



Focus is the Future

About the Company

Trimeris, Inc. (Nasdaq: TRMS) is a biopharmaceutical company based in Morrisville, North Carolina. The company is engaged in the discovery, development and commercialization of new drugs for the treatment of viral diseases. Our core technology platform focuses on compounds that inhibit viral replication by blocking viral fusion with healthy immune cells.

FUZEON® (enfuvirtide), approved by the U.S. Food and Drug Administration (FDA) and European Commission in 2003, is the first in a new class of anti-HIV drugs called fusion inhibitors. For more information about FUZEON, please visit www.fuzeon.com.



Steven D. Skolsky
Chief Executive Officer

Mr. Skolsky brings almost twenty-five years of U.S. and international commercial and clinical development experience to his role as Chief Executive Officer of Trimeris. Mr. Skolsky came to Trimeris from GlaxoSmithKline (GSK), where he most recently managed product strategy and worldwide clinical development for the GSK portfolio as Senior Vice President, Global Commercial Strategy. Mr. Skolsky had previously served as Managing Director of GlaxoSmithKline's operations in New Zealand and Australia, successively. Mr. Skolsky's previous leadership as Vice President of Sales and Marketing of the HIV/Oncology division at Glaxo Wellcome firmly grounded his expertise in HIV where he oversaw the launch of some of the most successful AIDS drugs — Efavir® (3TC®) and Combivir®. Mr. Skolsky is a graduate of the University of North Carolina at Chapel Hill.

The start of Trimeris' second decade in 2004 coincided with the first full year of FUZEON® (enfuvirtide) commercial success. FUZEON is the first representative of a new class of Human Immunodeficiency Virus (HIV) drugs approved by the U.S. FDA in seven years. The entry of FUZEON into the marketplace has fulfilled the promise of the scientific discovery on which our company was founded, and its success has now become the unwavering focus of our team.

To Our Shareholders

We are aligning our objectives to achieve focus on four critical strategic imperatives:

- *Portfolio & Commercialization*
 - ♦ Maximizing FUZEON use among those who will benefit from our product's ability to fight HIV in combination with other drugs;
 - ♦ Focusing our Research and Development (R&D) efforts on efficacy, convenience and ease-of-use of FUZEON and next generation fusion inhibitors; and
 - ♦ Building our pipeline with new products of our own invention or through acquisition.
- *Fiscal management* with an emphasis on our cash position and eliminating unnecessary costs.
- *Value creation* for our shareholders and partners.
- *Establishing a culture of trust* that values, recognizes and rewards individual and team contributions, as well as overall achievement in executing our strategy.

Achievements

2004 was a year of significant achievements, including:

- Steady growth of FUZEON in its first full year post-launch with worldwide sales of \$135MM representing growth of \$100MM over 2003;
- A 31% reduction in operating expenses resulting in a 39% improvement in our net loss versus 2003;
- Increased product penetration with steady growth in new and total prescriptions of 87% and 37%, respectively;
- Reimbursement approval for FUZEON in all major European markets;
- Full approval of FUZEON from the FDA and European Medicines Evaluation Agency (EMA) based upon 48-week safety and efficacy data;
- Significant progress in research and development of next-generation drug candidates, which could improve convenience and durability of clinical response; and
- Expanded distribution of FUZEON in the United States to all specialty and retail pharmacy outlets.

FUZEON Strategy

The focus of our strategy for FUZEON is to serve all patients who would benefit from our product due to the outstanding clinical profile that this new class of antiretroviral (ARV) agents provides. At the 2002 World Aids Conference in Barcelona, the very first data emerging from the phase III TORO studies of FUZEON were hailed as one of the most significant advancements in combating HIV to date. This new class of ARV's—fusion inhibitors—demonstrated statistically significant and superior activity against pan-resistant HIV compared to the best combination of approved ARV's. Patients receiving FUZEON as part of their HIV regimen achieved levels of HIV suppression and immune system restoration that were previously unattainable. Since that time, FUZEON has continued to prove its efficacy in combating HIV. We are now focused on conveying results from new clinical trials as well as on programs that will improve the ease of initiating FUZEON therapy and retain patients over time through improvements in their therapeutic experience.

Emerging clinical data from three major studies showing FUZEON to be a powerful new treatment strategy for patients who have experience using agents from each of the traditional classes of HIV drugs forms the platform of our commercialization efforts. The results from these studies indicate that the use of FUZEON with an active, boosted protease inhibitor can deliver unprecedented virological and immunological response heretofore seen in patients initiating their first antiretroviral treatment. These data clearly demonstrate that FUZEON is the preferred agent for achieving maximum HIV suppression and immune restoration in treatment-experienced patients and presents the opportunity to achieve undetectable HIV status and thus redefine treatment success in this population. The opportunity to achieve this goal can be expanded as new agents, particularly other inhibitors of HIV entry, become available.

This growing body of clinical evidence is not only consistent with new treatment guidelines from the International AIDS Society and the U.S. Department of Health and Human Services but has also created an excellent opportunity for Trimeris to gain conviction and support from healthcare practitioners to prescribe FUZEON more broadly.

In addition to an enhanced marketing program based on the new clinical data and the final FDA approval, work is underway to develop needle-free delivery systems for FUZEON. In 2004, we demonstrated the bioequivalence of the Biojector® 2000 device compared to standard syringe needles used in administering FUZEON. As a result, we have since submitted a

supplemental New Drug Application (sNDA) to the FDA in May 2005, and we continue to explore promising alternative syringe and needle systems such as small gauge insulin needles. This effort could play an important role in improving patient acceptance and the overall patient experience with the product.

In an effort to provide improved continuity of care, our nursing support programs have been enhanced to provide a broad network of highly experienced HIV nurses to interact directly with patients, clinicians and AIDS service organizations who are key to acceptance of FUZEON and to continuity of care for patients who enter into therapy. We have also embarked on a number of post-marketing clinical studies designed to help patients initiate and sustain FUZEON-based therapies. We will pursue further work on needle-free systems, and our R&D team is assessing the role that FUZEON could play in earlier lines of treatment as well as a substitute for other HIV therapies that have unacceptable toxicities.

The Future of HIV-AIDS Treatment

The evolution of care and the advent of new treatments have undoubtedly had a major impact on long-term survival rates in patients with HIV. However, there is room for improvement. The U.S. Centers for Disease Control and Prevention has indicated that there has been a 37% increase in young people aged 13-24 who are living with HIV. This alarming statistic is underscored by data concerning patient compliance and persistence with current regimens—patients who do not adhere to their treatments do not survive. This challenges our company to provide a product that not only will be useful in the fight against HIV-AIDS, but one that will be used consistently to ensure long-term treatment success.

Resistance to existing medications raises another ominous issue. A 2004 study indicated an overall resistance rate of 76% in a cohort of treatment-experienced patients, and the recent case of an HIV infected individual in New York City, published in the journal *Lancet*, demonstrated the challenge of treating patients who have rapidly progressing disease with significant multi-drug resistance. In the New York case, the virus exhibited full sensitivity to only one drug, FUZEON, which further demonstrates its utility in treating multi-drug resistant virus. Our research team intends to better define the role that fusion inhibitors can play in the future of therapy, and we believe FUZEON could develop as an essential backbone to many future treatment regimens.

Company Outlook

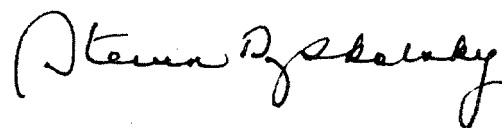
As we look ahead to 2005, we look forward to other key milestones:

- Conducting additional clinical studies to support the expanded use of FUZEON;
- The approval of the sNDA for needle-free systems, which will allow Trimeris and our partner, Roche, to actively promote advantages of needle-free systems in conjunction with FUZEON;
- The generation of additional quality-of-life and pharmacoeconomic data to support the value of FUZEON;
- Achieving our goal of declaring a next generation clinical candidate by year-end; and
- The approval of new agents that demonstrate the profound benefit of combining FUZEON into new treatment regimens.

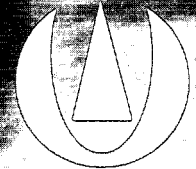
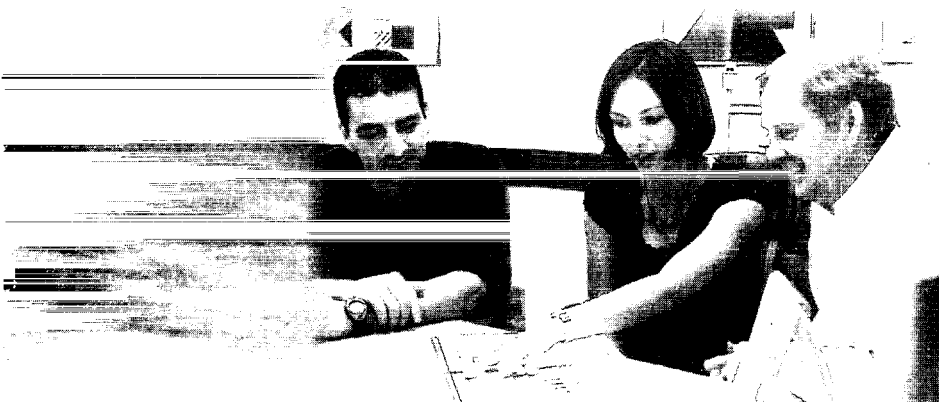
Great progress has been made following the redesign of our R&D organization into a matrix structure and focusing our efforts on advancing the next generation fusion inhibitor targeting a product profile with improved efficacy, convenience and ease of administration.

We have an ambitious agenda for the years ahead and look forward to sharpening our focus by building our leadership team, gaining additional traction with a refined set of commercial initiatives, developing our pipeline with our revitalized R&D organization, and enhancing business development capabilities. The strong foundation and core that brought our revolutionary new therapy to the marketplace provides us a significant head start for our next decade.

We possess an innovative, first-in-class, technology, a well conceived and focused strategy, and a highly motivated team committed to building our enterprise and delivering success. I thank you, our shareholders, for your ongoing encouragement and support, and look forward to our continued growth in 2005.



Steven D. Skolsky
Chief Executive Officer

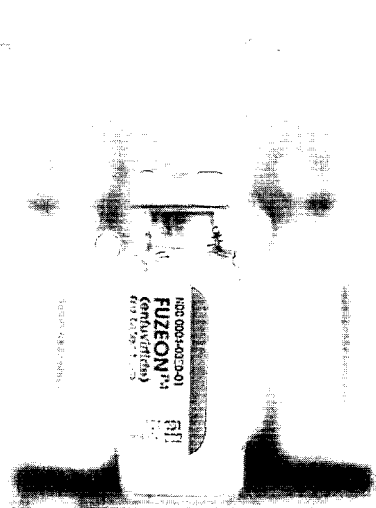


TRIMERIS

Form 10-K

Research • Innovation • Patient Support • Treatment Options • Resistance Profiles • Novel Antiviral Therapies • Scientific Expertise • Extra-Cellular Activity • GP-41 Protein Target • **FUZEON®** • Blocking Viral Entry • Strategic Marketing • Clinical Candidate • GP-120

Protein Target • Sustained Release • Alignment • Execution • FDA Full Approval • Fusion Inhibition • Discovery • Development • Unprecedented Efficacy • New Treatment Paradigm • Research • Innovation • Patient Support • Treatment Options • Resistance Profiles • Novel Antiviral Therapies • Scientific Expertise • Extra-Cellular Activity • **FIRST IN CLASS** • GP-41 Protein Target • Blocking Viral Entry • Strategic Marketing • **COMMERCIALIZATION** • Clinical Candidate • GP-120 Protein Target • Sustained Release • Alignment • Execution • FDA Full Approval • Fusion Inhibition • Discovery • Development • Unprecedented Efficacy • New Treatment Paradigm • Research • Innovation • Patient Support • Treatment Options • Resistance Profiles • Novel Antiviral Therapies • Scientific Expertise • Extra-Cellular Activity • GP-41 Protein Target • Blocking Viral Entry • Strategic Marketing • Clinical Candidate • GP-120 Protein Target • Sustained Release • Alignment • Execution • **FOCUS IS THE FUTURE** • FDA Full Approval • Fusion Inhibition • Discovery • Development • Unprecedented Efficacy • New Treatment Paradigm • Research • Innovation • Patient Support • Treatment Options • Resistance Profiles • Novel Antiviral Therapies • Scientific Expertise • Extra-Cellular Activity • **SAVE AND IMPROVE LIVES** • GP-41 Protein Target • Blocking Viral Entry • Strategic Marketing • Clinical Candidate • GP-120 Protein Target • Sustained Release • Alignment • Execution • **CREATIVITY** • FDA Full Approval • Fusion Inhibition • Discovery • Development • Unprecedented Efficacy • New Treatment Paradigm • Research • Innovation • Patient Support • Treatment Options • **ACHIEVEMENT** • Resistance Profiles • Novel Antiviral Therapies • Scientific Expertise • Extra-Cellular Activity • GP-41 Protein Target • Blocking Viral Entry • Strategic Marketing • Clinical Candidate • GP-120 Protein Target • Sustained Release • Alignment • Execution • FDA Full Approval • **TEAMWORK** • Fusion Inhibition • Discovery • Development • **INTEGRITY** • Unprecedented Efficacy • New Treatment Paradigm • Research • Innovation • Patient Support • Treatment Options • Resistance Profiles • Novel Antiviral Therapies • Scientific Expertise • Extra-Cellular Activity • GP-41 Protein Target • Blocking Viral Entry • Strategic Marketing • Clinical Candidate • GP-120 Protein Target • Sustained Release • Alignment • Execution • FDA Full Approval • Fusion Inhibition • **EXCELLENCE** • Discovery • Development • Unprecedented Efficacy • New Treatment Paradigm • Research • Innovation • Patient Support • Treatment Options • Resistance Profiles • Novel



 **FUZEON.**
enfuvirtide

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

FORM 10-K

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

**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 0-23155

TRIMERIS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of
incorporation or organization)

56-1808663
(I.R.S. Employer
Identification No.)

**3500 PARAMOUNT PARKWAY
MORRISVILLE, NORTH CAROLINA 27560**
(Address of principal executive offices, including zip code)

(919) 419-6050

Registrant's telephone number, including area code:

SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT:

None

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT:

Common Stock, \$.001 par value (Title of Class)

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 No

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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Annual Report on Form 10-K or any amendment to this Annual Report on Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 30, 2004 was approximately \$259,050,000 (based on the last sale price of such stock as reported by the Nasdaq National Market System on June 30, 2004).

The number of shares of the registrant's common stock outstanding as of March 3, 2005 was 21,806,535.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year are incorporated by reference in Part III of this Form 10-K.

TRIMERIS, INC.
FORM 10-K ANNUAL REPORT
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

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PART I

ITEM 1. BUSINESS

Statements in this Annual Report on Form 10-K that are not historical fact are forward-looking statements. These forward-looking statements include statements regarding Trimeris, Inc.'s expectations, hopes, beliefs, intentions or strategies regarding the future and are subject to a number of known and unknown risks and uncertainties, many of which are beyond our control. While we believe these statements are accurate, our business is dependent on many factors, some of which are discussed in the "Risk Factors" and "Business" sections of this Annual Report on Form 10-K. Many of these factors are beyond our control, and any of these and other factors could cause actual clinical and financial results to differ materially from the forward-looking statements made in this Annual Report on Form 10-K. The results of our previous clinical trials are not necessarily indicative of the results of future clinical trials and our previous financial results are not necessarily indicative of our future financial results. Please read the "Risk Factors" section in this Annual Report on Form 10-K for further information regarding these factors. We undertake no obligation to release publicly the results of any revisions to the statements contained in this report to reflect events or circumstances that occur subsequent to the date of this Annual Report on Form 10-K.

