contract only with manufacturers who comply with current Good Manufacturing Practices (cGMP) regulations and other applicable laws and regulations. Typically our manufacturing contracts are short-term. We review our manufacturing arrangements on a regular basis and assess the viability of alternative manufacturers if our current manufacturers are unable to fulfill our needs.

Patheon, Inc. (Patheon) manufactures the capsule form of our DYNACIN® branded products under a supply agreement that automatically renews on an annual basis, unless terminated by either party. Par Pharmaceutical, Inc. (Par) manufactures the tablet form of our DYNACIN® branded products in accordance with a supply agreement that expires in June 2012.

Our PLEXION® and TRIAZ® branded products are manufactured by Contract Pharmaceuticals Limited pursuant to a manufacturing agreement that automatically renews on an annual basis, unless terminated by either party.

Our LOPROX® gel branded products are manufactured by Aventis S.A. (Aventis) in accordance with a supply agreement that renews automatically on an annual basis, unless terminated by either party. Our LOPROX® TS and LOPROX® shampoo branded products are manufactured by Patheon under a supply agreement that automatically renews on an annual basis, unless terminated by either party. Our LOPROX® cream branded product is manufactured by both Aventis and Patheon.

Our OMNICEF® branded product, which we promote through a license agreement with Abbott, is manufactured, warehoused and distributed by Abbott. The license agreement expires in 2013.

Our RESTYLANE® branded product is manufactured by Q-Med pursuant to a long-term supply agreement that expires no earlier than 2013.

Our VANOS™ branded product is manufactured by Patheon under a supply agreement that automatically renews on an annual basis, unless terminated by either party.

LICENSE AND ROYALTY AGREEMENTS

Pursuant to license agreements with third parties, we have acquired rights to manufacture, use or market certain of our existing products, as well as many of our development products and technologies. Such agreements

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typically contain provisions requiring us to use our best efforts or otherwise exercise diligence in pursuing market development for such products in order to maintain the rights granted under the agreements and may be canceled upon our failure to perform our payment or other obligations. In addition, we have licensed certain rights to manufacture, use and sell certain of our technologies outside the United States and Canada to various licensees.

TRADEMARKS, PATENTS, AND PROPRIETARY RIGHTS

We believe that trademark protection is an important part of establishing product and brand recognition. We own a number of registered trademarks and trademark applications and have acquired the rights to several trademarks by license. U.S. federal registrations for trademarks remain in force for 10 years and may be renewed every 10 years after issuance, provided the mark is still being used in commerce.

We have obtained and licensed a number of patents covering key aspects of certain of our products, including a U.S. patent expiring in October 2015 covering various formulations of TRIAZ®, a U.S. patent expiring in 2015 covering RESTYLANE®, a U.S. patent expiring in 2020 covering PLEXION® cleanser formulation, a U.S. patent expiring in 2020 covering PLEXION® topical suspension and SCT formulations and a U.S. patent expiring in December 2021 covering VANOS®. We have patent applications pending relating to our PLEXION® cleansing cloths formulation and our LOPROX® gel and shampoo formulations. We are also pursuing several other U.S. and foreign patent applications.

We rely and expect to continue to rely upon unpatented proprietary know-how and technological innovation in the development and manufacture of many of our principal products. Our policy is to require all our employees, consultants and advisors to enter into confidentiality agreements with us.

COMPETITION

The pharmaceutical and dermal aesthetics industries are characterized by intense competition, rapid product development and technological change. Competition is intense among manufacturers of prescription pharmaceuticals and dermal injection products, such as for our core brands.

Many of our competitors are large, well-established pharmaceutical, chemical, cosmetic or health care companies with considerably greater financial, marketing, sales and technical resources than those available to us. Additionally, many of our present and potential competitors have research and development capabilities that may allow them to develop new or improved products that may compete with our product lines. Our products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions addressed by our products, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our competitors. Each of our products competes for a share of the existing market with numerous products that have become standard treatments recommended or prescribed by dermatologists and podiatrists and administered by plastic surgeons and aesthetic dermatologists.

