UNITED THERAPEUTICS CORP
Form 424B3
March 01, 2005

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Registration No. 333-122703

PROSPECTUS

5,000,000 Shares of Common Stock
(par value, $.01 per share)

We may offer to sell, from time to time, up to 5,000,000 shares of our common stock. The common stock will be offered at prices and on terms to be set forth in an accompanying prospectus supplement.

This prospectus provides you with a general description of the securities that may be offered. Each time securities are sold, we will provide one or more supplements to this prospectus that contain more specific information about the offering and the terms of the securities being offered. The supplements may also add, update or change information contained in this prospectus. This prospectus may not be used to offer or sell securities without a prospectus supplement describing the method and terms of the offering.

You should carefully read this prospectus and the prospectus supplements to this prospectus before you invest in our common stock. **You should carefully consider information under the headings *Cautionary Statement Regarding Forward-Looking Statements* and *Risk Factors* before you make an investment in our common stock.**

Our common stock is traded on the Nasdaq National Market under the symbol UTHR . On February 22, 2005 the closing price of our common stock as reported on the Nasdaq National Market was $43.13 per share.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is February 28, 2005.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, which we will refer to herein as the Commission, using a shelf registration process. Under this shelf registration process, we may, over time, offer and sell up to 5,000,000 shares of our common stock in one or more offerings. This prospectus provides you with a general description of our common stock. Each time we offer common stock, we will provide one or more prospectus supplements that will contain specific information about the terms of that offering. A prospectus supplement may also add, update or change information contained in this prospectus. Any statement that we make in this prospectus will be modified or superseded by any inconsistent statement made by us in a prospectus supplement. You should read both this prospectus and any prospectus supplement together with the additional information described under the heading *Where You Can Find More Information* .

You should rely only on the information contained or incorporated by reference in this prospectus and the prospectus supplement. We have not authorized anyone else to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We will not make an offer to sell these securities in any state where the offer or sale is not permitted. You should assume that the information appearing in this prospectus, as well as the information we previously filed with the Commission and incorporated by reference into this prospectus, is accurate only as of the date of the documents containing the information.

Unless the context requires otherwise or unless otherwise noted, all references in this prospectus or any prospectus supplement to United Therapeutics and to the company, we, us or our are to United Therapeutics Corporation an subsidiaries.

ABOUT UNITED THERAPEUTICS

We are a biotechnology company focused on the development and commercialization of unique products for patients with chronic and life-threatening diseases. We are active in three therapeutic areas cardiovascular medicine, cancer and infectious disease with five therapeutic platforms:

Prostacyclin Analogs, which are stable synthetic forms of prostacyclin, an important molecule produced by the body that has powerful effects on blood-vessel health and function. Our drug Remodulin has been approved by the United States Food and Drug Administration, or FDA, for the treatment of pulmonary arterial hypertension, or PAH, in patients with NYHA Class II-IV symptoms to diminish symptoms associated with exercise, and in other countries for similar use;

Immunotherapeutic Monoclonal Antibodies, which are antibodies that activate patients immune systems to treat cancer, including OvaRex, which is being developed for the treatment of metastatic ovarian cancer;

Glycobiology Antiviral Agents, which are a novel class of small molecules that may be effective as an oral therapy for hepatitis C and other infections;

Telemedicine, which involves portable digital devices that enable physicians to remotely monitor patients bodily measurements such as heart function, including the CardioPAL family of cardiac event recorders and the Decipher Holter monitors; and

Arginine Formulations, including the HeartBar and other products, which deliver the amino acid arginine that is necessary for maintaining cardiovascular function.

Most of our resources are focused on our prostacyclin analogs for the treatment of cardiovascular disease and immunotherapeutic monoclonal antibodies for the treatment of cancer. Our other principal focus area is the development of glycobiology antiviral agents for the treatment of hepatitis and other diseases. We also devote resources to the commercialization and further development of arginine supplementation therapy, especially in cardiovascular health, and of telecardiology, principally for the detection of cardiac arrythmias.

We field a sales and marketing organization that supports the commercial availability of Remodulin in the United States, Canada and Europe, the latter on a named patient basis. These professionals target the estimated 230 physicians who prescribe PAH therapies to five or more patients. The high pulmonary arterial pressure caused by PAH makes it difficult for the heart to pump blood through the lungs to be oxygenated. This condition strains the heart and can result in heart failure and death. We estimate that PAH afflicts approximately 50,000 people in the United States. Because the symptoms of PAH resemble other diseases and historically treatment options have been limited, only an estimated 10,000 people are currently diagnosed and under various treatments, including

prostacyclins. We believe that the number of patients under treatment will grow because of increased awareness of PAH among healthcare professionals as a result of the introduction of new treatment options.

We anticipate that Remodulin will become the preferred prostacyclin treatment for many PAH patients because Remodulin is longer-acting and avoids many of the drawbacks associated with existing prostacyclin therapies. Remodulin delivers precise amounts of prostacyclin on a reliable, 24-hour-a day basis, thereby reducing many of the side effects and risks associated with periodic inhalation. In addition, Remodulin avoids much of the rebound hypertension associated with short-acting forms of prostacyclin and with nocturnal non-inhalation periods for inhaled forms of prostacyclin. We believe Remodulin is also more convenient than other prostacyclin treatments due to its stability at room temperature, which stability also lends itself to use through a miniaturized pump system. Finally, because Remodulin is provided continuously through either subcutaneous or intravenous delivery, it avoids the risks of potential under-dosing associated with inhalation during periods of respiratory illness.

PAH is a progressive disease despite available therapies. Given the decline in patient health seen in the normal course of PAH, physicians have indicated an interest in combining drugs with different mechanisms of action. We believe combination therapy is becoming more prevalent in the treatment of PAH due to anticipated additive benefits. Positive results of a combination therapy trial of Remodulin with sildenafil (Viagra) have already been shown in a small uncontrolled trial. We are also developing Remodulin for peripheral vascular disease, or PVD.