Overview

We are a biopharmaceutical company primarily engaged in the discovery, development and commercialization of a new class of antiviral drug treatments called fusion inhibitors. Fusion inhibitors impair viral fusion, a complex process by which viruses attach to, penetrate and infect host cells. If a virus cannot enter a host cell, the virus cannot replicate. By inhibiting the fusion process of particular types of viruses, like the Human Immunodeficiency Virus (HIV), our first commercial product and our compounds under research offer a novel mechanism of action with the potential to treat a variety of medically important viral diseases.

In September 2004, Trimeris appointed Steven D. Skolsky as its Chief Executive Officer and a member of the board of directors. Mr. Skolsky succeeds company founder Dr. Dani Bolognesi, who continues to serve as Chief Scientific Officer of the company and Vice-Chairman of the board of directors. Drawing on his general management experience and knowledge of HIV therapeutics, Mr. Skolsky is working with management to set a clear vision for the future of our Company.

We aspire to become a premier, fully integrated biotechnology company dedicated to innovating therapy for viral diseases. Our strategy is to create value for patients, caregivers, employees and shareholders by discovering, developing, and commercializing novel medicines that save and improve lives. Our strengths include a leadership position in HIV viral entry, world-class peptide drug development expertise and a proven collaborative partner.

Fuzeon is our first-generation HIV fusion inhibitor, developed in collaboration with F. Hoffmann-La Roche Ltd, or Roche. Fuzeon has been shown to inhibit HIV viral fusion with host cells by blocking the conformational rearrangement of an HIV protein called gp41. The FDA approved the use of Fuzeon in combination with other anti-HIV drugs for the treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing anti-HIV therapy. The FDA granted accelerated approval for the commercial sale of Fuzeon in 2003, and commercial sales of Fuzeon began in March that same year. Full approval was granted in October 2004. Roche also filed an application for European marketing approval of Fuzeon in September 2002 and was granted marketing approval under exceptional circumstances by the European Agency for the Evaluation of Medicinal Products, in May 2003.

Roche is manufacturing Fuzeon drug substance in its Boulder, Colorado facility. Fuzeon finished drug product is produced using this drug substance at Roche's manufacturing facility in Basel, Switzerland, and at another third party facility. Fuzeon is distributed and sold by Roche through Roche's sales and distribution network throughout the world in countries where regulatory approval has been received.

Commercial sales of Fuzeon began in the United States in March 2003. Under our collaboration agreement with Roche, we share profits equally from the sale of Fuzeon in the United States and Canada. During 2004, net sales of Fuzeon in the United States and Canada were \$85.7 million compared to \$28.3 million in 2003. Net sales outside the United States and Canada were \$49.5 million compared to \$8.2 million in 2003. Unit sales of Fuzeon are expressed in kits shipped. A kit represents a one-month supply of Fuzeon for a patient. During 2004, Roche shipped approximately 58,900 kits to paying patients in the United States and Canada.

T-1249 is a second-generation HIV fusion inhibitor that has been investigated successfully in four separate clinical trials. Phase I/II trials of T-1249 demonstrated satisfactory efficacy and safety, including in patients who had previously failed on or had developed resistance to Fuzeon. In January 2004, Roche and Trimeris announced that further clinical development of T-1249 was being put on hold due to technical challenges in achieving a formulation capable of delivering a once daily injection. The compound's safety, efficacy and tolerability were not factors affecting the decision. The clinical trial, T1249-105, was ongoing when the decision was made to put the development of T-1249 on hold. T1249-105 is now a compassionate use protocol for patients that were already receiving T-1249, as these patients have exhausted all treatment options. To date, 26 patients have completed 96 weeks of treatment with T-1249. T-1249 remains one of our next-generation drug candidates having established the proof-of-concept in overcoming Fuzeon resistant virus in the clinic. However, our focus will be to pursue formulations that will allow significantly less frequent dosing.

Our goal is to continue to strengthen and expand our fusion inhibitor franchise. In January 2004, we announced an extension of our research agreement with Roche to discover, develop and commercialize the next generation of HIV gp41 peptide fusion inhibitors. The research agreement will focus on the discovery of new HIV gp41 peptide fusion inhibitors with enhanced efficacy and resistance profiles along with the investigation of improved formulation and delivery technologies to enable less frequent and more convenient administration of peptide fusion inhibitors. Our objective is to develop an HIV gp41 fusion inhibitor that can be administered with significantly less frequent dosing. Although, the research agreement itself does not require that a specific amount be spent on any annual research plan, at their discretion, either party has the option to supplement the budgeted research plan at their own additional expense. We are still in discussions with Roche to define the research plan and budget for 2005.

We are also working with Roche to develop improvements in delivery, convenience and other enhancements to Fuzeon. We believe that any product enhancements made to Fuzeon could potentially be applied to other HIV gp41 peptide fusion inhibitors as well. We have also established discovery programs outside the scope of our Roche collaboration, which are focused on the development of small molecule HIV fusion inhibitors that could be administered orally.

Commercial Products

Fuzeon

Fuzeon is our first marketed product for the treatment of HIV. The FDA has approved the use of Fuzeon in combination with other anti-HIV drugs for the treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing anti-HIV therapy. The standard approach to treating HIV infection has been to lower viral loads by using a combination of drugs. There are twenty FDA-approved drugs for the treatment of HIV.

Fuzeon Mechanism of Action

Fuzeon is a 36-amino acid synthetic peptide that binds to a key region of an HIV surface protein called gp41. Fuzeon blocks HIV viral fusion by interfering with certain structural rearrangements within gp41 that are required for HIV to fuse to and enter a host cell.

In the HIV infection process, the gp120 surface protein is stripped away from the virus after gp120 binds to host cell receptors. Two specific regions in the gp41 protein are thus freed and can bind to one another and cause the viral membrane to fuse with the host cell membrane. If Fuzeon is present in the bloodstream, it binds tightly to one of these regions within the gp41 protein and blocks the structural rearrangement necessary for the virus to fuse with the host cell. Since the virus cannot fuse with the host cell, it cannot penetrate and release its genetic material into the cell. HIV infection of the host cell is inhibited, and HIV replication within that cell is prevented.

Commercial Results

Under our collaboration agreement with Roche, Trimeris and Roche share profits from the sale of Fuzeon in the United States and Canada equally. This amount is reported as collaboration profit (or loss), as a component of revenue, in the Statements of Operations. Collaboration profit/loss is calculated as follows: Total gross sales of Fuzeon in the United States and Canada is reduced by any discounts, returns or rebates resulting in total net sales. Net sales are reduced by costs of goods sold resulting in gross margin. Gross margin is reduced by selling, marketing and other expenses related to the sale of Fuzeon, resulting in operating income or loss. The Company's 50% share of the operating income or loss is reported as collaboration income or loss. For the year ended December 31, 2004, net sales of Fuzeon in the United States and Canada totaled approximately \$85.7 million compared to \$28.3 million in 2003. During the year ended December 31, 2004, sales, marketing and other expenses exceeded the gross margin from the sale of Fuzeon resulting in the Company's 50% share of operating loss from the sale of Fuzeon in the United States of \$16.1 million. Unit sales of Fuzeon are expressed in kits shipped. A kit represents a one-month supply of Fuzeon for a patient. For the year ended December 31, 2004, Roche shipped approximately 58,900 kits to wholesalers compared to 19,400 kits in 2003. The number of kits shipped and the resulting sales levels may not remain constant and may increase or decrease in the future.

Roche previously had an exclusive distribution arrangement with Chronimed, Inc. ("Chronimed") to distribute Fuzeon in the United States during 2003 and the first part of 2004. This exclusive arrangement terminated on April 26, 2004. Effective April 26, 2004, Fuzeon became available through retail and specialty pharmacies across the U.S. Prior to April 26, 2004, revenue from product sales had been recognized when title and risk of loss had passed to Chronimed, which was when Chronimed allocated drug for shipment to a patient. Beginning April 26, 2004, revenue is recognized when Roche ships drug and title and risk of loss passes to wholesalers.

Under our collaboration agreement with Roche, we receive a royalty based on net sales of Fuzeon, as recorded by Roche, outside the United States and Canada. For the year ended December 31, 2004, net sales of Fuzeon, as recorded by Roche, outside the United States and Canada were \$49.5 million compared to \$8.2 million in 2003. Fuzeon is commercially available in over thirty-five countries, including all the major countries in Europe.

Regulatory

In October 2004, the FDA granted full approval to Fuzeon. The FDA had previously granted accelerated approval to Fuzeon on the basis of 24-week data in March 2003. Accelerated approval is a special regulatory status designed to expedite the approval of therapies for serious or life-threatening illnesses, which provide meaningful benefit to patients over existing treatments. The traditional approval of Fuzeon was based on results from two Phase III clinical trials, called TORO-1 and TORO-2, over 48 weeks which confirmed the durable efficacy and safety of Fuzeon-based regimens.

In September 2002, Roche filed an application for European marketing approval. Roche received marketing approval under exceptional circumstances from the European Medicines Evaluation Agency, or EMEA, for use of Fuzeon in the European Union in May 2003. Roche submitted a full analysis of 48-week clinical data to the Committee for Human Medicinal Products, or CHMP, in December 2003 seeking a label change for Fuzeon. In April 2004, the CHMP recommended inclusion of the 48 week data in the label. This was followed by approval by the EMEA for this label change in June 2004. This approval allows Roche to market Fuzeon using the full 48 week safety and efficacy data. Outside the United States and the European Union, Roche has received approval and reimbursement for Fuzeon in over thirty-five countries, and is in the process of negotiating reimbursement from additional countries in which they plan to market Fuzeon.

Manufacturing

Roche manufactures the bulk drug substance of Fuzeon. Based on our progress and experience to date, we believe that Roche will be able to produce supply of Fuzeon sufficient to meet anticipated demand. If Fuzeon sales levels do not meet Roche's and our expectations, the resulting production volumes may not allow Roche to achieve their anticipated economies of scale for Fuzeon. If Roche does not achieve these economies of scale, the costs of goods for Fuzeon could be higher than previous and current expectations.

Treatment Guidelines

In October 2004, a panel of experts convened by the U.S. Department of Health and Human Services published updated anti-HIV drug treatment guidelines. For treatment-experienced patients with virologic failure, the panel recommended Fuzeon be added to an optimized background regimen and that inclusion of Fuzeon as part of new regimens can add significant antiretroviral activity.

In July 2004, International AIDS Society (IAS)—USA published anti-HIV drug guidelines that recommend Fuzeon for use in treatment-experienced HIV patients that require a change in therapy after the second, third, or fourth drug regimen failure. The guidelines caution that Fuzeon should not be delayed to a point when a patient's outcome may be compromised by the inability to combine it with other active anti-HIV drugs. The guidelines further state that there is no evidence that Fuzeon should be discontinued once a patient achieves a viral load that is below the level of detection.

While these guideline publications provide guidance to clinicians on the recommended role and use of Fuzeon in clinical practice, physicians are not required to adhere to these recommendations. The actual use of Fuzeon may or may not be positively affected by these guidelines.

Optimizing Long-Term Response

In October 2004, we announced that in a retrospective, subset analysis of 48-week data from the TORO Phase III studies, almost twice as many treatment experienced patients (52%) who took Fuzeon with an active protease inhibitor (PI) regimen (including at least two other active anti-HIV drugs) achieved undetectable levels of HIV (less than 400 copies/mL), compared to those receiving an active boosted PI regimen without Fuzeon (27%). Patients taking Fuzeon with an active boosted PI regimen also experienced a significantly greater immunological response, with a median increase of 104 CD4 cells / mm³ versus an increase of 57 CD4 cells / mm³ among patients receiving an active boosted PI regimen without Fuzeon.

Earlier Treatment with Fuzeon

Also in October 2004, Trimeris and Roche presented data showing that earlier use of Fuzeon in treatment-experienced HIV patients results in better treatment outcomes and preserves future drug options. A new analysis of the TORO studies highlighted the benefits of earlier use of Fuzeon, with regard to both virological outcomes and preservation of future treatment options. The analysis found that 33% of patients who did not receive Fuzeon in their regimen at the beginning of the TORO studies developed resistance to at least one active treatment option after week 48 or virological failure. By comparison, only 13% of those who began with a Fuzeon -based regimen experienced loss of at least one active treatment option after 48 weeks or virological failure. Furthermore, significantly more patients who were treated with a Fuzeon -based regimen from the outset of the study achieved undetectable levels of HIV (less than 400 copies/mL), compared to the control arm, even including patients who switched to a Fuzeon -based regimen after failing a regimen without Fuzeon (32% vs. 22%, respectively). These data indicate that in triple class experienced patients, a Fuzeon-based regimen should be initiated at the next switch in therapy and not delayed until failure of additional regimens.

Key Initiatives: 2004 and 2005

Given the demonstrated efficacy, durability and safety of Fuzeon-based therapies in treatment experienced patients, we are focusing much of our promotional efforts on three primary objectives; expanding the adoption and initiation of therapy with Fuzeon, enhancing retention of patients on therapy, and ensuring full access for individuals that have been prescribed Fuzeon. We have developed and are implementing specific programs that address these three objectives. These programs complement our more traditional marketing and sales efforts and specifically address the issues pertaining to chronic use of an injectable therapy.

First, Trimeris and Roche have launched two nursing support programs that are designed to augment the existing Fuzeon Answer Center—a patient treatment hotline. The first of these programs is a local nursing program that offers virtually full-time support via a dedicated nursing call center for Fuzeon patients. This support includes assistance with

drug preparation, administration, and the management of ongoing therapy. A total of 2,606 patients received assistance from the Fuzeon Answer Center in 2004, with an additional 161 patients enrolled in our outreach support initiative. The second program utilizes a team of nurses specially trained on the preparation and administration of Fuzeon, who travel to physician's offices or patient's homes to assist with the proper use of the drug. Through the first four months following initiation (as of December 31, 2004), 275 patients had received assistance from this program. We believe that these adherence and persistency initiatives will continue to improve patient retention from the first week of therapy initiation and address some of the problems identified in our field experience to date.

Second, we are initiating various promotional campaigns. At the time of commercial launch in 2003, we believed that demand for Fuzeon would exceed our ability to manufacture drug supply in the period immediately following launch. As a result, we conducted limited direct promotion to stimulate demand during 2003. Now that supply limitations have been overcome, and given the broader experience with Fuzeon among clinicians and patients, we are positioned to leverage and communicate their experiences in the broadest manner possible. Trimeris and Roche are working to heighten awareness of Fuzeon through ongoing advertising and promotional campaigns. These print and internet campaigns, directed to patients, clinicians, pharmacists, nurses, and treatment educators, were implemented across the U.S. in 2004 and will continue in various forms in 2005.

Prior to launch, only about 250 of the top 2,000 AIDS treating physicians in the U.S. had any experience with Fuzeon. This differs from other HIV medications that had very large Expanded Access Programs (EAP) prior to launch, allowing for a greater number of physicians and patients to have experience with the medication prior to approval. Because of prior supply constraints, we were unable to have an EAP of the size and scope associated with most HIV products. We believe that more than 2,500 physicians in the United States have prescribed Fuzeon through December 31, 2004. We now have the physician and patient experience that most HIV drugs experience when they launch.

To address the needs of treatment experienced patients living with HIV disease, Trimeris and Roche have launched the Fuzeon Accelerated Simultaneous Access Program (ASAP). This new initiative provides immediate access to Fuzeon for patients who are starting treatment with Fuzeon in combination with an investigational anti-HIV drug obtained through an expanded access program (EAP). Fuzeon ASAP helps to facilitate simultaneous initiation of Fuzeon with an active investigational agent in a regimen deemed medically appropriate by a physician. For patients starting treatment with Fuzeon in combination with an investigational drug in expanded access, Fuzeon ASAP provides up to a 60-day supply of Fuzeon at no cost to the patient, which consists of an immediate shipment of a 30-day supply and an additional 30-day supply if reimbursement is still pending. Upon request, patient support and adherence programs, including at-home nurse visits, are provided to help facilitate successful initiation and continuation of therapy throughout the duration of treatment. Trimeris and Roche cannot ensure access to Fuzeon for all patients beyond the initial 60 days if reimbursement is not then established. However, reimbursement assistance is available to assist in securing coverage for continued Fuzeon use.