Several of our core prescription brands compete or may compete in the near future with generic (non-branded) pharmaceuticals, which claim to offer equivalent therapeutic benefits at a lower cost. In some cases, insurers and other third-party payors seek to encourage the use of generic products, making branded products less attractive, from a cost perspective, to buyers. On July 18, 2004, Glades Pharmaceuticals, LLC (Glades), a wholly owned subsidiary of Stiefel Laboratories, Inc., announced the launch of myrac™ (minocycline hydrochloride tablets, USP), as a branded pharmaceutical product. Myrac™ tablets is a prescription product that competes directly with our DYNACIN® tablet products. During the third quarter of our fiscal 2005, myrac™ began being marketed as a generic product. On August 6, 2004, the FDA approved an Abbreviated New Drug Application (ANDA) submitted by Altana, Inc. (Altana) for its ciclopirox topical suspension, a generic version of our LOPROX® TS product. On December 29, 2004, the FDA approved an ANDA submitted by Altana for its ciclopirox cream, a generic version of our LOPROX® Cream product. On August 10, 2005, the FDA approved an ANDA submitted by Taro Pharmaceuticals U.S.A. Inc. (Taro) for its ciclopirox topical suspension, a generic version of our LOPROX® topical suspension.

There are several dermal filler products under development and/or in the FDA pipeline for approval which claim to offer equivalent or greater facial aesthetic benefits to RESTYLANE® and, if approved, the companies producing such products could charge less to doctors for their products.

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GOVERNMENT REGULATION

The manufacture and sale of biological products, drugs and medical devices are subject to regulation principally by the FDA, but also by other federal agencies and state and local authorities in the United States, and by comparable agencies in certain foreign countries. The Federal Trade Commission (FTC), the FDA and state and local authorities regulate the advertising of over-the-counter drugs and cosmetics. The Federal Food, Drugs and Cosmetics Act and the regulations promulgated thereunder, and other federal and state statutes and regulations, govern, among other things, the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, sale, distribution, advertising and promotion of our products.

Our RESTYLANE® dermal filler product is a medical device intended for human use and is subject to regulation by the FDA in the United States. Unless an exemption applies, each medical device we market in the U.S. must have a Premarket Approval Application (PMA) in accordance with the Federal Food, Drug, and Cosmetic Act, as amended, or a 510(k) clearance (a demonstration that the new device is substantially equivalent to a device already on the market). FDA device regulations generally require reasonable assurance of safety and effectiveness prior to marketing, including safety data obtained under approved clinical protocols and require compliance with current good manufacturing practices (cGMPs), as verified by detailed FDA investigations of manufacturing facilities. These regulations also require post-approval reporting of alleged product defects and certain adverse experiences to the FDA. FDA regulations divide medical devices into three classes. Class I devices are subject to general controls that require compliance with device establishment registration, product listing, labeling, cGMPs and other general requirements that are also applicable to all classes of medical devices. Class II devices are subject to special controls in addition to general controls and generally require the submission of a premarket notification before marketing is permitted. Class III devices are subject to the most extensive regulation and in most cases require submission to the FDA of a PMA application that includes clinical data supporting the safety and effectiveness of the device as well as compliance with the same provisions applicable to all medical devices, such as cGMPs. Periodic reports must be submitted to the FDA, including descriptions of certain adverse events that are reported to the sponsor. RESTYLANE® is regulated as a Class III medical device. RESTYLANE® has been approved by the FDA under a PMA.

In general, products falling within the FDA s definition of new drugs require premarketing approval by the FDA. Products falling within the FDA s definition of cosmetics or of drugs (if they are not also new drugs,) and that are generally recognized as safe and effective do not require premarketing clearance although all drugs must comply with a host of post-market regulations, including manufacture under cGMP. The steps required before a new drug may be marketed in the United States include (i) preclinical laboratory and animal testing; (ii) manufacture under cGMP; (iii) submission to the FDA of an Investigational New Drug (or IND) application, which must become effective before clinical trials may commence; (iv) at least two adequate and well-controlled clinical trials to establish the safety and efficacy of the drug; (v) submission to the FDA of a New Drug Application (or NDA); and (vi) FDA approval of the NDA prior to any commercial sale or shipment of the drug. In addition to obtaining FDA approval for each product, each domestic drug-manufacturing establishment must be registered with, and approved by, the FDA.