We were incorporated in Delaware in June 1996. Our principal executive offices are located at 1110 Spring Street, Silver Spring, MD 20910, and our telephone number at that address is (301) 608-9292. We maintain an Internet website at *http://www.unither.com*. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

RISK FACTORS

This offering involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information in and incorporated by reference in this prospectus before deciding whether to invest in our common stock. If any of the following risks actually occur, our business, financial condition or operating results could be materially adversely affected. This could cause the market price of our common stock to decline, and you may lose part or all of your investment.

RISKS RELATED TO OUR BUSINESS

Actual revenue run rates, consolidated revenues and net income or losses may differ from our projections. In addition, we have a history of losses and may not continue to be profitable.

We have made public projections of our estimated Remodulin annual revenue run rate, a range of potential 2004 consolidated revenues and achieving profitability in 2004. These projections were based on numerous factors and assumptions taken into consideration at the time the estimates were made. Those factors and assumptions are inherently subject to a degree of uncertainty. As a result, the actual revenues and net income or losses may be greater or less than projected. Even small differences in the factors and assumptions can lead to significant changes in our stock price. We achieved net income of approximately $15.5 million for the year ended December 31, 2004. Prior to 2004, we incurred net losses aggregating to $195.8 million.

In addition, although we were profitable for the three-month periods ended June 30, 2004, September 30, 2004, and December 31, 2004, we lost money from the date of our inception in 1996 through March 31, 2004. At December 31, 2004, our accumulated deficit was approximately $180.3 million. We may incur additional losses and may not stay a profitable company.

Factors that could affect the accuracy of our expectations of revenue run rates, consolidated revenues, and profitability and cause our quarterly and annual operating results to fluctuate include the following:

- Extent and timing of sales of Remodulin to distributors;
- Level of patient demand for Remodulin and other products;
- Levels of research and development, selling, general and administrative expenses;
- Timing of payments to licensors and corporate partners;
- Retention and growth of patients treated with Remodulin;
- Remodulin side effects, including impact of infusion site pain and reaction from subcutaneous use of Remodulin;
- Changes in the current pricing and dosing of Remodulin;
- Willingness of private insurance companies, Medicare and Medicaid to reimburse Remodulin at current pricing levels;
- Impacts of new legislation and regulations and changes to the Medicare and Medicaid programs;

Diligent and timely completion, as well as the outcome, of the Phase IV post-marketing study of Remodulin;

Our ability to maintain regulatory approval of Remodulin in the United States and other countries;

Additional regulatory approvals in other countries for Remodulin;

Status and impact of other approved and investigational competitive products;

Continued performance by current Remodulin distributors under existing agreements;

Size, scope and outcome of development efforts for existing and additional products;

Future milestone and royalty payments;

Cost, timing and outcomes of regulatory reviews;

Rate of technological advances;

Establishing, defending and enforcing intellectual property rights;

Development of manufacturing resources or the establishment, continuation or termination of third-party manufacturing arrangements;

Establishment, continuation or termination of third-party clinical trial arrangements;

Development of sales and marketing resources or the establishment, continuation or termination of third-party sales and marketing arrangements;

Recovery of goodwill, intangible assets and investments in affiliates;

Collection of accounts receivable and realization of inventories;

Unforeseen expenses;

Actual growth in sales of telemedicine and arginine products;

Actual expenses incurred in future periods; and

Establishment of additional acquisitions or licensing agreements.

Most of our pharmaceutical products are in clinical studies. We might not maintain or obtain regulatory approvals for our pharmaceutical products and may not be able to sell our pharmaceutical products commercially. Even if we sell our products, we may not be profitable and may not be able to sustain any profitability we achieve.

If third-party payers will not reimburse patients for our drug products or if third-party payers limit the amount of reimbursement, our sales will suffer.

Our commercial success depends heavily on third-party payers, such as Medicare, Medicaid and private insurance companies, agreeing to reimburse patients for the costs of our pharmaceutical products. Third-party payers frequently challenge the pricing of new and expensive drugs. Remodulin and the associated infusion pump and supplies are very expensive. Intravenous infusion of Remodulin was just approved in November 2004 and payers may or may not agree to reimburse it. We believe our investigational products, if approved, will also be very expensive. Presently, most third-party payers, including Medicare and Medicaid, reimburse patients for the cost of Remodulin therapy. In the past, Medicare has not reimbursed the full cost of the therapy for some patients. Third-party payers may not approve our new products for reimbursement or continue to approve Remodulin for reimbursement. If third-party payers do not approve a product of ours for reimbursement or limit the amount of reimbursement, sales will suffer, as patients will opt for a competing product that is approved for reimbursement.

We rely on third parties to develop, market, distribute and sell most of our products and those third parties may not perform.

We are currently marketing products in three of our five therapeutic platforms: Remodulin in the prostacyclin analog platform, the HeartBar and other product lines in the arginine formulations platform, and CardioPAL cardiac event monitors and Holter monitors in the telemedicine platform. We do not have the ability to independently conduct clinical studies, obtain regulatory approvals, market, distribute or sell most of our products and intend to rely substantially on experienced third parties to perform all of those functions. We may not locate acceptable contractors or enter into favorable agreements with them. If third parties do not successfully carry out their contractual duties or meet expected deadlines, we might not be able to obtain marketing approvals and sell our products. Medtronic

MiniMed is our exclusive partner for the subcutaneous delivery of Remodulin using the MiniMed microinfusion device for pulmonary arterial hypertension. We are relying on Medtronic MiniMed s experience, expertise and performance. Similarly, we are relying on Accredo Therapeutics, Inc., Priority Healthcare Corporation and Caremark, Inc. to market, distribute, and sell Remodulin in the United States. If our partners and contractors do not achieve acceptable profit margins, they may not continue to distribute our products. If our partners in the United States and internationally are unsuccessful in their efforts, our revenues will suffer.

If we cannot maintain regulatory approvals for our products, we cannot sell those products and our revenues will suffer.