In order to further enhance a patient's ability to initiate and remain on Fuzeon containing therapies, we have initiated a number of studies to assess the acceptance and utility of novel subcutaneous injection (SCI) delivery systems. Among these are the Becton Dickinson 31 gauge, thin-walled syringe/needle (BD31G) and the Biojector 2000 (B2000) needle-free delivery system. The BD31G is a shorter, insulin-type of needle that may afford more consistent SCI dosing that may lead to improvement in the incidence or severity of potential injection site reactions associated with Fuzeon administration. The BD31G is currently being evaluated in the Phase IIIb/IV study known as T-20 Qualité. We anticipate publishing the findings of the T-20 Qualité study later this year. The B2000 has been used to deliver millions of injections in a wide range of healthcare settings since receiving FDA approval in 1996. Since 1996, the use of the B2000 has ranged from vaccine administration to chronic therapy dosing for multiple sclerosis and diabetes. B2000 needle-free injection works by forcing medication rapidly through a tiny orifice held against the skin. This creates a fine stream of high-pressure fluid that penetrates the skin and deposits medication in the tissue beneath. Patient satisfaction surveys conducted by Bioject and their partners indicate a high preference (>70%) for drug administration via this needle-free system for a range of medications as compared to conventional needle/syringe delivery. The reasons expressed for such preference include elimination of needle-phobia, ease of injection process, and amelioration of injection site reactions. Recently, we have completed a single-dose cross-over trial with Fuzeon known as T-20 405 that was designed to compare the Bioject B2000 needle-free injection device with a standard

needle/syringe administered by a health care practitioner. Data from this trial indicates that in this setting use of the needle-free device results in bioequivalent levels of Fuzeon when compared to the standard needle/syringe. A second study has been proposed which is designed to compare the Bioject B2000 needle-free injection device with standard needle/syringe self-administration. We plan to pursue labeling discussions with regulatory agencies to allow the promotion of the administration of Fuzeon via the B2000 system.

Phase III Clinical Trials of Fuzeon

Trial Design

TORO-1, a 48-week Phase III clinical trial was conducted in North America and Brazil. The trial evaluated the activity and safety of Fuzeon in 491 HIV-infected patients who had previously used all three classes of currently-approved anti-HIV drugs. In this clinical trial, all patients received an individually optimized background regimen of three to five anti-HIV drugs other than Fuzeon. In the control group, patients received only the optimized background regimen which was selected based on the patient’s treatment history and the genotype and phenotype of the patient’s virus. A genotypic resistance analysis involves examination of the genetic sequence of the strains of virus present in the sample. A phenotypic resistance analysis involves an assessment of the ability of a drug to block infection caused by strains of a virus grown in culture.

TORO-2, a 48-week Phase III clinical trial was conducted in Western Europe and Australia. The protocol for TORO-2 was substantially similar to TORO-1 and studied 504 HIV-infected patients.

Clinical Trial Results

In 2003, we presented data from a 48-week pooled analysis of TORO-1 and TORO-2. The primary endpoint for the clinical trials, the difference in the magnitude of decrease in HIV viral loads between the Fuzeon group and the control group, was met in both the TORO-1 and TORO-2 clinical trials and was statistically significant. Additionally, the increase of CD4 count from baseline and suppression of viral load below the level of detection were also statistically significant. An increase in CD4 cell count is indicative of immune system restoration and is important in reducing the likelihood of opportunistic infection. The following table summarizes the 48-week pooled data, calculated in accordance with FDA guidelines. Patients in the control group that experienced virologic failure after eight weeks on therapy were allowed to add Fuzeon, with or without changing their background regimen. The last observations for viral load and CD4 cell count prior to the regimen change for these patients was used for analysis of the group response. All data depicted below were statistically significant. Stated otherwise, the statistical measures, p-values, for all the data shown below were less than 0.05. In both of the trials, the p-values for the primary endpoints were less than 0.0001.

	POOLED	
	Fuzeon	Control
Primary Endpoint		
Mean decrease in viral load (log ₁₀)	1.48	0.63
Mean decrease in viral load (% reduction)	97	77
Incremental reduction of viral load (log ₁₀)	0.85	—
Secondary Endpoints		
Mean increase in CD4 cell count (cells/cubic millimeter)	91	45
Patients achieving viral load below 400 copies (%)	30	12
Patients achieving viral load below 50 copies (%)	18	8
Patients achieving viral load reduction greater than 1.0 log ₁₀ (%)	37	17
Patients experiencing virologic failure (%)	52	78
Other Data		
Patients discontinuing from trial (%)	27	25
Patients discontinuing from trial for virological failure (%)	6	10
Patients discontinuing from trial for injection site reactions (%)	4	—
Patients switching from control to Fuzeon (%)	—	66

The response of patients in the Fuzeon group surpassed that of the control group across all subgroups studied, including age, race, baseline CD4 count and baseline viral load. In both treatment groups, greater viral load reduction was seen in patients who had more active drugs in their optimized background regimen, less treatment experience and less advanced disease, defined as a patient with a CD4 count greater than 100 cells.

The superiority of virological response achieved with Fuzeon-based regimens was observed regardless of the number of active agents in the background regimen. Among patients whose virus was sensitive to one drug in the background regimen, 29% of patients in the Fuzeon group achieved levels of HIV below 400 copies, compared to 7% in the control group. Among patients whose virus was sensitive to two active agents in the background regimen, 39% of patients achieved levels of HIV below 400 copies in the Fuzeon group at 48 weeks compared to 15% in the control group. These results were statistically significant.

48-Week Efficacy Data

Combined TORO-1 and TORO-2 48-week data showed that 30% of patients in the Fuzeon group had undetectable levels of HIV, defined as less than 400 copies per milliliter of blood, compared to 12% in the control group. In addition, 80% of the patients in the Fuzeon group who achieved a reduction of HIV viral load to below 400 copies per milliliter of blood at 24 weeks maintained this response at 48 weeks, compared to 70% in the control group. Thirty-seven percent of patients in the Fuzeon group maintained at least a 90%, or 1.0 log₁₀, reduction in blood levels of HIV at 48 weeks compared to 17% of patients in the control group. Previous clinical studies in HIV have shown that a 68%, or 0.5 log₁₀ reduction in HIV levels may be associated with clinical benefit to patients. On average, patients in the Fuzeon group experienced an increase of twice as many CD4 immune cells from baseline as those achieved by patients in the control group at 48 weeks. In addition, the median duration of virological benefit in the Fuzeon group of 32 weeks was approximately three times longer than the median duration of 11 weeks in the control group. All of these results were highly statistically significant.

96 Week Efficacy Data

In July 2004, we announced data from patients in TORO-1 and TORO-2 that have completed 96 weeks of treatment with Fuzeon. Fuzeon durably suppresses HIV and provides continuous increases in CD4 cells over a period of 96 weeks.

Additional analyses indicate that there is a distinct disadvantage to patients who wait to initiate Fuzeon based therapy. In the TORO study, patients originally randomized to the control group were allowed to add Fuzeon to a re-optimized regimen at virological failure or after 48 weeks on study. Data continued to be collected from these patients that we have now defined as the "switch" patient. Patients in the Fuzeon treatment group from the outset of the studies achieved a mean viral load reduction in blood levels of HIV of 2.1 log₁₀ through 96 weeks of treatment. This reduction was markedly greater than that achieved by the "switch" patients who achieved a mean reduction in viral load at 96 weeks of 1.1 log₁₀. Patients in the Fuzeon treatment group saw continuous improvements in CD4 cells over the study period with the mean CD4 increase from baseline of 166 cells per cubic millimeter at week 96 compared to 116 cells per cubic millimeter in the "switch" patient group.

More than half of treatment-experienced patients who began using Fuzeon at the outset of the study were successful in completing 96 weeks of treatment.

Impact of Fuzeon on Activities of Daily Living

Data collected from a survey of patients in TORO-1 and TORO-2 suggest that subcutaneous delivery of Fuzeon was well-accepted by a majority of patients after 48 weeks of treatment.

Conducted among 492 patients in TORO-1 and TORO-2 at week 48, the survey assessed whether the subcutaneous delivery of Fuzeon influenced a patient's ability to conduct normal activities of daily living, or ADL. Most patients reported little or no impact of injection on familiar routines of work (81%), sleep (90%), social life (84%), travel (65%), intimacy (77%), or privacy (69%). These findings suggest that motivated patients who receive instruction were able to manage self-injection with little difficulty and without the need for substantial changes in daily routines.

The survey found that 67% of patients scored self-injection as “very easy” or “easy.” Other responses were “neutral” (18%), “difficult” (13%) and “very difficult” (3%). Most patients also rated as “very easy” or “easy” various activities relating to the preparation and usage of Fuzeon, such as administration (67%), dissolution of study drug (78%), refrigeration (79%) and disposal of needles/syringes (79%).

Results from this survey after 48 weeks of treatment suggest that subcutaneous injection of Fuzeon was manageable for a majority of patients. Data was collected from 581 patients remaining on treatment at 24 weeks. After 24 weeks, most patients reported little or no impact of injection on familiar routines of work (85%), sleep (90%), social life (84%), travel (68%), intimacy (77%), privacy (70%), or appearance (75%).

Safety Results

The following safety results reflect the data included in the original FDA-approved package insert for Fuzeon. The overall safety profile of Fuzeon is based on 1,188 subjects who received at least one dose of Fuzeon during various clinical trials. This includes 1,153 adults, 608 of whom received the recommended dose for greater than 24 weeks, and 35 pediatric subjects. Assessment of adverse events is based on the pooled data from the two Phase III studies, TORO-1 and TORO-2.

Local Injection Site Reactions. Local injection site reactions, or ISRs, were the most frequent adverse events associated with the use of Fuzeon. In TORO-1 and TORO-2, 98% of subjects had at least one local ISR. Three percent of subjects discontinued treatment with Fuzeon because of ISRs. The majority of ISRs were associated with mild to moderate pain at the injection site, redness, induration and the presence of bumps. Nine percent of patients had local reactions that required analgesics or limited usual activities.

Other Adverse Events. Serious allergic reactions have been attributed to Fuzeon in less than 1% of patients and in some cases have recurred upon subsequent re-dosing. The events most frequently reported in patients in the Fuzeon group, excluding injection site reactions, were diarrhea (26.8%), nausea (20.1%), and fatigue (16.1%). These events were also commonly observed in the control group and occurred more frequently: diarrhea (33.5%), nausea (23.7%), and fatigue (17.4%).

An increased rate of bacterial pneumonia was observed in the Fuzeon group in TORO-1 and TORO-2, compared to the control group. There were 4.68 pneumonia events per 100 patient-years in the Fuzeon group, versus 0.61 events per 100 patient-years in the control group. Approximately half of the study subjects with pneumonia required hospitalization. One subject death in the Fuzeon group was attributed to pneumonia. Risk factors for pneumonia included low baseline CD4 cell count, high baseline viral load, intravenous drug use, smoking and a prior history of lung disease. It is unclear if the increased incidence of pneumonia was related to Fuzeon use. The study design, which allowed patients in the control group that experienced virologic failure after eight weeks on therapy to change their regimen to a Fuzeon containing regimen, may have contributed to this observation. Trimeris and Roche are studying this further in an epidemiology study of pneumonia in HIV-infected patients on antiretroviral therapy.

48-week Safety Data

The 48-week analysis of safety data from the combined TORO-1 and TORO-2 trials revealed that, on at least one study visit, 98% of patients in the Fuzeon group experienced at least one localized ISR, such as pain/discomfort, redness, hardness, bumps, itching or bruising. Less than 5% of patients discontinued treatment due to ISRs. Due to a substantial difference in the duration of treatment for patients in the Fuzeon group compared with the control group, the rate of adverse events was measured as number of events per 100 years of patient experience. Aside from ISRs, the incidence of the three most common adverse events was less frequent in the Fuzeon group compared to the control group. Adverse events included diarrhea (38 per 100 patient-years in the Fuzeon group vs. 73 in the control group), nausea (27 vs. 50, respectively) and fatigue (24 vs. 38, respectively). Other common signs and symptoms reported at a lower frequency in the Fuzeon group than the control group were headache, insomnia, and vomiting. Among events reported more commonly in the Fuzeon group compared to the control group were pain or numbness in the peripheral nervous system, weight decrease, decreased appetite, swelling of lymph nodes and pneumonia. Other than treatment-emergent eosinophilia, grade 3 and grade 4 laboratory abnormalities, when adjusted for exposure, generally showed higher rates in the control group compared to the Fuzeon group. The eosinophilia was not associated with clinical events of hypersensitivity in either treatment group.

96-week Safety Data

No new safety issues were identified in the 96-week analysis, and there was no evidence of long-term or cumulative toxicities. Rather, patients in the Fuzeon treatment group experienced less diarrhea, nausea and fatigue, side effects often associated with anti-HIV drug therapy. The frequency and severity of injection site reactions remained constant and did not increase in severity over 96 weeks.

Current and Future Fuzeon Clinical Trials

We expect to continue our ongoing clinical trials as well as initiate new clinical trials with Fuzeon during 2005. These trials will focus on the following primary needs for current and potential Fuzeon patients: evaluation of new delivery systems that may reduce needle-phobia and/or ameliorate the rate/severity of injection site reactions; the effect of Fuzeon in patients with less treatment experience than in our TORO trials; and the potential for reducing other anti-HIV drug related toxicities and/or adverse events. The table below summarizes our current on-going, or recently completed, clinical trials.

<u>Name</u>	<u>Description</u>
T20-401	Pilot trial of once daily administration of Fuzeon vs. standard twice daily regimen.
T20-405	Single dose crossover study comparing needle-free injection device vs. standard needle/syringe administered by a health care professional.
ENF-404	Multi-dose crossover study comparing needle-free injection device vs. standard needle/syringe with self-administration.
T20 Qualité	Quality of life study of standard needle and syringe vs. 31g needle and insulin syringe.
T20 Intense	Comparative trial in earlier line patients assessing ongoing Fuzeon use compared to an induction/maintenance approach.
T20 SwitchTox	An assessment of the substitution of ARV's associated with undesirable side-effects/toxicities in favor of Fuzeon.

The T20-405 and ENF-404 trials involve the use of the currently approved Biojector 2000 needle-free injection device manufactured by Bioject Medical Technologies, Inc., described above.

Collaborations

Roche

We have entered into a worldwide agreement, as amended, with Roche to develop and market Fuzeon and T-1249, or a replacement compound. Our agreement with Roche grants them an exclusive, worldwide license for Fuzeon and T-1249 and certain other peptide compounds in the field of HIV. Roche may terminate its license as a whole or for a particular country or countries in its sole discretion with advance notice. We will share development expenses and profits for Fuzeon and T-1249, or a replacement compound, in the United States and Canada equally with Roche. Outside of the United States and Canada, Roche will fund all development costs and pay us royalties on net sales of Fuzeon and T-1249, or a replacement compound, for a specified term. In addition, the agreement calls for Trimeris to receive up to \$68 million in upfront and milestone payments, of which we have achieved \$28.3 million as of December 31, 2004. Our collaboration with Roche is a contractual one and is not a separate legal entity. Consequently, we have no investment in any collaboration entity. All assets used in the manufacture of Fuzeon by Roche are owned and operated by Roche.