New drugs may also be approved by the agency pursuant to an ANDA for generic drugs if the same active ingredient has previously been approved by the agency and the original sponsor of the NDA no longer has patent protection or statutory marketing exclusivity. Approval of an ANDA does not require the submission of clinical data on the safety and effectiveness of the drug product. However, the applicant must provide dissolution and/or metabolic studies to show that the active ingredient in the generic drug sponsor s application is comparably available to the patient as the original product in the NDA upon which the ANDA is based.

Preclinical testing is generally conducted on laboratory animals to evaluate the potential safety and toxicity of a drug. The results of these studies are submitted to the FDA as a part of an IND application, which must be approved before clinical trials in humans can begin. Typically, clinical evaluation of new drugs involves a time consuming and costly three-phase process. In Phase I, clinical trials are conducted with a small number of subjects to determine the early safety profile, the relationship of safety to dose, and the pattern of drug distribution and metabolism. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease to determine preliminary efficacy and expanded evidence of safety. In Phase III, large-scale, multi-center, comparative trials are conducted with patients

afflicted with a target disease to provide sufficient confirmatory data to support the efficacy and safety required by the FDA. The FDA closely monitors the progress of each of the three phases of clinical trials and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based upon the data that have been accumulated to that point and its assessment of the risk/benefit ratio to the patient.

FDA approval is required before a new drug product may be marketed in the United States. However, many historically over-the-counter drugs are exempt from the FDA s premarketing approval requirements. In 1972, the FDA instituted the ongoing over-the-counter Drug Review to evaluate the safety and effectiveness of over-the-counter drugs in the market before enactment of the Drug Amendments of 1962. Through this process, the FDA issues monographs that set forth the specific active ingredients, dosages, indications and labeling statements for over-the-counter drugs that the FDA will consider generally recognized as safe and effective and therefore not subject to premarket approval. Before issuance of a final over-the-counter drug monograph as a federal regulation, over-the-counter drugs are classified by the FDA in one of three categories: Category I ingredients which are

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deemed safe and effective for over-the-counter use; Category II ingredients which are deemed not generally recognized as safe and effective for over-the-counter use; and Category III ingredients which are deemed possibly safe and effective with studies ongoing. Based upon the results of these ongoing studies, the FDA must reclassify all Category III ingredients as either Category I or Category II before issuance of a final monograph. For certain categories of over-the-counter drugs not yet subject to a final monograph, the FDA usually permits such drugs to continue to be marketed until a final monograph becomes effective, unless the drug will pose a potential health hazard to consumers. Stated differently, the FDA generally permits continued marketing only of Category I and III products during the pendency of a final monograph. Drugs subject to final monographs, as well as drugs that are subject only to proposed monographs, are subject to various FDA regulations concerning, for example, cGMP, general and specific over-the-counter labeling requirements and prohibitions against promotion for conditions other than those stated in the labeling. Over-the-counter drug manufacturing facilities are subject to FDA inspection, and failure to comply with applicable regulatory requirements may lead to administrative or judicially imposed penalties.

Each of the active ingredients in LOPROX® products and OMNICEF® products have been approved by the FDA under an NDA. The active ingredient in DYNACIN® branded products has been approved by the FDA under an ANDA. The active ingredient in the TRIAZ® products has been classified as a Category III ingredient under a tentative final FDA monograph for over-the-counter use in treatment of labeled conditions. The FDA has requested, and a task force of the Non-Prescription Drug Manufacturers Association (or NDMA), a trade association of over-the-counter drug manufacturers, has undertaken further studies to confirm that benzoyl peroxide, an active ingredient in the TRIAZ® products, is not a tumor promoter when tested in conjunction with UV light exposure. The TRIAZ® products, which we sell on a prescription basis, have the same ingredients at the same dosage levels as the over-the-counter products. When the FDA issues the final monograph, we may be required by the FDA to sell TRIAZ® products as an over-the-counter drug or cease its distribution unless we file an NDA covering such product. There can be no assurance as to the results of these studies or any FDA action to reclassify benzoyl peroxide. In addition, there can be no assurance that adverse test results would not result in withdrawal of TRIAZ® products from marketing. An adverse decision by the FDA with respect to the safety of benzoyl peroxide could result in the assertion of product liability claims against us and could have a material adverse effect on our business, financial condition and results of operations.