The process of obtaining and maintaining regulatory approvals for new drugs is lengthy, expensive and uncertain. The manufacturing, distribution, advertising and marketing of these products are subject to extensive regulation. Any new product approvals we receive in the future could include significant restrictions on the use or marketing of the product. Product approvals, if granted, can be withdrawn for failure to comply with regulatory requirements or upon the occurrence of adverse events following commercial introduction of the products.

The FDA has approved Remodulin for the treatment of pulmonary arterial hypertension in patients with NYHA Class II-IV symptoms to diminish symptoms associated with exercise. This approval is subject to the requirement that we perform a post-marketing Phase IV clinical study to further assess the clinical benefits of Remodulin. Continued FDA approval of Remodulin is subject to the diligent and timely completion of that trial, as well as its outcome. The Phase IV clinical trial was required to be one-half enrolled by June 2004 and must be fully enrolled by June 2005; however, the FDA has permitted an interim assessment and opportunity to terminate the Phase IV study after only 21 patients have completed the study. The final study report is required to be submitted in December 2005. To date, we have only enrolled 15 patients in this 39-patient Phase IV trial. Enrolling patients in this study is difficult, in part because it involves randomizing some of the patients to placebo despite the fact that approved drugs are available for these patients.

We are not currently enrolling the Phase IV trial within the time frame specified by the FDA, and therefore are at risk of the FDA at any time instituting a public hearing to withdraw marketing approval for Remodulin. We are in discussions with the FDA about our due diligence in enrolling the Phase IV trial and have made a proposal which we believe will ensure that we are able to provide interpretable results of this trial by the December 2005 final study report delivery deadline. Specifically, we have proposed that the FDA evaluate the results of the Phase IV trial based on the number of patients enrolled through September 15, 2005. The FDA is reviewing our proposal. The FDA could, among other things, accept this proposal, grant us an extension of time to continue to enroll the trial, or institute a public hearing to withdraw marketing approval for Remodulin. If a withdrawal hearing were instituted by the FDA, we would pursue the opportunity to participate as we believe that we have exercised good faith due diligence in pursuing enrollment of this trial.

We rely heavily on sales of Remodulin. During the year ended December 31, 2004, our Remodulin sales accounted for 90% of our total revenues. If approvals are withdrawn for a product, we cannot sell that product and our revenues will suffer. In addition, if product approvals are withdrawn, governmental authorities could seize our products or force us to recall our products.

Our products may not be commercially successful because physicians and patients may not accept them.

Even if regulatory authorities approve our products, these products may not be commercially successful. We expect that most of our products, including Remodulin, which is already approved by the FDA, will be very expensive. Patient acceptance of and demand for our products will depend largely on the following factors:

Acceptance by physicians and patients of our products as safe and effective therapies;

Willingness of payers to reimburse and the level of reimbursement of drug and treatment costs by third-party payers such as Medicare, Medicaid and private insurance companies;

Pricing of alternative products;

Convenience and ease of administration of our products; and

Prevalence and severity of side effects associated with our products, including the infusion site pain and reaction associated with the use of subcutaneous Remodulin and the potential for infections associated with intravenous Remodulin.

We may not successfully compete with established drug companies.

We compete with established drug companies during product development for, among other things, funding, access to licenses, expertise, personnel and third-party collaborators. We will also compete with these companies following approval of our products. Almost all of these competitors have substantially greater financial, marketing, sales, distribution and technical resources, and more experience in research and development, clinical trials and regulatory matters, than we do.

We are aware of existing treatments that compete with our products. For the treatment of pulmonary arterial hypertension, approved products that compete with Remodulin include the intravenous prostacyclin, Flolan, marketed by GlaxoSmithKline PLC, the inhaled prostacyclin, Ventavis, marketed by CoTherix, Inc., and Tracleer, an oral endothelin antagonist marketed by Actelion, Ltd. Products that are being developed that may also compete with Remodulin include sitaxsentan being developed by Encysive Pharmaceuticals, Inc., and ambrisentan, being developed by Myogen, Inc. In December 2004, Pfizer, Inc. submitted an application seeking FDA permission to market sildenafil for the treatment of pulmonary arterial hypertension. (Currently, Pfizer markets sildenafil as Viagra for erectile dysfunction.) Many companies are marketing and developing products containing arginine which will compete with the HeartBar product line. Cardiac Holter and event monitoring services and systems are provided by many local and regional competitors and a few national competitors. A number of drug companies are pursuing treatments for ovarian and other cancers and hepatitis that will compete with products in our immunotherapeutic monoclonal antibody platform and glycobiology antiviral agents platform.

We have limited experience with manufacturing and depend on third parties, who may not perform, to synthesize and manufacture many of our products.

Prior to the 1999 acquisition of SynQuest, Inc., a company that manufactured treprostinil, the bulk active ingredient in Remodulin, we had no experience with manufacturing. Presently, treprostinil is being manufactured only by us. We rely on third parties for the manufacture of all our products other than treprostinil. We rely on Baxter Healthcare Corporation for the formulation of Remodulin from treprostinil. We rely on Cardinal Health Inc. for stability studies on Remodulin and to analyze other products that we are developing. We rely on Mnemonics Inc. to manufacture our telemedicine devices and Nellson Nutraceutical and Garden State Nutritionals to manufacture our arginine products. We rely on other manufacturers to make our investigational drugs for use in trials. Although there are a limited number of companies that could replace each of these suppliers, management believes that other suppliers could provide similar services and materials. A change in suppliers, however, could cause a delay in distribution of Remodulin and other products, and in the conduct of clinical trials and commercial launch, which would adversely affect our research and development efforts and future sales efforts. Our manufacturing strategy presents the following risks:

- The manufacturing processes for some of our products have not been tested in quantities needed for commercial sales;
- Delays in scale-up to commercial quantities could delay clinical studies, regulatory submissions and commercialization of our products;
- A long lead time is needed to manufacture Remodulin, and the manufacturing process is complex;
- We and manufacturers of our products are subject to the FDA s good manufacturing practices regulations and similar foreign standards, and although we control compliance issues with respect to synthesis and manufacturing conducted internally, we do not have control over compliance with these regulations by our third-party manufacturers;
- If we have to change to another manufacturing contractor or abandon our captive manufacturing operations, FDA and comparable foreign regulators would require new testing and compliance inspections and the new manufacturer would have to be educated in the processes necessary for the production of the affected product;
- We may not be able to develop or commercialize our products, other than Remodulin, as planned or at all and will have to rely solely on internal manufacturing capacity;

In the future, we intend to transfer all of our drug laboratory operations to the Silver Spring, Maryland facility currently being built, and such transfer could result in manufacturing inefficiencies or delays;

Without substantial experience in operating a manufacturing facility, we may not be able to successfully manufacture Remodulin without a third party manufacturer; and

We may not have intellectual property rights, or may have to share intellectual property rights, to many improvements in the manufacturing processes or new manufacturing processes for our products.

Any of these factors could delay clinical studies or commercialization of our products, entail higher costs and result in our being unable to effectively sell our products.

If our products fail in clinical studies, we will not be able to obtain or maintain FDA and foreign approvals and will not be able to sell those products.

In order to sell our pharmaceutical products, we must receive regulatory approvals. To obtain those approvals, we must conduct clinical studies demonstrating that the drug product, including its delivery mechanism, is safe and effective. If we cannot obtain approval from the FDA for a product, that product cannot be sold, and our revenues will suffer.

We are currently conducting a Phase IV clinical study for Remodulin. For a description of the status of this Phase IV study, see our discussion above under Risk Factors *If we cannot maintain regulatory approvals for our products, we cannot sell those products and our revenues will suffer.* We have initiated a Phase II clinical study of an inhaled formulation of treprostinil and Phase I studies of an oral formulation of Remodulin. Our lead glycobiology antiviral agent, UT-231B, recently completed a Phase II, proof-of-concept study. In that trial, UT-231B did not demonstrate efficacy against hepatitis C in a population of patients that previously failed conventional treatments. We are now planning a trial in patients who responded positively to conventional treatments to determine if UT-231B can prevent disease relapse in such patients. We are also currently conducting two Phase III pivotal studies of OvaRex for the treatment of metastatic ovarian cancer. We are still completing or planning pre-clinical studies for our other products. Our ongoing and planned clinical studies might be delayed or halted for various reasons, including:

- The drug is not effective, or physicians think that the drug is not effective;
- Patients do not enroll in the studies at the rate we expect;
- Patients experience severe side effects during treatment, including site pain;
- Other investigational or approved therapies are viewed as more effective or convenient by physicians or patients;
- Patients die during the clinical study because their disease is too advanced or because they experience medical problems that are not related to the drug being studied;
- Drug supplies are not available or suitable for use in the studies; and
- The results of preclinical testing cause delays in clinical trials.

In addition, the FDA and foreign regulatory authorities have substantial discretion in the approval process. The FDA and foreign regulatory authorities may not agree that we have demonstrated that our products are safe and effective.

Discoveries or developments of new technologies by others may make our products obsolete or less useful.

Other companies may conduct research, make discoveries or introduce new products that render all or some of our technologies and products obsolete or not commercially viable. Researchers are continually making new discoveries that may lead to new technologies to treat the diseases for which our products are intended. In addition, alternative approaches to treating chronic diseases, such as gene therapy, may make our products obsolete or noncompetitive. One therapy recently approved in the United States in 2001 is Tracleer, an oral endothelin antagonist developed by Actelion, Ltd. which competes with Remodulin. More recently, in December 2004, Ventavis, an inhaled prostacyclin developed by CoTherix, Inc., was approved in the United States. Ventavis will also compete with Remodulin. We are aware that other endothelin antagonists are being developed, such as sitaxsentan by Encysive Pharmaceuticals, Inc. and ambrisentan by Myogen, Inc. In December 2004, Pfizer, Inc. submitted an application seeking FDA permission to market sildenafil for the treatment of pulmonary arterial hypertension. (Currently, Pfizer markets sildenafil as Viagra for erectile dysfunction.)

Other approved or investigational therapies for pulmonary hypertension could be used in combination with Remodulin. If this happens, doctors may reduce the dose of Remodulin given to their patients. This could result in less Remodulin being used by such patients and, hence, reduced sales of Remodulin.

If the licenses, assignments and alliance agreements we depend on are breached or terminated, we would lose our right to develop and sell the products covered by the licenses, assignments and alliance agreements.

Our business depends upon the acquisition, assignment and license of drugs and other products which have been discovered and initially developed by others, including Remodulin, all of the products in the immunotherapeutic monoclonal antibody platform, all of the products in the glycobiology antiviral agents platform, and the HeartBar line of products. Under our product license agreements, we retain ownership of the intellectual property subject to the terms of each license agreement, whereas assignment agreements transfer all right, title and ownership of the intellectual property to us, subject to the terms of each assignment agreement. In addition, we have obtained licenses to other third-party technology to conduct our business, including licenses for our products and an alliance agreement for the use of the Medtronic MiniMed microinfusion device for the administration of Remodulin. In addition, we may be required to obtain licenses to other third-party technology to commercialize our early-stage products. This dependence has the following risks:

We may not be able to obtain future licenses, assignments and agreements at a reasonable cost or at all;

If any of our licenses or assignments are terminated, we will lose our rights to develop and market some or all of our products;

The licenses and assignments that we hold generally provide for termination by the licensor or assignor in the event we breach the license or assignment agreement, including failing to pay royalties and other fees on a timely basis;

In the event that GlaxoSmithKline (formerly Glaxo Wellcome) terminates its assignment agreement or Pfizer (formerly Pharmacia) terminates its license agreement, we will have no further rights to utilize the assigned patents or trade secrets to develop and commercialize Remodulin. For the year ended December 31, 2004, sales of Remodulin accounted for approximately 90% of our revenues. GlaxoSmithKline or Pfizer could seek to terminate the assignment in the event that we fail to pay royalties based on sales of Remodulin; and

If licensors fail to maintain the intellectual property licensed or assigned to us as required by most of our license and assignment agreements, we may lose our rights to develop and market some or all of our products and may be forced to incur substantial additional costs to maintain the intellectual property ourselves or force the licensor or assignor to do so.