Roche is responsible for the sales, marketing and distribution of Fuzeon; all sales are made through their sales force. The results of our commercial operations are reported on our financial statements as "Collaboration profit/loss" which is calculated as follows: Total gross sales of Fuzeon by Roche in the United States and Canada is reduced by estimates for discounts, rebates and returns resulting in total net sales. Net sales are reduced by costs of goods sold resulting in gross margin. Gross margin is reduced by selling and marketing expenses and other expenses related to the sale of Fuzeon, resulting in operating income or loss. The Company's 50% share of the operating income or loss is

reported as collaboration income or loss. This information is disclosed below in "Management's Discussion and Analysis of Financial Condition and Results of Operation—Critical Accounting Policies—Collaboration Loss."

Substantially all of the data used to calculate the Collaboration income or loss is derived from information provided by Roche. We compare sales amounts to data from third party services such as IMS for accuracy. Roche's estimate of discounts, rebates and returns is first reviewed by Trimeris marketing personnel based on their knowledge of the payor mix and other factors and is then reviewed by the Trimeris finance staff. The collaboration has a North American Joint Marketing Committee, or NAJMC, that oversees the commercialization activities related to Fuzeon. The NAJMC consists of representatives from Roche and Trimeris. The NAJMC reviews the budgets for the direct marketing costs and Roche sales force costs charged to Fuzeon and the costs of departments at Roche that devote time on Fuzeon-related issues, such as government affairs and reimbursement. The actual costs are reviewed by the Trimeris NAJMC members and compared to budgeted amounts prior to inclusion in collaboration income/loss. In the event that we are not satisfied after reviewing the actual costs, we will withhold payment until presented with satisfactory documentation or appropriate adjustments to the charges are made. Historically the calculation of the collaboration income/loss has been consistent from period to period but we cannot guarantee that fluctuations will not occur.

We recognize 50% of the total Collaboration profit/loss, which includes estimates made by and recorded by Roche for reductions to gross sales for expected returns of expired products, government rebate programs, such as Medicaid reimbursements, and customer incentives, such as cash discounts for prompt payment. Estimates for government rebate programs and cash discounts are determined by Roche based on contractual terms, historical information from Roche's anti-HIV drug portfolio, and Roche's expectations regarding future utilization rates for these programs. Estimates for product returns are based on an on-going analysis of industry return patterns and historical return patterns by Roche for its anti-HIV drug portfolio. This includes the purchase of third-party data by Roche to assist Roche and us in monitoring channel inventory levels and subsequent prescriptions for Fuzeon. We also monitor the activities and clinical trials of our key competitors and assess the potential impact on future Fuzeon sales and return expectations where necessary. Expected returns for Fuzeon are generally low as Fuzeon has a high Wholesale Acquisition Cost, or WAC, compared to other anti-HIV drugs, and requires significantly more storage space than other anti-HIV drugs due to the size of a monthly kit because Fuzeon requires twice daily injections. Consequently wholesalers tend to stock only the necessary volumes of Fuzeon inventory. We believe that wholesalers hold about three weeks supply that has been sold by Roche to wholesalers, but not yet purchased by patients. The current shelf life of Fuzeon is 36 months. Roche reviews the estimates discussed above on a quarterly basis and adjusts estimates as appropriate for changes in facts or circumstances. This estimate reduces our share of collaboration income or loss under our collaboration agreement.

We have also entered into a research agreement with Roche to discover, develop and commercialize additional anti-HIV gp41 fusion inhibitor peptides. Pursuant to the agreement, Trimeris and Roche agreed to share the worldwide research, development and commercialization expenses and profits from the worldwide sales of anti-HIV gp41 fusion inhibitor peptides created after July 1, 1999. Although, the research agreement itself does not require that a specific amount be spent on any annual research plan, at their discretion, either party has the option to supplement the budgeted research plan at their own additional expense. At present we are still in discussions with Roche to define the research plan and budget for 2005. Our agreement with Roche grants them an exclusive, worldwide license for these peptides. Either party may terminate the agreement as a whole or for a particular drug, country or countries in its sole discretion with advance notice. In 2004, we announced that Trimeris and Roche had renewed the joint research obligations under the agreement through December 31, 2005.

Array Biopharma

In 2001, we entered into an agreement with Array BioPharma, Inc., or Array, to discover orally-available small molecule fusion inhibitors of HIV and respiratory syncytial virus, or RSV. We will initially screen a library of small molecule compounds provided by Array against HIV and RSV fusion protein targets. A small molecule is defined as a molecule that has a molecular weight of less than 2000 daltons. Array will use its drug discovery platform to select the optimal lead compounds. We will collaborate with Array to identify preclinical candidates, and we will be responsible for further development of those candidates. Array will provide the initial library of compounds on a non-exclusive basis and will work exclusively with us on the HIV fusion protein targets during the term of the collaboration. We will work with Array on a non-exclusive basis on these targets. Array will be entitled to receive payments and royalties

based on achievement of certain developmental and commercial milestones. In June 2004, the companies announced the renewal of this research agreement. As part of this renewed agreement, Trimeris will screen small molecule compounds created by Array against HIV entry inhibitor targets. The terms of the agreement are substantially similar to those of the initial agreement, signed in 2001.

Neokimia, Inc.

In 2002, we entered into an agreement with Neokimia Inc., or Neokimia, to discover and develop small molecule HIV fusion inhibitors. We will initially screen a library of small molecule compounds provided by Neokimia. Neokimia will use its proprietary drug discovery platform to optimize lead compounds. We will collaborate with Neokimia to identify preclinical drug candidates. Neokimia will provide the initial library of compounds on a non-exclusive basis and will work exclusively with us on the HIV gp41 fusion protein target during the term of the collaboration. We exercised our option to select an additional target to add to the collaboration related to HIV fusion. We will work with Neokimia on a non-exclusive basis on these targets. We, with Neokimia, will equally fund all research activities through the declaration of a development candidate. We will be responsible for all future clinical development, regulatory and commercial activities on a worldwide basis. Neokimia will be entitled to receive payments and royalties on net product sales based on achievement of certain developmental and commercial milestones. Neokimia also has an option to co-fund clinical development activities for development compounds through the end of Phase I human clinical trials, in exchange for increased royalties on net product sales. In December 2003, Neokimia merged with Tranzyme, Inc., or Tranzyme, and Tranzyme acquired Neokimia's rights and obligations under the 2002 agreement.

Research

As part of our business strategy, we conduct research and development activities both internally and with our collaborative partners. Our research efforts focus primarily on treating viral diseases by identifying novel mechanisms for blocking viral fusion. In total, our research and development (R&D) expenses for 2004 were \$21.3 million, compared with \$36.8 million for 2003 and \$51.2 million for 2002.

Viral Fusion Inhibitors

Viruses utilize the intracellular machinery of a cell to make components that are necessary for viral replication. Viruses cause disease when their uncontrolled replication interferes with the basic function of the invaded cells. The attraction of a virus to the cell it infects is based upon a specific interaction between the receptors on the surface of the target cell and the virus.

Viral infection of cells occurs through a cyclical, multi-step process, consisting of viral entry, intracellular replication and release. Once the viral genetic material is inside the target cell, this material then directs the target cell to produce viral proteins and enzymes that are necessary to complete the replication cycle of the virus. When viral replication is completed, newly formed viruses are released from the cell. These newly formed viruses spread by infecting new cells. The cycle is repeated when the replicated virus infects the new cells.

Currently marketed antiviral therapies typically target specific enzymes that viruses use to replicate. Other compounds that are in clinical development, including ours, focus on the entry of the viruses into target cells. We have pioneered the discovery and development of a new class of anti-HIV compounds, called fusion inhibitors, that prevents one of the crucial steps in viral entry from occurring by blocking the conformational rearrangement of HIV required to allow HIV to fuse with a host cell. Fuzeon is a first-generation fusion inhibitor that prevents HIV from entering and infecting cells. T-1249 is a rationally designed second-generation fusion inhibitor. Our third generation, or next generation peptides, are also rationally designed peptides with the goal of being long-acting and having an enhanced resistance profile as compared to Fuzeon.

Novel HIV gp41 Peptide Fusion Inhibitors. One of the goals of the research agreement with Roche is to identify technologies that improve our anti-HIV peptides. This could be achieved through improving the potency and/or the time that a peptide remains active in the bloodstream, commonly referred to as the molecule's half-life. This improved

half-life may be achieved by attaching additional molecular entities to a peptide. The resulting dosing regimen could be significantly less frequent than the current twice-daily subcutaneous injection that Fuzeon requires.

Another goal of the research agreement is to discover a peptide with an enhanced resistance profile. This profile could include effectiveness against HIV strains that may become resistant to other HIV gp41 peptide fusion inhibitors. A second resistance profile improvement would be a peptide that makes it more difficult for HIV to generate resistant virus strains to the peptide, therefore improving the durability of the peptide in therapy. We believe these resistance profile improvements could lead to additional market acceptance of such a peptide.

With respect to our next generation peptide program, our intention is to identify a next generation fusion inhibitor candidate that has an optimized virological and pharmacokinetic profile as well as to identify a sustained-release formulation for that peptide that will allow significantly less frequent dosing. We, together with our partner Roche, are currently researching several promising anti-viral peptides, with the hope of selecting one of these peptides for advanced pre-clinical studies. In the near future, we plan to select a lead candidate and a back-up candidate that will proceed to advanced formulation studies. The results of these studies will determine how rapidly we move towards naming a clinical candidate.

Other Research Programs

Fuzeon Product Optimization. We believe we may be able to improve upon the potential product attributes of Fuzeon by enhancing methods of delivery. Fuzeon is currently delivered via a twice-daily subcutaneous injection. We believe that incremental improvements in delivery convenience could enhance its market acceptance resulting in enhanced adoption, broader use and improved therapy adherence over time. We are currently working with Roche to explore more convenient delivery, such as use of smaller gauge needles, needle-free delivery devices, multi-dose vials, and other enhancements. We continue to evaluate the ability to administer Fuzeon once daily with the current formulation in the clinical trial known as T20-401. While we are no longer actively pursuing once daily dosing formulations of Fuzeon with our internal research efforts, we continue to evaluate the technologies of third parties that might allow once daily dosing.

Small Molecule HIV Fusion Inhibitors. We also have discovery programs that are focused on orally available small molecule HIV fusion inhibitors. The development of small molecule HIV fusion inhibitors is not within the scope of our collaboration with Roche. We have entered into two agreements with Array BioPharma, Inc., and Neokimia, Inc., to discover small molecule fusion inhibitors of HIV.

Sales, Marketing and Distribution

Trimeris does not exercise direct control over the sales, marketing or distribution of Fuzeon. We currently rely on Roche for the sales, marketing and distribution of Fuzeon and, if they are approved by the FDA, any other drug candidates covered by our collaboration with Roche, in accordance with the marketing terms contained in our development and license agreement with Roche. Roche may terminate this agreement at any time with advance notice. If Roche fails to market Fuzeon or our other drug candidates, if approved, adequately, we do not have the ability under our collaboration agreement to establish our own sales, marketing or distribution capabilities. If Roche ceases to market Fuzeon or our other drug candidates by terminating our agreement, and we were unable to reach agreement with one or more other marketing partners, we would be required to develop internal sales, marketing and distribution capabilities. We may not be able to establish cost-effective sales, marketing or distribution capabilities or make arrangements with third parties to perform these activities on acceptable terms on a timely basis, if at all. This would have a material adverse effect on our business, financial condition, results of operations and the market price of our stock.

Our agreement with Roche and any sales, marketing or distribution arrangements we establish with other parties gives Roche, and may give those parties, significant control over important aspects of the commercialization of Fuzeon and our other drug candidates, including:

- market identification;

- marketing methods;
- pricing;
- drug positioning;
- composition and deployment of sales force; and
- promotional effort and activities.

We may not be able to control the amount or timing of resources that Roche or any third party may devote to our drug candidates.

Roche previously had entered into an exclusive distribution arrangement with Chronimed, Inc. to distribute Fuzeon in the United States during the initial commercial launch in 2003 and the first part of 2004. This exclusive arrangement terminated in April 2004 and Fuzeon became available through retail and specialty pharmacies across the U.S. This development has enhanced and simplified access to Fuzeon for patients and their healthcare providers by allowing physicians to write prescriptions for Fuzeon in the same manner as they prescribe other medications. Furthermore, patients are now able to get Fuzeon from the retail or specialty pharmacy of their choice, including Chronimed.

Patents, Proprietary Technology and Trade Secrets

Our success will depend, in part, on our ability, and the ability of our collaborators or licensors, to obtain protection for our products and technologies under United States and foreign patent laws, to preserve our trade secrets and to operate without infringing the proprietary rights of third parties.

We own or have exclusive licenses to 35 issued United States patents, numerous pending United States patent applications, and certain corresponding foreign patents and patent applications. Most of our United States patents issued to date are currently set to expire between 2013 and 2022.

We also rely on trade secrets, know-how and other proprietary information, which we seek to protect, in part, through the use of confidentiality agreements with employees, consultants, advisors and others. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized disclosure. Our employees, consultants or advisors could disclose our trade secrets or proprietary information to competitors, which would be detrimental to us.

We have an exclusive, worldwide, royalty-bearing license from the New York Blood Center under certain U.S. and foreign patents and patent applications relating to certain HIV peptides. Under this license we are required to pay the New York Blood Center a royalty equal to one-half of one percent of the net sales of Fuzeon up to \$100 million in a calendar year, and one-quarter of one percent of net sales in excess of \$100 million for that calendar year. For 2004, we recognized expense of approximately \$575,000 for royalty payments due to the New York Blood Center related to the sales of Fuzeon.

Competition

We are engaged in segments of the biopharmaceutical industry, including the treatment of HIV, that are intensely competitive and change rapidly. Fuzeon and any other HIV fusion inhibitors we may develop will compete with numerous existing therapies. For example, at least 20 drugs are currently approved in the United States for the treatment of HIV. In addition, a number of companies are pursuing the development of novel pharmaceutical products that target HIV. Some companies, including several multi-national pharmaceutical companies, are simultaneously marketing several different drugs and may therefore be able to market their own combination drug therapies. We believe that a significant number of drugs are currently under development and will become available in the future for the treatment of HIV.

Fuzeon is delivered via twice daily subcutaneous injections, each delivering 90 mg of Fuzeon. The other approved anti-HIV drugs are delivered orally at various dosing intervals. We believe that this delivery method is one factor that

may limit its uptake as compared to other competing drugs. In addition, the Wholesale Acquisition Cost, or WAC, of Fuzeon is approximately \$21,000 for one year of therapy. This price is significantly higher than any of the other approved anti-HIV drugs. Fuzeon's price relative to other approved anti-HIV drugs may also limit patient demand.

The need for drugs that have a novel mechanism of action has stimulated interest in the inhibition of HIV entry into the cell. We believe that several companies are developing or attempting to develop HIV drug candidates that inhibit entry of the virus into the cell via mechanisms other than fusion. Several companies including GlaxoSmithKline PLC, Pfizer, Inc., and Schering Plough Corp, are developing CCR5 inhibitors that inhibit entry of the virus into the cell through a different mechanism. These compounds are in various stages of development and none are currently approved by the FDA.

The standard of care for the treatment of HIV is to administer a regimen that combines drugs from each of the different classes of anti-HIV drugs. In the event drug candidates are approved that are effective against HIV virus that has become resistant to currently approved drugs, we believe that using these drugs in combination with Fuzeon may provide patients with additional treatment options that do not currently exist. These drugs may be both competitive with Fuzeon in some cases, and synergistic with Fuzeon in other cases.

We believe that there is a significant future market for therapeutics that treat HIV and other viral diseases. However, we anticipate that we will face intense and increasing competition in the future as new products enter the market and advanced technologies become available. Existing products or new products for the treatment of HIV developed by our competitors may be more effective, less expensive or more effectively marketed than any products eventually commercialized by us.