Our TRIAZ® branded products must meet the composition and labeling requirements established by the FDA for products containing their respective basic ingredients. We believe that compliance with those established standards avoids the requirement for premarketing clearance of these products. There can be no assurance that the FDA will not take a contrary position. Our PLEXION® branded products, which contain the active ingredients sodium sulfacetamide and sulfur, are marketed under the FDA compliance policy entitled Marketed New Drugs without Approved NDAs or ANDAs.

We believe that certain of our products, as they are promoted and intended by us for use, are exempt from being considered new drugs based upon the introduction date of their active ingredients and therefore do not require premarketing clearance. There can be no assurance that the FDA will not take a contrary position. If the FDA were to do so, we may be required to seek FDA approval for these products, market these products as over-the-counter products or withdraw such products from the market. We believe that these products are compliant with applicable regulations governing product safety, use of ingredients, labeling, promotion and manufacturing methods.

We also will be subject to foreign regulatory authorities governing clinical trials and pharmaceutical sales for products we seek to market outside the United States. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing the product in those countries. The approval process varies from country to country, the approval process time required may be longer or shorter than that required for FDA approval, and any foreign regulatory agency may refuse to approve any product we submit for review.

EMPLOYEES

At June 30, 2005, we had 359 full-time employees. No employees are subject to a collective bargaining agreement. We believe our relationship with our employees is good.

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AVAILABLE INFORMATION

We make available free of charge on or through our Internet website, www.medicis.com, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, if any, filed or furnished pursuant to Section 13(a) of 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after they are electronically filed with, or furnished to, the Securities and Exchange Commission. We also make available free of charge on or through our website our Business Code of Conduct and Ethics, Corporate Governance Guidelines, Nominating and Corporate Governance Committee Charter, Compensation Committee Charter and Audit Committee Charter. The information contained on our website is not intended to be incorporated into this annual report on Form 10-K.

RISK FACTORS THAT MAY AFFECT FUTURE RESULTS

Our discussion and analysis in this report, in other reports that we file with the Securities and Exchange Commission, in our press releases and in public statements of our officers and corporate spokespersons contain forward-looking statements. Forward-looking statements give our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current events. They use words such as anticipate, estimate, expect, intend, will , plan, believe and other words of similar meaning i with discussion of future operating or financial performance. These include statements relating to future actions, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, expenses, the outcome of contingencies such as legal proceedings and financial results.

Forward-looking statements may turn out to be wrong. They can be affected by inaccurate assumptions or by known or unknown risks and uncertainties. Many factors mentioned in this report for example, governmental regulation and competition in our industry will be important in determining future results. No forward-looking statement can be guaranteed, and actual results may vary materially from those anticipated in any forward-looking statement.

Medicis undertakes no obligation to update any forward-looking statement. We provide the following discussion of risks and uncertainties relevant to our business. These are factors that we think could cause our actual results to differ materially from expected and historical results. Our business, financial condition or results of operations could also be adversely affected by other factors besides those listed here. However, these are the risks our management currently believes are material.