If our patent and other intellectual property protection is inadequate, our sales and profits could suffer or competitors could force our products completely out of the market.

The United States patent for the method of treating pulmonary hypertension with Remodulin was originally set to expire in 2009. The patent for OvaRex and its method of use are the subject of a combination of issued patents and pending applications in the United States and around the world. The issued patents have expiration dates ranging from 2017 to 2020. We believe that some of the patents to which we have rights may be eligible for extensions of up to five years based upon patent term restoration procedures in Europe and in the United States under the Waxman-Hatch Act. For instance, in February 2005 under Waxman-Hatch, the United States patent relating to the method of treating pulmonary hypertension using Remodulin was extended by five years, giving the product patent protection until October 6, 2014. In addition, patent extensions are available under similar laws in Europe. Competitors may develop products based on the same active ingredients as our products, including Remodulin, and market those products after the patents expire, or may design around our existing patents. If this happens, our sales would suffer and our profits could be severely impacted.

Patents may be issued to others which prevent the manufacture or sale of our products. We may have to license those patents and pay significant fees or royalties to the owners of the patents in order to keep marketing our products. This would cause profits on sales to suffer.

We have been granted patents in the United States for the synthesis of Remodulin, but patent applications that have been, or may in the future be, filed by us may not result in the issuance of additional patents. The scope of any patent issued may not be sufficient to protect our technology. The laws of foreign jurisdictions in which we intend to sell our products may not protect our rights to the same extent as the laws of the United States.

In addition to patent protection, we also rely on trade secrets, proprietary know-how and technology advances. We enter into confidentiality agreements with our employees and others, but these agreements may not be effective in protecting our proprietary information. Others may independently develop substantially equivalent proprietary information or obtain access to our know-how.

Litigation, which is very expensive, may be necessary to enforce or defend our patents or proprietary rights and may not end favorably for us. We are currently a party to pending litigation initiated by us against other parties believed to have violated our patents related to our arginine products line. We may also choose to initiate litigation against other parties who we come to believe are infringing these patents. If such litigation is unsuccessful or if the patents are invalidated or canceled, we may have to write off the related intangible assets and such an event could significantly reduce our earnings. Any of our licenses, patents or other intellectual property may be challenged, invalidated, canceled, infringed or circumvented and may not provide any competitive advantage to us.

If our highly qualified management and technical personnel leave us, our business may suffer.

We are dependent on our current management, particularly our founder and Chief Executive Officer, Martine Rothblatt, Ph.D., our President and Chief Operating Officer, Roger Jeffs, Ph.D., our Executive Vice President for Business Development and Chief Financial Officer, Fred Hadeed, and our Executive Vice President for Strategic Planning, General Counsel and Corporate Secretary, Paul Mahon, all of whom are employed pursuant to multi-year employment agreements. We do not maintain key person life insurance on these officers. Our success will depend in part on retaining the services of our existing management and key personnel and attracting and retaining new highly qualified personnel. Expertise in the field of cardiovascular medicine, infectious disease and oncology is not generally available in the market, and competition for qualified management and personnel is intense.

We may not have adequate insurance and may have substantial exposure to payment of product liability claims.

The testing, manufacture, marketing, and sale of human drugs involve product liability risks. Although we currently have product liability insurance covering claims up to $20 million per occurrence, we may not be able to maintain this product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential losses. If claims or losses exceed our liability insurance coverage, we may go out of business.

We may not have, or may have to share rights to, future inventions arising from our license, assignment and alliance agreements and may lose potential profits or savings.

Pursuant to our agreements with certain business partners, any new inventions or intellectual property that arise from our activities will be owned jointly by us and these partners. If we do not have rights to new developments or inventions that arise during the terms of these agreements, or we have to share the rights with others, we will lose the benefit of the new rights which may mean a loss of future profits or savings generated from improved technology.

If we need additional financing and cannot obtain it, product development and sales may be limited.

We may need to spend more money than currently expected because we may need to change our product development plans or product offerings to address difficulties with clinical studies, to prepare for commercial sales or to continue sales of Remodulin. We may not be able to obtain additional funds on commercially reasonable terms or at all. If additional funds are not available, we may be compelled to delay clinical studies, curtail operations or obtain funds through collaborative arrangements that may require us to relinquish rights to certain products or potential markets.

RISKS RELATED TO OWNING OUR COMMON STOCK

Our stock price could be volatile and could decline.

The market prices for securities of drug and biotechnology companies are highly volatile, and there are significant price and volume fluctuations in the market that may be unrelated to particular companies operating performances. The table below sets forth the high and low closing prices for our common stock for the periods indicated:

		High	Low
January 1, 2002	December 31, 2002	$17.61	$ 9.10
January 1, 2003	December 31, 2003	$24.65	$14.70
January 1, 2004	December 31, 2004	$46.73	$20.51
January 1, 2005	February 22, 2005	$45.82	$41.37

Our stock price could decline suddenly due to the following factors, among others:

Quarterly and annual financial and operating results;

Failure to meet estimates or expectations of securities analysts or our projections;

Public concern as to the safety of products developed by us or by others;

Changes in or new legislation and regulations affecting reimbursement of Remodulin by Medicare or Medicaid;

Announcements by us or others of technological innovations or new products or announcements regarding our existing products;

Developments in patent or other proprietary rights;

Future sales of substantial amounts of common stock by our existing stockholders;

Results of clinical trials;

Future sales of common stock by our directors and officers;

Failure to maintain approvals to sell Remodulin;

Timing and outcome of additional regulatory approvals; and

General market conditions.

Future sales of shares of our common stock may depress our stock price.