Many of our competitors have significantly greater financial, technical and human resources than we have and may be better able to develop, manufacture, sell, market and distribute products. Many of these competitors have products that have been approved or are in late-stage development. These competitors also operate large, well-funded research and development programs. In addition, smaller companies may prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Furthermore, academic institutions, governmental agencies and other public and private research organizations are becoming increasingly aware of the commercial value of their inventions for the treatment of HIV and are more actively seeking to commercialize the technology they have developed.

New developments in our areas of research and development are expected to continue at a rapid pace in both industry and academia. If our drug candidates are successfully developed and approved, we will face competition based on:

- the safety and effectiveness of the products;
- the convenience of the dosing regimen;
- the timing and scope of regulatory approvals;
- availability of manufacturing, sales, marketing and distribution capabilities;
- reimbursement coverage;
- price; and
- patent position.

Our competitors may develop more effective or more affordable technology or products, or achieve earlier patent protection, product development or product commercialization than we can. Our competitors may succeed in commercializing products more rapidly or effectively than we can, which could have a material adverse effect on our business, financial condition, results of operations and the market price of our stock.

Government Regulation

Human pharmaceutical products are subject to lengthy and rigorous preclinical testing and clinical trials and other extensive, costly and time-consuming procedures mandated by the FDA and foreign regulatory authorities. The regulatory approval process includes:

- the establishment of the safety and effectiveness of each product candidate; and

- confirmation by the FDA that good laboratory, clinical and manufacturing practices were maintained during testing and manufacturing.

This process typically takes a number of years, depending upon the type, complexity and novelty of the pharmaceutical product. This process is expensive and gives larger companies with greater financial resources a competitive advantage over us.

The steps required by the FDA before new drugs may be marketed in the United States include:

- preclinical studies;
- the submission to the FDA of a request for authorization to conduct clinical trials on an investigational new drug, or IND;
- adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for its intended use;
- adequate control of a reliable manufacturing process;
- submission to the FDA of a New Drug Application, or NDA; and
- review and approval of the NDA by the FDA before the drug may be shipped or sold commercially.

In the United States, preclinical testing includes both culture and animal laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation. Certain laboratories involved in preclinical testing must comply with FDA regulations regarding good laboratory practices. Preclinical testing results are submitted to the FDA as part of the IND and, unless there is objection by the FDA, the IND will become effective 30 days following its receipt by the FDA. Submission of an IND does not guarantee that human clinical trials will ever commence.

Clinical trials involve the administration of the investigational drug to healthy volunteers or to patients under the supervision of a qualified principal investigator. These clinical trials typically are conducted in three sequential phases, although the phases may overlap with one another.

Phase I clinical trials represent the initial administration of the investigational drug to a small group of healthy human subjects or, more rarely, to a group of selected patients with a targeted disease or disorder. The goal of Phase I clinical trials is typically to test for safety, dose tolerance, absorption, bio-distribution, metabolism, excretion and clinical pharmacology.

Phase II clinical trials involve a small sample of the actual intended patient population and seek to assess the effectiveness of the drug for the specific targeted indications, to determine dose tolerance and the optimal dose range and to gather additional information relating to safety and potential adverse effects.

Phase III clinical trials are initiated to establish further clinical safety and effectiveness of the investigational drug in a broader sample of the general patient population at geographically dispersed study sites in order to determine the overall risk-benefit ratio of the drug and to provide an adequate basis for all labeling for promotion and use. The results of the research and product development, manufacturing, preclinical testing, clinical trials and related information are submitted to the FDA in the form of an NDA for approval of the marketing and shipment of the drug.

The FDA closely monitors the progress of each of the three phases of clinical trials and may, at its discretion, reevaluate, alter, suspend or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. Once Phase III trials are completed, drug developers submit the results of preclinical studies, clinical trials and information on the manufacturing of the drug to the FDA in the form of an NDA for approval to commence commercial sales. Once submitted, the FDA is required to take action on an NDA within a specified period of time. FDA action may be any one of the following: approval to market the drug, request for additional information or denial of approval. FDA approvals may not be granted on a timely basis, or at all. Furthermore, the FDA may prevent a drug developer from marketing a product under a label for its desired indications, which may impair commercialization of the product. Similar regulatory procedures must be complied with in countries outside the United States.

Congress enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA), in part, to ensure the timely availability of safe and effective drugs, biologics and medical devices by expediting the FDA review process for new products. Among other things, FDAMA establishes a statutory program for so-called fast track products, which are defined as new drugs or biologics intended for the treatment of serious or life-threatening conditions that demonstrate the potential to address unmet medical needs for such conditions. Under the fast track program, the sponsor of the new drug or biologic may request the FDA to designate the drug or biologic as a fast track product at any time during clinical development of the product. FDAMA also provides for "rolling" submission of an NDA for a fast track product, where a sponsor may submit portions of the application to the FDA on a rolling basis. Drugs designated for the fast track development program may be considered for priority review and for accelerated approval based on an endpoint other than that required for full approval.

Our potential drug candidates may never receive commercialization approval in any country on a timely basis, or at all, even after substantial time and expenditures. If we are unable to demonstrate the safety and effectiveness of our product candidates to the satisfaction of the FDA or foreign regulatory authorities, we will be unable to commercialize our drug candidates. This would have a material adverse effect on our business, financial condition, results of operations and market price of our stock. Even if regulatory approval of a drug candidate is obtained, the approval may limit the indicated uses for which the drug candidate may be marketed.

We, Roche and any existing or potential future collaborative partners are also subject to various federal, state and local laws and regulations relating to:

- safe working conditions;
- laboratory and manufacturing practices;
- the experimental use of animals; and
- the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents.

Compliance with these laws, regulations and requirements may be costly and time-consuming and the failure to maintain such compliance by us or our existing and potential future collaborative partners could have a material adverse effect on our business, financial condition and results of operations.

The FDA gave fast track designation for the treatment of HIV-infected individuals to Fuzeon in January 1999 and to T-1249 in May 1999. In October 2004, the FDA granted Fuzeon full approval.

Drugs are also subject to extensive regulation outside the U.S. In the European Union, there is a centralized approval procedure that authorizes marketing of a product in all countries in the European Union (which include most of the major countries in Europe). If this procedure is not used, under a decentralized system an approval in one country of the European Union can be used to obtain approval in another country of the European Union under simplified application process. After approval under the centralized procedure, pricing and reimbursement approvals are also required in most countries. Fuzeon received full approval for use in the European Union in June 2004.

Third-Party Reimbursement and Healthcare Reform Measures

In the United States and elsewhere, sales of prescription drugs depend, in part, on the consumer's ability to obtain reimbursement for the cost of the drugs from third-party payors, such as private and government insurance programs. Third-party payors are increasingly challenging the prices charged for medical products and services in an effort to promote cost containment measures and alternative health care delivery systems. Because of the high cost of the treatment of HIV, many state legislatures are also reassessing reimbursement policies for these therapies. If third-party payor reimbursements for any drugs we commercialize are not available or are not available at a level that will allow us or our potential collaborative partners to sell these drugs on a competitive basis, our results of operations will be materially and adversely affected. In addition, an increasing emphasis in the United States on the reduction of the overall costs of health care through managed care has increased and will continue to increase the pressure to reduce the prices of pharmaceutical products. The announcement and/or adoption of these types of proposals or efforts could also

materially and adversely affect our business, since the amount of revenues that we may potentially be able to generate in the future for any products we may commercialize could affect an investor's decision to invest in us, the amount of funds we decide to spend now on our development and clinical trial efforts, and/or our decision to seek regulatory approval for certain drug candidates.

Recently, several major pharmaceutical companies have offered to sell their anti-HIV drugs at or below cost to certain countries in Africa, which could adversely affect the reimbursement climate, and the prices that may be charged, for HIV medications in the United States and the rest of the world. Third-party payors could exert pressure for price reductions in the United States and the rest of the world based on these offers to Africa. This price pressure could limit the amount that we would be able to charge for our drugs.

The WAC of a one year's supply of Fuzeon in the United States is approximately \$21,000. This price is significantly higher than any of the other approved anti-HIV drugs. Furthermore, the indication approved by the FDA is for the use of Fuzeon in combination with other anti-HIV drugs. Physicians may not readily prescribe Fuzeon due to cost-benefit considerations when compared with other anti-HIV drug treatments. Higher prices could also limit our ability to receive reimbursement coverage for our drugs from third-party payors, such as private or government insurance programs. If Roche is unable to obtain and maintain reimbursement from a significant number of third-party payors, it would have a material adverse effect on our business, financial condition and results of operations.

Roche has made significant progress in achieving reimbursement from the various payors in the United States. Currently Fuzeon is covered by Medicaid in all 50 states, 43 of the state and territorial AIDS Drug Assistance Programs, or ADAPs, and a majority of private insurers. However there are reimbursement challenges remaining. Some of the payors require patients to meet minimum medical requirements, such as CD4 cell levels, to receive reimbursement. Other payors limit the number of patients that can receive reimbursement for Fuzeon under their plans. And other payors may require co-payments by the patient in order to receive reimbursement for Fuzeon that are significantly higher than those required for other anti-HIV drugs. We and Roche will continue to actively address these issues during 2005. Outside the United States, Roche is in the process of negotiating reimbursement from the countries in which they plan to market Fuzeon.

Human Resources

During January of 2004, we and Roche put further clinical development of T-1249 on hold. In connection with this programmatic change, the Company reduced its workforce by approximately 25%. As of February 15, 2005, we had 97 full-time employees, including a technical scientific staff of 60. None of our employees are covered by collective bargaining arrangements, and management considers relations with our employees to be good.

Website

Our website address is www.trimeris.com. We make available free of charge through our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our director and officers' Section 16 reports, and all amendments to these reports as soon as reasonably practicable after filing, by providing a hyperlink to the EDGAR website directly to our reports.

RISK FACTORS

You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.

Our business, financial condition or results of operations could be adversely affected by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment.

If Fuzeon does not maintain or increase its market acceptance, our business will be materially harmed.

We have invested a significant portion of our time and financial resources since our inception in the development of Fuzeon. Fuzeon is the only drug candidate for which we have obtained FDA approval. We anticipate that for the foreseeable future, our ability to generate revenues and profits, if any, will depend entirely on the successful commercialization of Fuzeon. Commercialization of Fuzeon will require the continued support of Roche and Roche's ability to manufacture commercial quantities of Fuzeon on a cost-effective basis with the requisite quality, and Roche's ability to successfully market Fuzeon throughout the world.

Fuzeon is delivered via a twice daily dosing by injection under the skin. All of the currently approved drug treatments for HIV are delivered orally. Patients and physicians may not readily accept daily injections of an anti-HIV drug treatment, which would limit their acceptance in the market. This delivery method may limit the use of Fuzeon compared to other competing drugs. Moreover, because peptides are expensive to manufacture, the price of Fuzeon is higher than the prices of currently approved anti-HIV drug treatments. The WAC of one year's supply of Fuzeon in the United States is approximately \$21,000. This price is significantly higher than any of the other approved anti-HIV drugs. Furthermore, the indication approved by the FDA is for the use of Fuzeon in combination with other anti-HIV drugs, and is more restrictive than the indication for other approved anti-HIV drugs. Physicians may not readily prescribe Fuzeon due to cost-benefit considerations when compared with other anti-HIV drug treatments. Higher prices could also limit our ability to receive reimbursement coverage for our drugs from third-party payors, such as private or government insurance programs. If Roche is unable to obtain and maintain reimbursement from a significant number of third-party payors, it would have a material adverse effect on our business, financial condition and results of operations.

We rely on Roche to manufacture, market and distribute Fuzeon throughout the world in countries where regulatory approval has been received. If Roche fails to market Fuzeon adequately, we do not have the ability under our collaboration agreement to establish our own sales, marketing or distribution capabilities.

Roche has significant inventory of both finished product and raw materials on hand, if Fuzeon sales do not increase we could face the risk of significant write-offs.

Commercial sales of Fuzeon began in March 2003. In advance of the commercial launch, Roche manufactured large quantities of commercial drug product in order to satisfy an anticipated large pent-up demand for Fuzeon. Since that time, sales levels have not matched the original demand forecasts resulting in larger than anticipated inventories of raw materials, bulk drug substance and finished drug. These raw materials, bulk drug substance and finished drug product lots cannot be used beyond a certain date due to shelf-life expiration. If drug product is not sold before expiration of the shelf-date or if raw materials are not consumed, then Roche may write off these inventories at a significant expense to us. This would have a material adverse effect on our business, financial condition, results of operations and the market price of our stock.

We have sustained operating losses since our inception, and we expect these losses to continue.

As of December 31, 2004, our accumulated deficit since beginning our operations in January 1993 was approximately \$370.4 million. We had net losses of approximately \$75.7 million in 2002, approximately \$65.7 million in 2003, and approximately \$40.1 million in 2004. Since inception, we have spent our funds on our drug development efforts relating primarily to the development of Fuzeon and T-1249. If Fuzeon sales levels do not increase beyond their

current levels, we expect that we will incur losses for the foreseeable future and that these losses may increase as we continue our research and development, preclinical testing, clinical trial and regulatory approval efforts. There can be no assurance that we will become profitable even if we do achieve increased Fuzeon sales levels.

Any additional financing we obtain may result in dilution to our stockholders, restrictions on our operating flexibility or the transfer of particular rights to technologies or drug candidates.

If we raise funds by selling equity, equity-like instruments (including offering convertible preferred stock or convertible debt), we may dilute our stockholders' percentage ownership interest in us. Any debt financings may contain restrictive terms that would limit our operating flexibility. Additionally, we may have to obtain funds through arrangements with collaborative partners. These partners may require us to relinquish rights to our technologies or drug candidates. Any of these forms of financing could materially and adversely affect our business, financial condition and results of operations.

If Roche does not meet its contractual obligations to us, our research and development efforts and the regulatory approval and commercialization of our drug candidates could be delayed or otherwise materially and adversely affected.

We have entered into an agreement with Roche to develop and market Fuzeon and T-1249, or a replacement compound, worldwide, manufacture clinical and commercial quantities of these compounds, and help conduct our clinical trials of these compounds. In addition to sharing with us the development expenses and profits for these compounds in North America and paying us royalties on net sales of these compounds outside of those countries, the agreement calls for Trimeris to receive up to \$68 million in upfront and milestone payments, of which we have achieved \$28.3 million as of December 31, 2004. In addition, we have entered into a research agreement with Roche to discover, develop and commercialize other anti-HIV fusion inhibitor peptides. The joint research obligations under the agreement were renewed in January 2004 through December 31, 2005. Our reliance on Roche in connection with these activities poses a number of risks, including the following:

- Roche has the right to terminate our development and license agreement, including its marketing provisions, and terminate or not renew the research agreement, in each case as a whole or with respect to any particular country or countries, at any time and from time to time in its sole discretion, even though we have a joint management committee consisting of members from Roche and Trimeris that oversees the strategy for our collaboration and research;
- Roche may not devote sufficient resources to the research, development or marketing of Fuzeon, or any other drugs that may be developed;
- Roche may not devote sufficient resources to manufacture Fuzeon in commercial quantities on a cost-effective basis and with the requisite quality;
- disagreements with Roche could lead to delays in or termination of the research, development or commercialization of Fuzeon or future drug candidates, or result in litigation or arbitration;
- Roche may choose to devote fewer resources to the research, development and marketing of Fuzeon or our future drug candidates than it does to drugs of its own development, or may choose to compete with us by seeking, on its own or in collaboration with our competitors, alternate means of developing drug therapies for the diseases we have targeted;
- Roche has the right to establish or change the market prices of Fuzeon or any other drug candidates covered by the Roche collaboration;
- disputes may arise in the future with respect to the ownership of rights to technology developed with Roche; and
- Roche may be a party to mergers, acquisitions or other corporate transactions in the future that result in a change in its business strategy relating to our collaboration.

If any of the foregoing occurs or if Roche otherwise fails to fulfill any of its obligations to us in accordance with our agreements, our research and development efforts and clinical trials, and the regulatory approval and commercialization of our drug candidates could be delayed or otherwise materially and adversely affected.