RISKS RELATED TO OUR BUSINESS

We Derive A Majority Of Our Sales From Our Core Products, And Any Factor Adversely Affecting Sales Of These Products Would Harm Our Business, Financial Condition And Results Of Operations

We believe that the prescription volume of our core prescription products and sales of our dermal aesthetic product, RESTYLANE®, which we began selling in the United States on January 6, 2004, will continue to constitute a significant portion of our sales for the foreseeable future. Accordingly, any factor adversely affecting our sales related to these products, individually or collectively, could harm our business, financial condition and results of operations. Many of our core prescription products, including DYNACIN® and LOPROX®, are subject to generic competition or may be in the near future. On July 18, 2004, Glades announced the launch of myrac™ (minocycline hydrochloride tablets, USP), as a branded pharmaceutical product. Myrac™ tablets is a prescription product that competes directly with our DYNACIN® tablet products. During the third quarter of our fiscal 2005, myrac™ began being marketed as a generic product. On August 6, 2004, the FDA approved an ANDA submitted by Altana for its ciclopirox topical suspension, a generic version of our LOPROX® TS product. On December 29, 2004, the FDA approved an ANDA submitted by Altana for its ciclopirox cream, a generic version of our LOPROX® cream product. On August 10, 2005, the FDA approved an ANDA submitted by Taro Pharmaceuticals U.S.A. Inc. (Taro) for its ciclopirox topical suspension, a generic version of our LOPROX® topical suspension. Each of our core products could be rendered obsolete or uneconomical by competitive changes, including generic competition.

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Sales related to our core prescription products and RESTYLANE® could also be adversely affected by other factors, including:

- manufacturing or supply interruptions;
- the development of new competitive pharmaceuticals and technological advances to treat the conditions addressed by our core products, including the introduction of new products into the marketplace;
- marketing or pricing actions by one or more of our competitors;
- regulatory action by the FDA and other government regulatory agencies;
- changes in the prescribing or procedural practices of dermatologists, plastic surgeons and/or podiatrists;
- changes in the reimbursement or substitution policies of third-party payors or retail pharmacies;
- product liability claims;
- the outcome of disputes relating to trademarks, patents, license agreements and other rights;
- changes in state and federal law that adversely affect our ability to market our products to dermatologists, plastic surgeons and/or podiatrists; and
- restrictions on travel affecting the ability of our sales force to market to prescribing physicians and plastic surgeons in person.

Our Operating Results And Financial Condition May Fluctuate

Our operating results and financial condition may fluctuate from quarter to quarter and year to year for a number of reasons. The following events or occurrences, among others, could cause fluctuations in our financial performance from period to period:

- changes in the amount we spend to develop, acquire or license new products, technologies or businesses;
- untimely contingent research and development payments under our third-party product development agreements;
- changes in the amount we spend to promote our products;
- delays between our expenditures to acquire new products, technologies or businesses and the generation of revenues from those acquired products, technologies or businesses;
- changes in treatment practices of physicians that currently prescribe our products;
- changes in reimbursement policies of health plans and other similar health insurers, including changes that affect newly developed or newly acquired products;
- increases in the cost of raw materials used to manufacture our products;
- manufacturing and supply interruptions, including failure to comply with manufacturing specifications;
- development of new competitive products by others;

the mix of products that we sell during any time period;

lower than expected demand for our products;

our responses to price competition;

expenditures as a result of legal actions;

market acceptance of our products;

the timing and receipt of FDA approvals;

the impairment and write-down of goodwill or other intangible assets;

implementation of new or revised accounting or tax rules or policies;

disposition of core products, technologies and other rights;

termination or expiration of, or the outcome of disputes relating to, trademarks, patents, license agreements and other rights;

increases in insurance rates for existing products and the cost of insurance for new products;

general economic and industry conditions, including changes in interest rates affecting returns on cash balances and investments that affect customer demand;

seasonality of demand for our products;

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our level of research and development activities;

new accounting standards and/or changes to existing accounting standards that would have a material effect on our consolidated financial position, results of operations or cash flows;

costs and outcomes of any tax audits or any litigation involving intellectual property, customers or other issues; and

timing of revenue recognition related to licensing agreements and/or strategic collaborations.

As a result, we believe that period-to-period comparisons of our results of operations are not necessarily meaningful and these comparisons should not be relied upon as an indication of future performance. The above factors may cause our operating results to fluctuate and adversely affect our financial condition and results of operations.