If our stockholders transfer their ownership of our common stock or sell a substantial number of shares of common stock in the public market, or investors become concerned that substantial sales might occur, the market price of our common stock could decrease. Each of our four executive officers has announced their adoption of 10b5-1 trading plans. In accordance with these plans, twice each month the executives sell a specified number of our common stock either owned by them or acquired through the exercise of stock options. In addition, Toray Industries Inc. has an option to acquire 500,000 shares of our common stock and piggyback registration rights with respect to such shares that arise if and when this option becomes exercisable. A decrease in our common stock price could make it difficult for us to raise capital by selling stock or to pay for acquisitions using stock. To the extent outstanding options are exercised or additional shares of capital stock are issued, existing stockholders may incur additional dilution.

Provisions of Delaware law and our certificate of incorporation, by-laws and rights plan could prevent or delay a change of control or change in management that could be beneficial to us and our public stockholders.

Certain provisions of Delaware law and our certificate of incorporation, by-laws and shareholder rights plan may prevent, delay or discourage:

A merger, tender offer or proxy contest;

The assumption of control by a holder of a large block of our securities; and

The replacement or removal of current management by our stockholders.

For example, our certificate of incorporation divides the board of directors into three classes, with members of each class to be elected for staggered three-year terms. This provision may make it more difficult for stockholders to change the majority of directors and may frustrate accumulations of large blocks of common stock by limiting the voting power of such blocks. This may further result in discouraging a change of control or change in current management.

Our existing directors and executive officers own a substantial block of our stock and might be able to influence the outcome of matters requiring stockholder approval.

Our directors and named executive officers beneficially owned approximately 9.8% percent of our outstanding common stock as of February 1, 2005 including stock options that could be exercised by those directors and executive officers within 60 days of that date. Accordingly, these stockholders as a group might be able to influence the outcome of matters requiring approval by our stockholders, including the election of our directors. Such stockholder influence could delay or prevent a change of control with respect to us.

If stockholders do not receive dividends, stockholders must rely on stock appreciation for any return on their investment in us.

We have never declared or paid cash dividends on any of our capital stock. We currently intend to retain our earnings for future growth and therefore do not anticipate paying cash dividends in the future.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

The following statements are or may constitute forward-looking statements:

statements set forth in this prospectus or statements incorporated by reference from documents we have filed with the Commission, including possible or assumed future results of our operations, concerning:

- expectations of revenues and profitability;
- the timing and outcome of clinical studies and regulatory filings;
- the achievement and maintenance of regulatory approvals;
- the ability to find alternate sources of supply and manufacturing for our products;
- the existence and activities of competitors;
- the expectation not to pay dividends on common stock in the foreseeable future;
- the pricing of Remodulin;
- the dosing and rate of patient consumption of Remodulin;
- the impacts of price changes and changes in patient consumption of Remodulin on future revenues;
- the expectation of reimbursement by third-party payers for intravenous Remodulin;
- the timing, impact, materiality and outcome of under-reimbursement by third party payers, such as Medicare;
- the timing and outcome of the Phase IV clinical trial;
- any actions that may or may not be taken by the FDA as a result of the timing and outcome of the Phase IV clinical trial;
- the rate of physician and patient acceptance of our products as safe and effective;
- the development and sale of products covered by licenses and assignments;
- the adequacy of our intellectual property protections;
- the outcome of any litigation in which we are or become involved;
- the ability of third parties to develop, market, distribute and sell our products;
- the composition of our management team;
- the adequacy of our insurance coverage;

the ability to obtain financing in the future;

the value of our common stock;

the funding of operations from future revenues;

the expectation of continued profits or losses;

expectations concerning milestone and royalty payments in 2005;

expectations concerning payments of contractual obligations in all future years and their amounts;

the use of net operating loss carryforwards and business tax credit carryforwards;

the completion of in-process research and development projects and their impact on United Therapeutics;

the pace and timing of enrollment in clinical trials;

the expectation, outcome and timing of new and continued regulatory approvals;

the expected levels and timing of Remodulin sales;

the adequacy of our resources to fund operations through 2007;

the potential amount of the minimum residual value guarantee to Wachovia;

events that could occur upon termination of the Wachovia agreements;

the timing and level of spending to construct a laboratory facility; and

the potential impacts of new accounting standards;

the sale of common stock at favorable terms under this primary registration statement;

any statements preceded by, followed by or that include the words believes, expects, predicts, anticipates, intends, estimates, should, may or similar expressions; and

other statements contained or incorporated by reference in this prospectus that are not historical facts.

Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause actual results to differ materially include, but are not limited to, the factors discussed under *Risk Factors.*

You should not place undue reliance on such statements, which speak only as of the date that they were made. These cautionary statements should be considered in connection with any written or oral forward-looking statements that we may issue in the future. We do not undertake any obligation to release publicly any revisions to such forward-looking statements in the future to reflect later events or circumstances or to reflect the occurrence of unanticipated events.

USE OF PROCEEDS

Unless indicated otherwise in a prospectus supplement, we intend to use the net proceeds from the offering of our common stock for acquisitions in the future, working capital and other general corporate purposes. Although we currently have no arrangements or understandings with respect to acquisitions, we continue to evaluate acquisition opportunities.

Although we have listed above how we currently intend to use the proceeds from the offering of our common stock, our management retains broad discretion over the use of the proceeds. We may ultimately use the proceeds for different purposes than what we currently intend. Any specific allocation of the net proceeds of an offering of securities to a specific purpose will be determined at the time of the offering and will be described in a prospectus supplement. Pending any ultimate use of any portion of the proceeds from the offering of our common stock, we intend to invest the proceeds in interest-bearing instruments such as money market funds, commercial paper, certificates of deposit, US government securities, corporate debt securities and municipal bonds.