We also may rely from time to time on the services of other third parties in connection with our research and development and clinical trial activities, including contract research organizations, manufacturers who produce clinical amounts of our drug candidates, licensors, collaborators and others. The failure of any of these persons to perform their obligations as agreed may also delay and otherwise adversely affect our research and development, clinical trial activities and regulatory approval of our future drug candidates.

In order to become profitable we will need to maintain arrangements with third parties for the sale, marketing and distribution of our current and future drug candidates or expend significant resources to develop these capabilities.

We have limited experience in sales, marketing and distribution of pharmaceuticals. We currently rely on Roche for the sales, marketing and distribution of Fuzeon and plan to rely on Roche for these activities for any other potential drug candidates covered by our collaboration with Roche, in accordance with the marketing terms contained in our development and license agreement with Roche. Roche may terminate this agreement at any time with advance notice. If Roche fails to adequately market Fuzeon or our future drug candidates, if approved, we do not have the ability under our collaboration agreement to establish our own sales, marketing or distribution capabilities. If Roche ceases to market Fuzeon or our future drug candidates by terminating our agreement, and we were unable to reach agreement with one or more other marketing partners, we would be required to develop internal sales, marketing and distribution capabilities. We may not be able to establish cost-effective sales, marketing or distribution capabilities or make arrangements with third parties to perform these activities on acceptable terms on a timely basis, if at all. This would have a material adverse effect on our business, financial condition, results of operations and the market price of our stock.

Our agreement with Roche and any sales, marketing or distribution arrangements we establish with other parties gives Roche, and may give those parties, significant control over important aspects of the commercialization of our drugs, including:

- market identification;
- marketing methods;
- pricing;
- drug positioning;
- composition of sales force; and
- promotional activities.

We may not be able to control the amount or timing of resources that Roche or any third party may devote to our drug candidates.

If sufficient amounts of Fuzeon or any other drugs we attempt to bring to market cannot be manufactured on a cost-effective basis, our financial condition and results of operations will be materially and adversely affected.

Peptide-based therapeutics are made from long chains of molecular building blocks called amino acids. Fuzeon is a large peptide composed of a precise 36-amino acid sequence. Large peptides are difficult and expensive to manufacture because the process of creating commercial quantities of a large peptide is lengthy and complicated. We and Roche have selected Roche's facility in Boulder, Colorado to manufacture commercial quantities of the bulk drug substance of Fuzeon. We and Roche have selected one of Roche's manufacturing facilities and another third party to produce the finished drug product from such bulk drug substance through a process involving lyophilization, or freeze-drying. The process Roche is currently using to manufacture Fuzeon bulk drug substance requires approximately five months to complete and is extremely complicated, requiring over 100 separate, precisely controlled chemical reactions. Roche is currently manufacturing Fuzeon bulk drug substance on a commercial scale, and Roche and another third party are producing the finished drug product on a commercial scale. However, as a result of this complex manufacturing process, Roche or the other third party may encounter unexpected difficulties or expense in manufacturing Fuzeon in the future.

In addition, if sales of Fuzeon do not increase, Roche could be forced to scale back manufacturing at the Boulder facility to levels that are less than optimal. Diminished sales of Fuzeon will not allow us to achieve the economies of scale that keep our costs of goods low. Any increase in costs of goods would, in turn, decrease our gross margin and would have a material adverse effect on our business, financial condition, results of operations and the market price of our stock.

We do not control the manufacturing and production schedule at Roche's Boulder facility where Fuzeon is manufactured and that we cannot ensure that significant costs associated with scheduling decisions will not be incurred.

Roche manufactures Fuzeon bulk drug substance at their facility in Boulder, Colorado. Roche coordinates the manufacture of Fuzeon with the balance of its manufacturing efforts. We do not have input into the manufacturing and production schedule at Roche, Boulder and Roche's decisions in this area may result in significant additional cost and expense relating to the manufacture of Fuzeon.

We are currently in the process of finalizing an amendment to our collaboration agreement with Roche that addresses several significant payments we have made and will make in the future and we cannot guarantee that these negotiations will lead to a final agreement.

We have been in discussions with Roche to attempt to clarify the responsibility of each of the parties with respect to certain expenses under our collaboration agreement. In the event that a final understanding regarding these items is not reached we could be exposed to significant financial risk and expense that we had previously not expected to be responsible for. This would have a material adverse effect on our business, financial condition, results of operations and the market price of our stock.

If Roche does not re-new our current research agreement to discover, develop and commercialize novel fusion inhibitors, we may not be able to proceed with the development of our most promising candidates.

We have entered into an agreement with Roche to discover, develop and commercialize novel fusion inhibitors. This research agreement covers several of our most promising potential drug candidates. If Roche chooses not to re-new this agreement after 2005 when it expires, we may not be able to proceed with the development and/or commercialization of these candidates due to both funding and intellectual property limitations.

We may not be able to effectively develop our drug pipeline.

The antiviral peptides and small molecules in our research programs will require extensive additional development, testing and investment, as well as regulatory approvals, prior to commercialization. Our product research and development efforts may not be successful. Our drug candidates may not enter preclinical, nonclinical or clinical studies as or when anticipated or receive the required regulatory approvals. Moreover, our products, if introduced, may not be commercially successful. The results of preclinical and initial clinical trials of products under development by us are not necessarily predictive of results that will be obtained from large-scale clinical testing. Clinical trials of products under development may not demonstrate the safety and efficacy of such products or result in a marketable product. Findings in nonclinical studies conducted concurrently with clinical studies could adversely impact the development of our products. In addition, the administration, alone or in combination with other drugs, of any product developed by us may produce undesirable side effects in humans.

The failure to demonstrate adequately the safety and efficacy of a therapeutic drug under development could delay or prevent regulatory approval of the product and could have a material adverse effect on us.

We face intense competition in our efforts to develop commercially successful drugs in the biopharmaceutical industry. If we are unable to compete successfully, our business will suffer.

We are engaged in sectors of the biopharmaceutical industry, including the treatment of HIV, that are intensely competitive and change rapidly. We expect that new developments by other companies and academic institutions in the areas in which we are conducting our research and development will continue at a rapid pace.

Fuzeon and our other drug candidates that are successfully developed will compete with numerous existing therapies, as well as a significant number of drugs that are currently under development and will become available in the future for the treatment of HIV. For example:

- At least 20 anti-HIV drugs are currently approved in the United States for the treatment of HIV, including drugs produced by GlaxoSmithKline, Bristol Myers Squibb, Merck, Roche and Abbott Laboratories. Only one of these currently-approved drugs, Fuzeon, is a viral fusion inhibitor.
- We believe that other companies may be currently engaged in research efforts to develop viral fusion inhibitors. To our knowledge, none of these potentially competing drug candidates have entered human clinical trials.
- Several companies, including Panacos, Progenics Pharmaceuticals, Pfizer, Schering-Plough, Tanox, Inc., Merck and GlaxoSmithKline, are in early stage human clinical trials with anti-HIV drug candidates that target viral processes different from those targeted by currently approved anti-HIV drugs, and different from the viral fusion process that our drug candidates target.

We expect to face intense and increasing competition in the future as these new drugs enter the market and advanced technologies become available. We cannot assure you that existing or new drugs for the treatment of HIV developed by our competitors will not be more effective, less expensive or more effectively marketed and sold than Fuzeon or any other drug treatment that we may develop.

Many of our competitors have significantly greater financial, technical, human and other resources than we do. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Furthermore, academic institutions, governmental agencies and other public and private research organizations are becoming increasingly aware of the value of their inventions for the treatment of HIV and are more actively seeking to commercialize the technology they have developed.

We may not receive all necessary regulatory approvals for future drug candidates or approvals may be delayed.

Our research and development activities and the testing, development, manufacturing and commercialization of any future drug candidates is subject to regulation by numerous governmental authorities in the United States and, to the extent that we may be engaged in activities outside of the United States, in other countries. The Federal Food, Drug and Cosmetic Act, the Public Health Service Act and other domestic and foreign statutes and regulations govern or affect the testing, manufacture, safety, labeling, storage, record keeping, approval, advertising and promotion of substances such as our drug candidates, as well as safe working conditions and the experimental use of animals. If our future drug candidates receive the regulatory approvals necessary for commercialization, we will be subject to continuing regulatory obligations, such as the submission of safety reports and other post-market information. Noncompliance with any applicable regulatory requirements can result in refusal of the government to approve product license applications, criminal prosecution and fines, recall or seizure of drugs, total or partial suspension of production, prohibitions or limitations on the commercial sale of drugs or refusal to allow us to enter into supply contracts. The FDA also has the authority to revoke product licenses and establishment licenses that it has previously granted.

A number of reasons, including those set forth below, may delay regulatory submissions for our drug candidates, cause us or our collaborators to cancel plans to submit proposed drug candidates for approval, or delay or prevent regulatory approval of proposed drug candidates:

- unanticipated preclinical testing or clinical trial results;
- changes in regulations, or the adoption of new regulations;
- unanticipated enforcement of existing regulations;
- the imposition of additional conditions on marketing or commercialization;
- limitations on the indicated uses for which our drug candidates may be marketed;
- unexpected technological developments;

- developments by our competitors; and
- delay in manufacturing validation or scale-up.

HIV is likely to develop resistance to Fuzeon and any of our future drug candidates, which could adversely affect demand for those drug candidates and harm our competitive position.

HIV is prone to genetic mutations that can produce viral strains resistant to particular drug treatments. HIV has developed resistance, in varying degrees, to each of the currently approved anti-HIV drug treatments, including Fuzeon. As a result, combination therapy, or the prescribed use of three or more anti-HIV drugs, has become the preferred method of treatment for HIV-infected patients, because in combination these drugs may prove effective against strains of HIV that have become resistant to one or more drugs in the combination. In the clinical trials we have conducted to date, HIV has demonstrated the ability to develop resistance to Fuzeon, as it has with respect to all other currently-marketed anti-HIV drugs. If HIV, in a wide patient population, in a short time period, develops resistance to Fuzeon or our other drug candidates when used in combination therapy, it would adversely affect demand for those drug candidates and harm our competitive position.

Our business is based on a novel technology called fusion inhibition, and unexpected side effects or other characteristics of this technology may delay or otherwise adversely affect the development, regulatory approval and/or commercialization of our drug candidates.

The technology platform underlying our drug development program is novel because it is designed to discover drug candidates that treat viral infection by preventing the virus from fusing to and entering host cells that viruses use to reproduce themselves. Historically, anti-HIV therapy has primarily involved the inhibition of specific viral enzymes that are necessary for HIV to replicate. We are not aware of any other approved anti-HIV pharmaceutical products that target the inhibition of viral fusion. As a result, existing preclinical and clinical data on the safety and efficacy of this technology are somewhat limited. Although the most common adverse side effect reported with respect to Fuzeon to date has been mild to moderate local skin irritations at the site of injection, we may discover other unacceptable side effects of our drug candidates, including side effects that may only become apparent after long-term exposure. We may also encounter technological challenges relating to these technologies and applications in our research and development programs that we may not be able to resolve. Any such unexpected side effects or technological challenges may delay or otherwise adversely affect the development, regulatory approval and/or commercialization of our drug candidates.

We are dependent on the successful outcome of clinical trials for our drug candidates.

The FDA granted full approval for the commercial sale of Fuzeon in October 2004. We do not have any other drug candidates that have received FDA or any other regulatory authority for approval of commercialization. In order to obtain the regulatory approvals necessary to sell a drug candidate commercially, we must demonstrate to the FDA and other applicable United States and foreign regulatory authorities that the drug candidate is safe and effective for use in humans for each target indication. We attempt to demonstrate this through a lengthy and complex process of preclinical testing and clinical trials, which typically takes a number of years. We also plan to do post-approval clinical trials for Fuzeon to provide additional clinical data to aid Roche and our marketing efforts. Our success will depend on the success of these clinical trials.

We cannot assure you that the results of prior clinical trials will warrant further clinical trials or the submission of NDAs for any potential drug candidates. We may not be able to demonstrate that potential drug candidates that appeared promising in preclinical testing and early clinical trials will be safe or effective in advanced clinical trials that involve larger numbers of patients studied over longer durations. We may be required to redesign, delay or cancel our preclinical testing and clinical trials for some or all of the following reasons, any of which may adversely affect our results of operations:

- unanticipated adverse or ambiguous results from our preclinical testing or clinical trials;
- change in the focus of Roche;

- the inability to achieve an acceptable commercial formulation;
- undesirable side effects that delay or extend the trials;
- our inability to locate, recruit and qualify a sufficient number of patients for our trials;
- difficulties in manufacturing sufficient quantities at the requisite quality of the particular drug candidate or any other components needed for our preclinical testing or clinical trials;
- regulatory delays or other regulatory actions;
- change in the focus of our development efforts; and
- re-evaluation of our clinical development strategy.

Given the uncertainty surrounding the clinical trial process, we may not be able to successfully develop, commercialize and market Fuzeon or any of our other drug candidates, which would severely harm our business, impair our ability to generate revenues and adversely affect our stock price.

Obtaining regulatory approvals and maintaining compliance with government regulations will entail significant costs that could harm our ability to achieve profitability.

Due to uncertainties inherent in the clinical development and government regulatory approval process, we may underestimate the cost and/or length of time associated with the development and commercialization of our drug candidates. We will be required to expend significant resources to comply with regulations affecting research and development, testing, manufacturing, marketing and commercialization activities for our drug candidates. We do not separately track as an accounting item the amounts we spend to comply with regulatory requirements, but the majority of our activities and expenditures to date, including our preclinical and clinical trial activities and expenditures, have been undertaken directly or indirectly in order to comply with applicable governmental regulations. If compliance with these regulations proves more costly than anticipated, our financial condition and results of operations could be materially and adversely affected.

Failure to raise additional capital necessary to support our development programs and expand our operations could lower our revenues and reduce our ability to compete.

We have incurred significant costs as a result of research and development, clinical trials, and the preparation and submission of the Fuzeon NDA to the FDA. We have continued to incur significant expenditures related to the manufacture, sale and marketing of Fuzeon. Under the current operating environment, excluding any extraordinary items, based on current sales levels of Fuzeon, we expect that our existing capital resources, together with the interest earned thereon, will be adequate to fund our current programs for at least the next 24 months. However, any reduction in Fuzeon sales below current levels or increase in expenditures beyond currently expected levels would increase our capital requirements substantially beyond our current expectations. In the event Roche becomes unable or unwilling to share future development expenses for Fuzeon or other compounds covered by our agreements, our capital requirements would increase substantially beyond our current expectations. We have an ongoing program of business development which may lead to the establishment of collaborative or licensing arrangements with third parties. In the event we enter into additional agreements with third parties, our expenditures may be increased.

We have financed our activities primarily through public offerings and private placements of our common stock, and we expect to continue to rely primarily on sales of our equity securities if we are required to raise additional funds in the future. Our access to capital could be limited if we do not achieve continued progress in our research and development programs, preclinical testing and clinical trials, and regulatory approvals for our product candidates. If we fail to meet the clinical and financial expectations of securities analysts and investors, it could have a material adverse effect on the market price of our common stock and restrict or eliminate our ability to raise additional funds by selling equity. We also could be limited by overall market conditions. The public capital markets in which our common stock trades have been extremely volatile. Our failure to raise additional funds or to generate sufficient revenues to support our operations would seriously harm our business.

If we cannot maintain commercial manufacturing arrangements with third parties on acceptable terms, or if these third parties do not perform as agreed, the commercial development of our drug candidates could be delayed or otherwise materially and adversely affected.