We Will Be Unable To Meet Our Anticipated Development And Commercialization Timelines If Clinical Trials For Our Products Are Unsuccessful Or Delayed

Before obtaining regulatory approvals for the commercial sale of any products, we and/or our partners must demonstrate through pre-clinical testing and clinical trials that our products are safe and effective for use in humans. Conducting clinical trials is a lengthy, time-consuming and expensive process.

Completion of clinical trials may take several years or more. Our commencement and rate of completion of clinical trials may be delayed by many factors, including:

lack of efficacy during the clinical trials;

unforeseen safety issues;

slower than expected patient recruitment; and

government or regulatory delays.

The results from pre-clinical testing and early clinical trials are often not predictive of results obtained in later clinical trials. A number of new products have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including perceived defects in the design of the clinical trials and changes in regulatory policy during the period of product development. Any delays in, or termination of, our clinical trials could materially and adversely affect our development and commercialization timelines, which could adversely affect our financial condition, results of operations and cash flows.

If The Proposed Merger With Inamed Is Not Completed, We Will Have Incurred Substantial Costs That May Adversely Affect Our Financial Results And Operations And The Market Price Of Our Common Stock

We have incurred and will continue to incur substantial costs in connection with the proposed merger with Inamed. These costs are primarily associated with the fees of financial advisors, attorneys, accountants and consultants. In addition, we have diverted significant management resources in an effort to complete the merger and are subject to restrictions contained in the merger agreement on the conduct of our business. If the merger is not completed, we will receive little or no benefit for these costs. If the merger agreement is terminated, we, in certain specified circumstances, may be required to pay a termination fee of up to $70.0 million to Inamed. In addition, under certain circumstances, we may be required to pay Inamed an expense fee of $10.0 million. As consideration for Inamed s dismissal of pending litigation against Medicis, we agreed to pay Inamed $16.5 million if either the $70.0 million termination fee or the $10.0 million expense fee becomes payable by us or if the merger agreement is terminated because our stockholder approval is not obtained at the stockholders meeting relating to the merger.

In addition, if the merger is not consummated, we may experience negative reactions from the financial markets and our collaborative partners, customers and employees. Each of these factors may adversely affect the trading price

of our common stock and our financial results and operations.

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We Will Have More Indebtedness After The Completion Of The Proposed Merger With Inamed, Which Could Adversely Affect Our Cash Flows and Business

In order to complete the proposed merger with Inamed, we anticipate arranging for and funding approximately $650 million of new financing. Our debt outstanding as of June 30, 2005 was approximately $453 million. As a result of this increase in debt, demands on our cash resources will increase after the completion of the proposed merger. The increased levels of debt could, among other things:

- require us to dedicate a substantial portion of our cash flow from operations to payments on our debt, thereby reducing funds available for working capital, capital expenditures, dividends, acquisitions and other purposes;
- increase our vulnerability to, and limit flexibility in planning for, adverse economic and industry conditions;
- adversely affect our credit rating;
- limit our ability to obtain additional financing to fund future working capital, capital expenditures, additional acquisitions and other general corporate requirements;
- create competitive disadvantages compared to other companies with less indebtedness; and
- limit our ability to apply proceeds from an offering or asset sales to purposes other than the repayment of debt.

If We Are Unable To Finance The Proposed Merger With Inamed Through Existing Cash Balances and Financings, The Completion Of The Proposed Merger Will Be Jeopardized

We intend to finance the proposed merger with Inamed with existing cash balances, cash flow from operations and equity or debt financings. In the event that we are unable to finance the merger, but are still obligated to complete the merger, we will have to adopt one or more alternatives, such as selling assets or restructuring debt, which may adversely affect our business, financial condition and results of operations. Additionally, these sources of funds may not be sufficient to finance the proposed merger, and other financing may not be available on acceptable terms, in a timely manner or at all. If we are unable to secure such additional financing, the completion of the proposed merger will be jeopardized and we could be in breach of the merger agreement.