PLAN OF DISTRIBUTION

Any securities that we may offer under this prospectus may be sold in or outside the United States through underwriters, dealers or agents, directly to one or more purchasers, including our existing stockholders, in a rights offering, or through a combination of any such methods of sale. The prospectus supplement relating to the securities offered by this prospectus will include, to the extent required, the following information:

the terms of the offering;

the names of any underwriters, dealers or agents;

the name or names of any managing underwriter or underwriters;

the purchase price of the securities offered by this prospectus;

the net proceeds to us from the sale of the securities;

any delayed delivery arrangements;

any underwriting discounts, commissions and other items constituting underwriters compensation;

any public offering price;

any discounts or concessions allowed or reallowed or paid to dealers;

any commissions paid to agents; and

any securities exchanges on which the securities offered by this prospectus may be listed.

In connection with the sale of securities offered by this prospectus, underwriters, dealers or agents may be deemed to have received compensation from us in the form of underwriting discounts or commissions and may also receive commissions from purchasers of the offered securities for whom they may act as agent. Underwriters may sell the securities offered by this prospectus to or through dealers, and such dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions from the purchasers for whom they may

act as agent.

If we use underwriters in the sale, the underwriters will acquire the securities for their own account. The underwriters may resell the securities from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Underwriters may offer securities to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters. Unless we inform you otherwise in the prospectus supplement, the obligations of the underwriters to purchase the securities will be subject to certain conditions, and the underwriters will be obligated to purchase all the offered securities if they purchase any of them. The underwriters may change, from time to time, any public offering price and any discounts or concessions allowed or reallowed or paid to dealers.

If we use dealers in the sale of securities, the securities will be sold directly to them as principals. They may then resell those securities to the public at varying prices determined by the dealers at the time of resale.

We may sell the securities directly. In this case, no underwriters or agents would be involved. We may sell securities upon the exercise of rights that we may issue to our security holders. We may sell the securities directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act with respect to any sale of those securities.

We may sell the securities through agents we designate from time to time. Any agent involved in the offer or sale of the securities as well as any commissions payable by us to such agent will be named in the prospectus supplement. Unless we inform you otherwise in the prospectus supplement, any agent will agree to use its reasonable best efforts to solicit purchases for the period of its appointment.

If we so indicate in the prospectus supplement, we may authorize underwriters, dealers or agents to solicit offers from certain types of institutions to purchase securities from us, at the public offering price under delayed delivery contracts. These contracts would provide for payment and delivery on a specified date in the future. The contracts would be subject only to those conditions described in the prospectus supplement. The prospectus supplement will describe the commission payable for solicitation of those contracts.

We may have agreements with the underwriters, dealers or agents to indemnify them against certain civil liabilities, including liabilities under the Securities Act, or to contribute with respect to payments that underwriters, dealers or agents may be required to make. Underwriters, dealers or agents may be customers of, engage in transactions with or perform services for us in the ordinary course of their business.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock summarizes general terms and provisions that apply to the capital stock. Since this is only a summary it does not contain all of the information that may be important to you. The summary is subject to and qualified in its entirety by reference to our certificate of incorporation and bylaws, which are on file with the Commission. See Where You Can Find More Information.

General

Our certificate of incorporation provides us with the authority to issue 100,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of preferred stock, par value $0.01 per share. As of February 1, 2005, there were 22,482,636 shares of our common stock outstanding, and no shares of our preferred stock were outstanding.

Our Common Stock

Dividends. Subject to the rights of any holders of our preferred stock, each share of our common stock is entitled to dividends if, as and when dividends are declared by our board of directors and paid. Under Delaware corporate law, we may declare and pay dividends only out of our surplus, or in case there is no such surplus, out of our net profits for the fiscal year in which the dividend is declared and/or the preceding year. We may not declare dividends, however, if our capital has been diminished by depreciation, losses or otherwise to an amount less than the aggregate amount of capital represented by any issued and outstanding stock having a preference on distribution. We will pay any dividend so declared and payable in cash, capital stock or other property equally, share for share, on our common stock.

Voting rights. The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of our stockholders.

Liquidation rights. In the event of our liquidation, dissolution or winding up, holders of the shares of our common stock are entitled to share equally, share for share, in the assets available for distribution to holders of our capital stock, subject to any liquidation preference on any outstanding shares of our preferred stock.

Other. The holders of our common stock have no cumulative voting rights with respect to the election of directors or any other matter. No stockholder of our common stock has preemptive or other rights to subscribe for additional shares of our common stock.

Our Preferred Stock

We may issue our preferred stock from time to time in one or more series as determined by our board of directors. Our board of directors is authorized to issue the shares of our preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption, redemption prices, liquidation preferences and the number of shares constituting any series or the designation of such series, without further vote or action by our stockholders. The issuance of our preferred stock may have the effect of delaying, deferring or preventing a change in control of our company without further action by the stockholders and may adversely affect the voting and other rights of the holders of our common stock by, for example, transferring voting control to others.

Preferred Stock Purchase Rights

Each share of our common stock trades with and has attached to it a right to purchase shares of preferred stock. The terms of the rights are set forth in a Rights Agreement dated as of December 17, 2000, between us and The Bank of New York, as Rights Agent. Each right entitles the holder to purchase from us one one-thousandth of a share of our Series A Junior Participating Preferred Stock, par value $0.01 per share, at a price of $129.50, subject to adjustment. The rights are currently evidenced by our common stock certificates and are not exercisable until the earlier of:

the close of business on the tenth business day following the date of public announcement, or the date on which we first have notice or determine, that a person or group of affiliated or associated persons has acquired, or has obtained the right to acquire, 15% or more of the outstanding shares of our voting stock without our prior express written consent following express approval by our board of directors, or

the close of business on the tenth business day following the commencement of a tender offer or exchange offer by a person, without our prior written consent following express approval by our board of directors, which offer, upon consummation, would result in such person s control of 15% or more of our voting stock.

If not exercised by the holders or earlier redeemed or exchanged by us, the rights will expire on December 29, 2010. The purchase price payable, and the number of shares of Series A Junior Participating Preferred Stock or other securities or property issuable upon exercise of the rights, are subject to adjustment from time to time to prevent dilution by action of our board of directors and in circumstances described in the Rights Agreement.