We do not have any manufacturing experience, nor do we have any manufacturing facilities. We and Roche have selected Roche's facility in Boulder, Colorado to manufacture commercial quantities of the bulk drug substance of Fuzeon. We and Roche have selected one of Roche's manufacturing facilities and another third party to produce the finished drug product from such bulk drug substance through a process involving lyophilization, or freeze-drying. The manufacture of pharmaceutical products requires significant expertise and capital investment. Moreover, under our agreement with Roche, we are required to reimburse a portion of the expenses incurred by Roche in connection with its manufacture of Fuzeon. Third-party manufacturers of pharmaceutical products often encounter difficulties in scaling up production, including problems involving production yields, quality control and assurance, shortage of qualified personnel, compliance with FDA regulations, production costs, and development of advanced manufacturing techniques and process controls. Our third-party manufacturers, including Roche, may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce and market Fuzeon and our other drug candidates. The number of third-party manufacturers with the expertise and facilities to manufacture bulk drug substance of Fuzeon on a commercial scale is extremely limited. In addition, only a limited number of third-party manufacturers have the capability to produce a finished drug product on a commercial scale through a process involving lyophilization.

Roche's facility in Boulder, Colorado is the only facility manufacturing Fuzeon bulk drug substance. In the event the intended manufacturing plan generates insufficient supplies of Fuzeon, or the Boulder facility ceases operation for any reason, we do not have an alternate manufacturing plan in place at this time, and it would take a significant amount of time to arrange for alternative manufacturers. We do not have insurance to cover any shortages or other problems in the manufacturing of Fuzeon or our other drug candidates. If our third-party manufacturers, including Roche, fail to deliver the required commercial quantities of bulk drug substance or finished drug product on a timely basis and at commercially reasonable prices, and we fail to promptly find one or more replacement manufacturers or develop our own manufacturing capabilities at a substantially equivalent cost and on a timely basis, the commercial development of Fuzeon or our other drug candidates could be delayed or otherwise materially and adversely affected. Dependence upon third parties for the manufacture of Fuzeon or our other drug candidates may harm our ability to develop and deliver products on a timely and competitive basis.

If Roche or our manufacturing partners do not maintain good manufacturing practices, it could negatively impact our ability to obtain regulatory approvals and commercialize our drug candidates.

The FDA and other regulatory authorities must approve the facilities that will be used to manufacture commercial quantities of our drug candidates before commencement of commercial sales. In addition, these authorities require that our products be manufactured according to good manufacturing practice regulations. The failure by us, Roche or other third-party manufacturers to maintain current good manufacturing practices compliance and/or our failure to increase our manufacturing processes as needed to meet demand for our drugs could lead to refusal by the FDA to approve marketing applications. Failure in either respect could also be the basis for action by the FDA to withdraw approvals previously granted and for other regulatory action.

In addition, if we change the source or location of supply or modify the manufacturing process with respect to Fuzeon or any of our other drug candidates, regulatory authorities will require us to demonstrate that the product produced by the new source or location or from the modified process is equivalent to the product used in any clinical trials we have conducted. If we are unable to demonstrate this equivalence, we will be unable to manufacture products from the new source or location of supply or use the modified process. As a result, we may incur substantial expenses in order to ensure equivalence, and our ability to generate revenues may be harmed.

Our internal research programs and our efforts to obtain rights to new products from third parties may not yield potential products for clinical development, which would adversely affect any future revenues.

Our long-term success depends in part on our ability to either identify through internal research programs, or to obtain through licenses from third parties, potential drug candidates that may be developed into new pharmaceutical

products. A significant portion of the research that we have conducted and will conduct involves new and unproven technologies. Research programs to identify drug candidates require substantial technical, financial and human resources, whether or not such programs identify any drug candidates. Our research programs may fail to yield drug candidates for clinical development for a number of reasons, including:

- the research methodology used may not successfully identify potential drug candidates;
- potential drug candidates may on further study be shown to have unduly harmful side effects or characteristics that indicate they are unlikely to be effective drugs;
- we may be unable to develop larger scale manufacturing methods for particular drug candidates that are efficient, cost-effective and capable of meeting stringent regulatory standards; and
- others may hold intellectual property rights that prevent us from developing, making or selling certain products.

We may be unable to obtain suitable drug candidates or products from third parties for a number of reasons, including:

- we may be unable to purchase or license such compounds on terms that would allow us to obtain an appropriate return on our investment in the product;
- third parties may be unwilling to assign or license product rights to us if they believe such rights would allow us to compete with them;
- we may be unable to identify suitable products or drug candidates within our areas of expertise; or
- drug candidates that we acquire may not be approved by regulatory authorities due to problems with their safety or effectiveness.

If we are unable to develop suitable potential drug candidates through internal research programs or by obtaining rights to new products from third parties, our future revenue growth will suffer.

We depend on patents and proprietary rights, which may offer only limited exclusive protection and do not protect against infringement. If we are unable to protect our patents and proprietary rights, our assets and business could be materially harmed.

Our success depends in part on our ability and the ability of our collaborators and licensors to obtain, maintain and enforce patents and other proprietary rights for our drugs and technologies. Patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and involves a great deal of uncertainty.

Although we own or exclusively license more than 35 issued United States patents, and numerous pending United States patent applications, corresponding foreign patents and patent applications, including issued patents and patent applications relating to Fuzeon, the issuance of a patent is not conclusive as to its validity or enforceability, and third parties may challenge the validity or enforceability of our patents. We cannot assure you how much protection, if any, our patents will provide if we attempt to enforce them and/or if the patents are challenged in court or in other proceedings. It is possible that a competitor may successfully challenge our patents or that challenges will result in limitations of their coverage. In addition, the cost of litigation to uphold the validity of patents can be substantial. If we are unsuccessful in such litigation, third parties may be able to use our patented technologies without paying licensing fees or royalties to us. Further, we cannot assure you that our pending patent applications will result in issued patents. Because U.S. patent applications may be maintained in secrecy until a patent issues or is otherwise published, we cannot assure you that others have not filed patent applications for technology covered by our pending applications. Moreover, we cannot assure you that we were the first to invent the technology, which, under U.S. patent law, is a prerequisite to obtaining patent coverage. In the event that a third party has also filed a U.S. patent application on the technology, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, i.e., which party was the first to invent. The costs of these proceedings can be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position.

Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims. Such proceedings are expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or enforceable or may refuse to stop the other party from using the technology at issue on the grounds that its technology is not covered by our patents. Policing unauthorized use of our intellectual property is difficult, and we cannot assure you that we will be able to prevent infringement or misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Recently, several generic drug-makers in countries such as India have offered to sell HIV drugs currently protected under United States patents to patients in Africa at prices significantly below those offered by the drugs' patent holders in other countries. There is a risk that these drugs produced by the generic drug-makers could be illegally made or imported into the United States and other countries at prices below those charged by the drugs' patent holders. If any of these actions occur with respect to our drugs, it could limit the amount we could charge for our drugs.

In addition to our patented technology, we also rely on unpatented technology, trade secrets and confidential information. We may not be able to effectively protect our rights to this technology or information. Other parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We require each of our employees, consultants and corporate partners to execute a confidentiality agreement at the commencement of an employment, consulting or collaborative relationship with us. However, these agreements may not provide effective protection of our technology or information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies.

The occurrence of any of these risks could have a material adverse effect on our business, financial condition, results of operations and market price of our stock.

The intellectual property of our competitors or other third parties may prevent us from developing or commercializing our drug candidates.

Other companies, universities and research institutions conduct research and development efforts in market segments, including viral fusion inhibition and the treatment of HIV infection, where we and our collaborators focus research and development activities. While we are not aware of any patents held by these third parties that we believe will limit our ability to use, manufacture, market or sell Fuzeon or our potential drug candidates, these third parties may have obtained or may obtain patents that do so. We cannot assure you that third parties will not assert patent infringement or other intellectual property claims against us or our collaborators with respect to technologies used in Fuzeon or our potential drug candidates. Any claims that might be brought against us relating to infringement of third party patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages. Even if we were to prevail, any litigation could be costly and time-consuming and could divert the attention of our management and key personnel from our drug development and commercialization efforts or other business operations. As a result of a patent infringement suit brought against us, we may have to cease or delay development activities, unless that party is willing to grant us rights to use its intellectual property. Thus we may have to obtain licenses from other parties before we could continue using, manufacturing, marketing or selling our potential drugs. Those licenses may not be available on commercially acceptable terms, if at all. If we do not obtain required licenses, we may not be able to market our potential drugs at all or we may encounter significant delays in drug development while we redesign potentially infringing drugs or methods.

Uncertainty relating to third-party reimbursement and health care reform measures could limit the amount we will be able to charge for our drugs and adversely affect our results of operations.

In the United States and elsewhere, sales of prescription drugs depend, in part, on the consumer's ability to obtain reimbursement for the cost of the drugs from third-party payors, such as private and government insurance programs. Third-party payors are increasingly challenging the prices charged for medical products and services in an effort to promote cost containment measures and alternative health care delivery systems. Because of the high cost of the treatment of HIV, many state legislatures are also reassessing reimbursement policies for this therapy. If third-party payor reimbursements for Fuzeon or any of our other drug candidates that we commercialize are not available or are not available at a level that will allow us or our current or future collaborative partners to sell these drugs on a

competitive basis, our results of operations will be materially and adversely affected. In addition, emphasis in the United States on the reduction of the overall costs of health care through managed care has increased and will continue to increase the pressure to reduce the prices of pharmaceutical products. The announcement and/or adoption of these types of proposals or efforts could also materially and adversely affect our business, because the amount of revenue that we may potentially be able to generate in the future for Fuzeon or any of our other drug candidates could affect an investor's decision to invest in us, the amount of funds we decide to spend now on our development and clinical trial efforts, and/or our decision to seek regulatory approval for certain drug candidates.

The WAC of a one year's supply of Fuzeon in the United States is approximately \$21,000. This price is significantly higher than any of the other approved anti-HIV drugs. Higher prices could also limit our ability to receive reimbursement coverage for our drugs from third-party payors, such as private or government insurance programs. If Roche is unable to obtain and maintain reimbursement from a significant number of third-party payors, it would have a material adverse effect on our business, financial condition and results of operations.

Roche has made significant progress in achieving reimbursement from the various payors in the United States. Currently Fuzeon is covered by Medicaid in all 50 states, 34 of the state and territorial AIDS Drug Assistance Programs, or ADAPs, and a majority of private insurers. However there are reimbursement challenges remaining. Some of the payors require patients to meet minimum medical requirements, such as CD4 cell levels, to receive reimbursement. Other payors limit the number of patients that they will provide reimbursement for Fuzeon. And other payors may require co-payments by the patient in order to receive reimbursement for Fuzeon that are significantly higher than those required for other anti-HIV drugs. We and Roche will continue to actively address these issues during 2005.

Several major pharmaceutical companies have offered to sell their anti-HIV drugs at or below cost to certain countries in Africa, which could adversely affect the reimbursement climate, and the prices that may be charged, for HIV medications in the United States and the rest of the world. Third-party payors could exert pressure for price reductions in the United States and the rest of the world based on these offers to Africa. This price pressure could limit the amount that we would be able to charge for our drugs.

If an accident or injury involving hazardous materials occurs, we could incur fines or liability, which could materially and adversely affect our business and our reputation.

In our drug development programs, we use hazardous materials that are subject to government regulations, including chemicals, radioactive compounds and infectious disease agents, such as viruses and HIV-infected blood. We believe that our handling and disposal of these materials comply with the standards prescribed by state and federal regulations, but we cannot completely eliminate the risk of contamination or injury from these materials. If we fail to comply with these regulations or if a contamination, injury or other accident occurs in connection with our development activities, we could be held liable for any damages or penalized with fines. Although our general liability insurance coverage may cover some of these liabilities, the amount of the liability and fines could exceed our resources. We currently maintain general liability insurance coverage in the amount of approximately \$1 million per occurrence and \$2 million in the aggregate. However, insurance coverage is becoming increasingly expensive and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against potential liabilities.

If the testing or use of our drug candidates harms people, we could face costly and damaging product liability claims far in excess of our liability and indemnification coverage.

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products, such as undesirable side effects or injury during clinical trials. In addition, the use in our clinical trials of drugs that we or our potential collaborators may develop and the subsequent sale of these drugs by us or our potential collaborators may expose us to liability risks relating to these drugs.

We have obtained an advanced medical technology policy which includes limited product liability insurance coverage for our clinical trials in the amount of \$10 million per occurrence and \$10 million in the aggregate. However, insurance coverage is becoming increasingly expensive and we may not be able to maintain insurance coverage at a

reasonable cost or in sufficient amounts to protect us against potential liabilities. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for drug candidates in development, but we cannot assure you that we will be able to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against our potential liabilities. Furthermore, our collaborators or licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have a net worth sufficient to satisfy any product liability claims. Claims or losses in excess of any product liability insurance coverage or indemnification payments that may be obtained by us could have a material adverse effect on our financial condition.

Our quarterly operating results are subject to fluctuations. If our operating results for a particular period deviate from the levels expected by securities analysts and investors, it could adversely affect the market price of our common stock.

Our operating results are likely to fluctuate over time, due to a number of factors, many of which are outside of our control. Some of these factors include:

- the market acceptance and sales levels for Fuzeon;
- the status and progress of our collaborative agreement with Roche;
- the status of our research and development activities;
- the progress of our drug candidates through preclinical testing and clinical trials;
- the timing of regulatory actions;
- our ability to establish manufacturing, sales, marketing and distribution capabilities, either internally or through relationships with third parties;
- technological and other changes in the competitive landscape;
- changes in our existing or future research and development relationships and strategic alliances; and
- the commercial viability of Fuzeon or our other drug candidates.

As a result, we believe that comparing our results of operations for one period against another period is not necessarily meaningful, and you should not rely on our results of operations in prior periods as an indication of our future performance. If our results of operations for a period deviate from the levels expected by securities analysts and investors, it could adversely affect the market price of our common stock.

If we lose any of our executive management or other key employees, we will have difficulty replacing them. If we cannot attract and retain qualified personnel on acceptable terms, the development of our drug candidates and our financial position may suffer.

Because our business is very science-oriented and relies considerably on individual skill and experience in the research, development and testing of our drug candidates, we depend heavily on members of our senior management and scientific staff. We have entered into employment agreements with Steven D. Skolsky, our Chief Executive Officer, Dani Bolognesi, our Chief Scientific Officer and Robert R. Bonczek, our Chief Financial Officer and General Counsel. Each of these agreements is automatically renewed, subject to termination by either of the parties. We have entered into employment agreements with all employees that are at the level of Vice President or above. These agreements have a term of one year and are renewable at the Company's option.

Future recruitment and retention of management personnel and qualified scientific personnel is also critical to our success. We cannot assure you that we will successfully attract and retain sufficient numbers of qualified personnel on acceptable terms given the competition among biotechnology, pharmaceutical and health care companies, universities and non-profit research institutions for experienced management personnel and scientists. If we cannot attract and retain a sufficient number of qualified personnel or if a significant number of our key employees depart, our drug development efforts and the timing and success of our clinical trials may be materially and adversely affected. Even if we do hire and retain a sufficient number of qualified employees, the expense necessary to compensate them may

adversely affect our operating results. In addition, we rely on scientific advisors and other consultants to assist us in formulating our research and development strategy. These consultants are employed by other parties and may have commitments to, or advisory or consulting agreements with, other entities, which may limit their availability to us.

Our charter requires us to indemnify our officers and directors to the fullest extent permitted by law, which obligates us to make substantial payments and to incur significant insurance-related expenses.