We May Not Realize All Of The Anticipated Benefits Of The Proposed Merger With Inamed

Our ability to realize the anticipated benefits of the merger will depend, in part, on our ability to integrate the businesses of Inamed with our company. The combined company will be required to devote significant management attention and resources to integrating the diverse business practices and operations of our company and Inamed. Neither company has previously completed a merger or acquisition comparable in size or scope to the merger. The combination of two independent companies is a complex, costly and time-consuming process. This process may disrupt the business of either or both of the companies, and may not result in the full benefits expected by our company and Inamed. The failure of the combined company to meet the challenges involved in integrating successfully the operations of our company and Inamed or otherwise to realize any of the anticipated benefits of the merger could cause an interruption of, or a loss of momentum in, the activities of the combined company and could seriously harm its results of operations. In addition, the overall integration of the two companies may result in unanticipated problems, expenses, liabilities and diversion of management s attention, and may cause the combined company s stock price to decline. The difficulties of combining the operations of the companies include, among others:

- coordinating sales and marketing, research and development and manufacturing functions;
- unanticipated issues in integrating information, communications and other systems;
- unanticipated incompatibility of purchasing, logistics, marketing and administration methods;
- maintaining employee morale and retaining key employees;

integrating the business cultures of both companies;

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preserving important strategic and customer relationships;

consolidating corporate and administrative infrastructures and eliminating duplicative operations;

the diversion of management s attention from ongoing business concerns; and

coordinating geographically separate organizations.

In addition, even if the operations of our company and Inamed are integrated successfully, the combined company may not realize the full benefits of the merger, including the synergies, cost savings, or sales or growth opportunities that we expect. These benefits may not be achieved within the anticipated time frame, or at all. Further, because the businesses of our company and Inamed differ, the results of operations of the combined company, and the market price of our company common stock, may be affected after the merger by factors different from those affecting the shares of our company and Inamed currently, and may suffer as a result of the merger. As a result, we cannot assure you that the combination of Inamed with our company will result in the realization of the full benefits anticipated from the merger.

Provisions Of The Merger Agreement May Deter Alternative Business Combinations And Could Negatively Impact The Stock Prices Of Medicis If The Merger Agreement Is Terminated In Certain Circumstances

Restrictions in the merger agreement on solicitation generally prohibit us from soliciting any acquisition proposal or offer for a merger or business combination with any other party, including a proposal that might be advantageous to our stockholders when compared to the terms and conditions of the merger with Inamed. If the merger is not completed, we may not be able to conclude another merger, sale or combination on as favorable terms, in a timely manner, or at all. If the merger agreement is terminated, we, in certain specified circumstances, may be required to pay a termination fee of up to $70.0 million to Inamed. In addition, under certain circumstances, we may be required to pay Inamed an expense fee of $10.0 million. As consideration for Inamed s dismissal of pending litigation against our company, we agreed to pay Inamed $16.5 million if either the $70.0 million termination fee or the $10.0 million expense fee becomes payable by us or if the merger agreement is terminated because our stockholders do not approve the issuance of shares pursuant to the merger agreement at the stockholders meeting relating to the merger. These provisions may deter third parties from proposing or pursuing alternative business combinations that might result in greater value to our stockholders than the merger with Inamed. In the event the merger is terminated by us or Inamed in circumstances that obligate us to pay the expenses or termination fee to Inamed, including where Inamed terminates the merger agreement because our board of directors withdraws its support of the merger, our stock price may decline.

If We Are Unable To Secure And Protect Our Intellectual Property And Proprietary Rights, Or If Our Intellectual Property Rights Are Found To Infringe Upon The Intellectual Property Rights Of Other Parties, Our Business Could Suffer

Our success depends in part on our ability to obtain patents or rights to patents, protect trade secrets, operate without infringing upon the proprietary rights of others, and prevent others from infringing on our patents, trademarks, service marks and other intellectual property rights.

We believe that the protection of our trademarks and service marks is an important factor in product recognition and in our ability to maintain or increase market share. If we do not adequately protect our rights in our various trademarks and service marks from infringement, their value to us could be lost or diminished. If the marks we use are found to infringe upon the trademark or service mark of another company, we could be forced to stop using those marks and, as a result, we could lose the value of those marks and could be liable for damages caused by an infringement.