Anti-Takeover Effect of Our Certificate of Incorporation and Bylaws

Election of the Board of Directors. Our certificate of incorporation and bylaws provide that our board of directors is divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors is elected each year. This classification of our board of directors will make it more difficult for an acquirer or for other stockholders to change the composition of our board of directors. Our bylaws also provide that a director may be removed only for cause by vote of the holders of at least 80% of the outstanding shares of our common stock entitled to vote generally in an election of directors. In addition, the bylaws provide that any vacancies in our board of directors will be filled by our board of directors. If the remaining directors do not constitute a quorum, our bylaws permit the vacancy to be filled by the affirmative vote of a majority of the remaining directors, though less than a quorum.

Stockholder advance notice procedure. Our bylaws establish an advance notice procedure for stockholders to make nominations of candidates for election as directors or to bring other business before an annual meeting of the stockholders. The stockholder notice procedure provides that only persons who are nominated by the board of directors, or a duly authorized board committee, or by a stockholder who has given timely written notice to the secretary of our company before the meeting at which directors are to be elected, will be eligible for election as directors. This notice is required to include specified information about the stockholder and each proposed director nominee and information regarding each proposed nominee that would be required to be included in a proxy statement filed under the Commission s Rules and Regulations. The stockholder notice procedure provides that the only business that may be conducted at an annual meeting is business that has been brought before the meeting by, or at the direction of, the board of directors or by a stockholder who has given timely written notice to the secretary of our company. This notice is required to include a brief description of the business desired to be brought before the meeting and specified information about the stockholder and the stockholder s ownership of our capital stock.

Delaware Anti-Takeover Law

As a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. Section 203 provides that, in general and subject to the exceptions specified in that section, a corporation may not engage in any business combination with any interested stockholder, as defined, for a three-year period following the time that such stockholder became an interested stockholder unless:

prior to that time, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced (excluding certain shares); or

at or subsequent to that time, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders by the affirmative vote of at least two-thirds of

the outstanding voting stock of the corporation that is not owned by the interested stockholder.

Subject to exceptions specified in Section 203 of the Delaware General Corporation Law, an interested stockholder is defined, in general, to include:

any person that is the owner of 15% or more of the outstanding voting stock of the corporation, or is an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of the corporation at any

time within the three-year period immediately prior to the date on which it is sought to be determined whether that person is an interested stockholder; and

the affiliates and associates of any person described in the preceding bullet point.

Section 203 of the Delaware General Corporation Law may make it more difficult for a person who would be an interested stockholder to effect various business combinations with us.

LEGAL MATTERS

Akin Gump Strauss Hauer & Feld LLP has acted as our counsel in connection with this offering and has issued a preliminary opinion regarding the validity of the issuance of the securities offered by this prospectus. Legal counsel to any underwriters may pass upon legal matters for such underwriters.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements and schedule included in our Annual Report on Form 10-K as of December 31, 2004 and 2003 and for each of the years in the two-year period ended December 31, 2004, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and schedule are incorporated by reference in reliance on Ernst & Young LLP s report, given on their authority as experts in accounting and auditing. Our consolidated financial statements and schedule for the year ended December 31, 2002, have been incorporated by reference herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing. KPMG LLP s audit report covering the December 31, 2002 financial statements refers to our adoption of Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets, effective January 1, 2002.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission, Washington, D.C., a registration statement on Form S-3 under the Securities Act of 1933, covering the securities offered by this prospectus. This prospectus does not contain all of the information that you can find in that registration statement and its exhibits and schedule. Certain items are omitted from this prospectus in accordance with the rules and regulations of the Commission. For further information about us and the common stock offered hereby, reference is made to the registration statement and the exhibits and schedules filed with the registration statement. Statements contained in this prospectus as to the contents of any contract or other document referred to are not necessarily complete and in each instance such statement is qualified by reference to each such contract or document filed with or incorporated by reference as part of the registration statement. We file reports, proxy statements and other information with the Commission. You may read any materials we have filed with the Commission free of charge at the Commission s Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of all or any part of these documents may be obtained from such office upon the payment of the fees prescribed by the Commission. The public may obtain information on the operation of the public reference room by calling the Commission at 1-800-SEC-0330. The Commission maintains an Internet site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Commission. The address of the site is *http://www.sec.gov*. The registration statement, including all exhibits thereto and amendments thereof, has been filed electronically with the Commission. In addition, we make available free of charge through our Internet site (*http://www.unither.com*) reports, proxy statements and other information that we file with the Commission.

The Commission allows us to incorporate by reference into this prospectus the information we provide in documents filed with the Commission, which means that we can disclose important information by referring to those documents. The information incorporated by reference is an important part of this prospectus. Any statement contained in a document that is incorporated by reference in this prospectus is automatically updated and superseded if information contained in this prospectus, or information that we later file with the Commission, modifies or replaces this information. We incorporate by reference the following documents we have filed with the Commission:

(1) Annual Report on Form 10-K for the fiscal year ended December 31, 2004.

(2) Current Report on Form 8-K filed on February 22, 2005.

(3) Description of our common stock contained in the Registration Statement on Form 8-A, filed on June 8, 1999, and description of our preferred stock purchase rights (which trade with our common stock) contained in the Registration Statement on Form 8-A, filed on January 2, 2001.

In addition, all documents filed by us with the Commission under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 (other than information furnished rather than filed) after the date of this prospectus and prior to the filing of a post-effective amendment that indicates that all securities offered hereby have been sold or that deregisters all securities remaining unsold, will be considered to be incorporated by reference into this prospectus and to be a part of this prospectus from the dates of the filing of such documents.

You may get copies of any of the incorporated documents (excluding exhibits, unless the exhibits are specifically incorporated) at no charge to you by writing or calling:

United Therapeutics Corporation
Vice President, Investor Relations
1110 Spring Street
Silver Spring, Maryland 20910
(301) 608-9292