The patents and patent applications in which we have an interest may be challenged as to their validity or enforceability. Challenges may result in potentially significant harm to our business. The cost of responding to these challenges and the inherent costs to defend the validity of our patents, including the prosecution of infringements and the related litigation, could be substantial. Such litigation also could require a substantial commitment of our management s time.

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We are pursuing several United States patent applications, although we cannot be sure that any of these patents will ever be issued. We also have acquired rights under certain patents and patent applications in connection with our licenses to distribute products and by assignment of rights to patents and patent applications from certain of our consultants and officers. These patents and patent applications may be subject to claims of rights by third parties. If there are conflicting claims to the same patent or patent application, we may not prevail and, even if we do have some rights in a patent or patent application, those rights may not be sufficient for the marketing and distribution of products covered by the patent or patent application.

The ownership of a patent or an interest in a patent does not always provide significant protection. Others may independently develop similar technologies or design around the patented aspects of our technology. We only conduct patent searches to determine whether our products infringe upon any existing patents when we think such searches are appropriate. As a result, the products and technologies we currently market, and those we may market in the future, may infringe on patents and other rights owned by others. If we are unsuccessful in any challenge to the marketing and sale of our products or technologies, we may be required to license the disputed rights, if the holder of those rights is willing, or to cease marketing the challenged products, or to modify our products to avoid infringing upon those rights. A claim or finding of infringement regarding one of our products could harm our business, financial condition and results of operations. The costs of responding to infringement claims could be substantial and could require a substantial commitment of our management s time. The expiration of patents may expose our products to additional competition.

We also rely upon trade secrets, unpatented proprietary know-how and continuing technological innovation in developing and manufacturing many of our core products. It is our policy to require all of our employees, consultants and advisors to enter into confidentiality agreements prohibiting them from taking or disclosing our proprietary information and technology. Nevertheless, these agreements may not provide meaningful protection for our trade secrets and proprietary know-how if they are used or disclosed. Despite all of the precautions we may take, people who are not parties to confidentiality agreements may obtain access to our trade secrets or know-how. In addition, others may independently develop similar or equivalent trade secrets or know-how.

If Q-Med Is Unable To Protect Its Intellectual Property And Proprietary Rights With Respect To Our Dermal Aesthetic Enhancement Products, Our Business Could Suffer

RESTYLANE®, PERLANE™ and RESTYLANE FINE LINES™ currently have patent protection in the United States until 2015, and the exclusivity period of the license granted to us by Q-Med ends on the last to occur of the last patent covering the products expiring and the licensed know-how becoming publicly known. If the validity or enforceability of these patents is successfully challenged, the cost to us could be significant and our business may be harmed. For example, if any such challenges are successful, Q-Med may be unable to supply products to us. We may be unable to market, distribute and commercialize the products or it may no longer be profitable for us to do so.

We May Not Be Able To Collect All Scheduled License Payments From BioMarin

As part of our asset purchase agreement, license agreement and securities purchase agreement with BioMarin Pharmaceutical Inc. (BioMarin) discussed in Note 7 to our consolidated financial statements, BioMarin will make license payments to us of $2.1 million per quarter for four quarters beginning in July 2005; $1.75 million per quarter for the subsequent eight quarters beginning in July 2006; and $1.5 million per quarter for the subsequent four quarters beginning in July 2008. While we did receive all scheduled quarterly license payments during the fiscal year ending June 30, 2005, we cannot give any assurances as to BioMarin s continuing ability to make payments to us. Currently, our revenue recognition of these payments is on a cash basis.

We Depend Upon Our Key Personnel And Our Ability To Attract, Train, And Retain Employees

Our success depends significantly on the continued individual and collective contributions of our senior management team. We have not entered into employment agreements with any of our key managers, with the exception of our Chairman and Chief Executive Officer. The loss of the services of any member of our senior

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management or the inability to hire and retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results. In addition, our future success depends on our ability to hire, train and retain skilled employees. Competition for these employees is intense.

Our Continued Growth Depends Upon Our Ability To Develop New Products