Our charter requires that we indemnify our directors and officers to the fullest extent permitted by Delaware corporate law. This could require us, with some legally prescribed exceptions, to indemnify our directors and officers against any and all expenses, judgments, penalties, fines and amounts reasonably paid in defense or settlement of an action, suit or proceeding brought against any of them by reason of the fact that he or she is or was a director or officer of Trimeris. In addition, expenses incurred by a director or officer in defending any such action, suit or proceeding must be paid by us in advance of the final disposition of that action, suit or proceeding if we receive an undertaking by the director or officer to repay us if it is ultimately determined that he or she is not entitled to be indemnified. We have also entered into indemnification agreements with each of our directors and executive officers. In furtherance of these obligations, we maintain directors' and officers' insurance in the amount of \$40 million. Our policies expire in October 2005. For future renewals, if we are able to retain coverage, we may be required to pay a higher premium for our directors' and officers' insurance than in the past and/or the amount of our insurance coverage may be decreased.

Available Information

We maintain a website on the World Wide Web at www.trimeris.com. We make available, free of charge, on our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the SEC. Our reports filed with, or furnished to, the SEC are also available at the SEC's website at www.sec.gov.

ITEM 2. PROPERTIES

We lease approximately 61,000 square feet of laboratory and office space at 3500 Paramount Parkway, Morrisville, North Carolina. We lease this space under a sublease agreement that expires on January 23, 2015. We also lease approximately 29,000 square feet of laboratory and office space in Durham under a lease agreement that expires on September 30, 2005. We also sublease approximately 18,000 square feet of laboratory and office space in Durham under a sublease agreement that expires on July 31, 2005. We believe that there will be suitable facilities available should additional space be needed.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings as of the date of this Annual Report on Form 10-K.

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

No matters were submitted to a vote of security holders during the fourth quarter of 2004.

PART II.

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS,
AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock has traded on the Nasdaq National Market System under the Nasdaq symbol "TRMS" since our initial public offering at \$12.00 per share was consummated on October 7, 1997. We have not paid cash dividends in the past and none are expected to be paid in the foreseeable future. As of March 7, 2005 we had approximately 124 shareholders of record, and believe we had approximately 11,000 beneficial shareholders. The following table sets forth the high and low bid prices for our common stock for the period indicated as reported on the Nasdaq National Market System. Such quotations reflect inter-dealer prices without mark-up, mark-down or commissions and may not necessarily represent actual transactions.

	Year ended December 31,			
	2004		2003	
	High	Low	High	Low
1st Quarter	\$21.35	\$14.14	\$47.36	\$39.03
2nd Quarter	\$16.60	\$13.06	\$55.59	\$38.05
3rd Quarter	\$15.54	\$10.58	\$55.29	\$23.58
4th Quarter	\$16.16	\$10.89	\$35.63	\$19.51

ITEM 6. SELECTED FINANCIAL DATA

SELECTED FINANCIAL DATA
(in thousands, except per share data)

The selected financial data below is taken from the audited financial statements of the Company, which are included elsewhere in this Annual Report on Form 10-K, or from audited financial statements not included in this Annual Report on Form 10-K. Please read the financial statements and notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" while reading this selected financial data.

	For the Years Ended December 31,				
	2004	2003	2002	2001	2000
Statements of Operations Data:					
Revenue:					
Milestone revenue	\$ 2,152	\$ 2,964	\$ 1,133	\$ 1,304	\$ 956
Royalty revenue	4,556	755	—	—	—
Collaboration loss	(16,125)	(25,515)	—	—	—
Total revenue and collaboration loss	(9,417)	(21,796)	1,133	1,304	956
Operating expense:					
Marketing expense	—	—	16,722	3,825	973
Research and development:					
Non-cash compensation	159	(1)	250	(969)	5,386
Other research and development expense	21,154	36,824	50,976	59,409	32,970
Total research and development expense	21,313	36,823	51,226	58,440	38,356
General and administrative:					
Non-cash compensation	311	767	1,645	1,905	7,018
Other general and administrative expense	9,840	7,810	9,340	8,048	7,142
Total general and administrative expense	10,151	8,577	10,985	9,953	14,160
Total operating expenses	31,464	45,400	78,933	72,218	53,489
Operating loss	(40,881)	(67,196)	(77,800)	(70,914)	(52,533)
Interest income	953	1,534	2,230	4,362	6,114
Interest expense	(160)	(41)	(108)	(189)	(257)
Total other income (expense)	793	1,493	2,122	4,173	5,857
Loss before cumulative effect of change in accounting principle	(40,088)	(65,703)	(75,678)	(66,741)	(46,676)
Cumulative effect of change in accounting principle	—	—	—	—	(4,180)
Net loss	\$(40,088)	\$(65,703)	\$(75,678)	\$(66,741)	\$(50,856)
Basic and diluted net loss per share (1):					
Before cumulative effect of accounting change	\$ (1.86)	\$ (3.06)	\$ (3.93)	\$ (3.96)	\$ (3.00)
Accounting change	—	—	—	—	(0.27)
Basic and diluted net loss per share	\$ (1.86)	\$ (3.06)	\$ (3.93)	\$ (3.96)	\$ (3.27)
Weighted average shares used in computing basic net loss per share (1)					
	21,608	21,460	19,272	16,870	15,548

(1) Computed on the basis described in Note 1 to Financial Statements.

	As of December 31,				
	2004	2003	2002	2001	2000
(in thousands)					
Balance Sheet Data:					
Cash and cash equivalents and Investment securities—					
available-for-sale	\$ 48,402	\$ 92,198	\$ 149,182	\$ 74,800	\$ 93,374
Working capital	49,204	75,741	128,389	51,636	73,998
Total assets	64,820	98,600	154,539	80,644	98,933
Long-term notes payable and capital lease obligations, less current installments					
	—	—	321	1,014	1,861
Accumulated deficit	(370,364)	(330,276)	(264,573)	(188,895)	(122,154)
Total stockholders' equity	30,346	68,668	130,127	53,494	73,379

Selected Quarterly Financial Data
(in thousands, except per share data)

	<u>Q1 2004</u>	<u>Q2 2004</u>	<u>Q3 2004</u>	<u>Q4 2004</u>
Statements of Operations Data:				
Milestone revenue	\$ 526	\$ 534	\$ 546	\$ 546
Royalty revenue	801	1,109	1,207	1,439
Collaboration loss	(2,546)	(9,850)	(2,280)	(1,449)
Total revenue and collaboration loss	<u>(1,219)</u>	<u>(8,207)</u>	<u>(527)</u>	<u>536</u>
Operating expense:				
Research and development:				
Non-cash compensation	(51)	(2)	109	103
Other research and development expense	6,300	5,382	5,360	4,112
Total research and development expenses	<u>6,249</u>	<u>5,380</u>	<u>5,469</u>	<u>4,215</u>
General and administrative:				
Non-cash compensation	—	12	146	153
Other general and administrative expense	2,666	2,818	2,344	2,012
Total general and administrative expenses	<u>2,666</u>	<u>2,830</u>	<u>2,490</u>	<u>2,165</u>
Total operating expenses	<u>8,915</u>	<u>8,210</u>	<u>7,959</u>	<u>6,380</u>
Operating loss	<u>(10,134)</u>	<u>(16,417)</u>	<u>(8,486)</u>	<u>(5,844)</u>
Interest income	261	199	254	239
Interest expense	(3)	(2)	(43)	(112)
Total other income, net	<u>258</u>	<u>197</u>	<u>211</u>	<u>127</u>
Net loss	<u>\$ (9,876)</u>	<u>\$ (16,220)</u>	<u>\$ (8,275)</u>	<u>\$ (5,717)</u>
Basic and diluted net loss per share (1)	<u>\$ (0.46)</u>	<u>\$ (0.75)</u>	<u>\$ (0.38)</u>	<u>\$ (0.27)</u>
Weighted average shares used in computing basic net loss per share (1)	<u>21,582</u>	<u>21,610</u>	<u>21,617</u>	<u>21,625</u>
	<u><u>Q1 2003</u></u>	<u><u>Q2 2003</u></u>	<u><u>Q3 2003</u></u>	<u><u>Q4 2003</u></u>
Statements of Operations Data:				
Revenue				
Milestone revenue	\$ 236	\$ 750	\$ 989	\$ 989
Royalty revenue	—	87	234	434
Collaboration loss	(4,452)	(5,763)	(5,231)	(10,069)
Total revenue and collaboration loss	<u>(4,216)</u>	<u>(4,926)</u>	<u>(4,008)</u>	<u>(8,646)</u>
Operating expense:				
Research and development:				
Non-cash compensation	(60)	203	(125)	(19)
Other research and development expense	9,683	10,694	10,850	5,597
Total research and development expense	<u>9,623</u>	<u>10,897</u>	<u>10,725</u>	<u>5,578</u>
General and administrative:				
Non-cash compensation	412	233	122	—
Other general and administrative expense	2,168	2,399	2,088	1,155
Total general and administrative expense	<u>2,580</u>	<u>2,632</u>	<u>2,210</u>	<u>1,155</u>
Total operating expenses	<u>12,203</u>	<u>13,529</u>	<u>12,935</u>	<u>6,733</u>
Operating loss	<u>(16,419)</u>	<u>(18,455)</u>	<u>(16,943)</u>	<u>(15,379)</u>
Interest income	506	414	323	291
Interest expense	(15)	(11)	(9)	(6)
Total other income, net	<u>491</u>	<u>403</u>	<u>314</u>	<u>285</u>
Net loss	<u>\$ (15,928)</u>	<u>\$ (18,052)</u>	<u>\$ (16,629)</u>	<u>\$ (15,094)</u>
Basic and diluted net loss per share (1)	<u>\$ (0.75)</u>	<u>\$ (0.84)</u>	<u>\$ (0.77)</u>	<u>\$ (0.70)</u>
Weighted average shares used in computing basic net loss per share (1)	<u>21,375</u>	<u>21,418</u>	<u>21,513</u>	<u>21,525</u>

(1) Computed on the basis described in Note 1 to Financial Statements. The sum of quarterly net loss per share amounts may not equal the net loss per share for the year due to the effects of rounding.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This discussion of our financial condition and results of operations should be read together with the financial statements and notes contained elsewhere in this Annual Report on Form 10-K. Certain statements in this section and other sections are forward-looking. While we believe these statements are accurate, our business is dependent on many factors, some of which are discussed in the "Risk Factors" and "Business" sections of this Annual Report on Form 10-K. Many of these factors are beyond our control and any of these and other factors could cause actual clinical and financial results to differ materially from the forward-looking statements made in this Annual Report on Form 10-K. The results of our previous clinical trials are not necessarily indicative of the results of future clinical trials. Please read the "Risk Factors" section in this Annual Report on Form 10-K. We undertake no obligation to release publicly the results of any revisions to the statements contained in this report to reflect events or circumstances that occur subsequent to the date of this Annual Report on Form 10-K.

OVERVIEW

Trimeris is a biopharmaceutical company engaged in the discovery, development and commercialization of novel therapeutic agents for the treatment of viral disease. The core technology platform of fusion inhibition is based on blocking viral entry into host cells. FUZEON, approved in the U.S., Canada and European Union, is the first in a new class of anti-HIV drugs called fusion inhibitors. Trimeris is developing FUZEON and future generations of peptide fusion inhibitors in collaboration with F. Hoffmann-La Roche Ltd, or "Roche."

In order to enhance our performance management is addressing several critical success factors. These critical success factors are broken down into short-term and mid- to long-term.

Short – Term Critical Success Factors and Initiatives:

Work to increase the market acceptance of Fuzeon: Fuzeon is delivered twice daily through subcutaneous injections. Injection site reactions are the most common adverse event associated with the use of Fuzeon. Management believes that aversion to twice daily injections and the potential for injection site reactions are the primary impediments to increasing the market acceptance of Fuzeon. We, together with Roche, are working on several initiatives to increase the market penetration of Fuzeon including:

- Alternative delivery methods aimed at improving acceptance of subcutaneous injections and reducing injection site reactions;
- Nursing programs to help facilitate patient self-administration of and persistency on Fuzeon; and
- Medical Education and promotional programs focusing on the appropriate use of Fuzeon for patients with ongoing viral replication who have been exposed to drugs from the three other anti-HIV classes (so-called third-line patients and beyond).

Focusing our research and development efforts: We, together with our partner Roche, are currently researching several promising anti-viral peptides, with the hope of selecting one of these peptides for advanced pre-clinical studies. In the near-future, we plan to select a lead candidate and back-up candidate that will proceed to advanced formulation studies. The results of these studies will determine how rapidly we move towards naming a clinical candidate.

Managing our resources and liquidity: We ended 2004 with \$48.4 million in cash, cash equivalents and investment securities—available-for-sale. Under the current operating environment, excluding any extraordinary items, based on current sales levels of Fuzeon, we believe that this will be sufficient to support our operations for at least the next 24 months. We will continue to evaluate opportunities to increase our liquidity. We will also continue to look for opportunities to increase our operational effectiveness.

Our people: Our people are very important to the operations of our business. Our success depends on the continued services and on the performance of our senior management and staff. In 2005, we will continue to create a culture of trust that values employee contributions and recognizes and rewards open communication, accountability and achievement.

Mid- to Long - Term Critical Success Factors and Initiatives

Enhance development of our product pipeline: The focus on our next generation peptide, as mentioned above, is one aspect to the development of our pipeline. We will also look to business development to strengthen our pipeline primarily through acquisitions and in-licensing of research programs and clinical stage products.

Overview of Roche Relationship

In July 1999, we entered into a worldwide agreement with Roche, to develop and market Fuzeon and T-1249, or a replacement compound. In the United States and Canada, we and Roche share equally in development expenses and profits for Fuzeon and T-1249, or a replacement compound. Outside of these two countries, Roche will fund all development costs and pay us royalties on net sales of these products.

Development costs for these compounds are incurred by both Roche and Trimeris. Quarterly, we reconcile the amounts expended and one party pays the other party on a 50/50 basis. Roche holds the New Drug Application, or NDA, for Fuzeon and is responsible for all regulatory issues and communications with the Food and Drug Administration or FDA.

Fuzeon was approved for commercialization in the United States in March 2003 and sales began in March 2003. It is important to recognize that Roche is responsible for the manufacture, sales, marketing and distribution of Fuzeon. Roche is manufacturing bulk quantities of Fuzeon drug substance in its Boulder, Colorado facility. One of Roche's manufacturing facilities and another third party are producing the finished drug product from such bulk drug substance. The finished drug product is then shipped to a Roche facility for distribution. Roche's sales force is responsible for selling Fuzeon. Under our collaboration agreement we do not have the ability or rights to co-market this drug or field our own Fuzeon sales force. All third party contracts for manufacturing, distribution, sale, and reimbursement are between Roche and the third party. We are not a party to any of the material contracts in these areas. Roche provides us with information on manufacturing, sales and distribution of Fuzeon. Roche is responsible for estimating reductions to gross sales for expected returns of expired products, government rebate programs, such as Medicaid reimbursements, and customer incentives, such as cash discounts for prompt payment. We review these items for accuracy and reasonableness. We receive 50% of the product profit for the United States and Canada.

We receive royalties on sales of Fuzeon in countries outside of the United States and Canada. Roche is responsible for all activities related to Fuzeon outside of the United States and Canada, including regulatory, manufacturing, sales and distribution. We receive a quarterly royalty report from Roche that summarizes these sales and the royalty amounts due to Trimeris.

Currently, our only significant source of revenue is from the sale of Fuzeon. Selling, marketing and other charges in the United States and Canada exceeded the gross margin from the sale of Fuzeon in these countries during the years ended December 31, 2004 and 2003, resulting in negative cash flow from the sale of Fuzeon in these countries. During the years ended December 31, 2004 and 2003, our share of this negative cash flow exceeded royalties received from the sale of Fuzeon outside these countries. As a result, we had negative cash flow from the collaboration agreement during the years ended December 31, 2004 and 2003.

We are in the process of finalizing an amendment to our collaboration agreement with Roche. This amendment will clarify certain responsibilities of the parties under the collaboration agreement. To date we have reached an agreement in principle regarding certain key terms of this amendment. With respect to the understanding we have with Roche pertaining to amounts owed for capital contributions and manufacturing milestones, we have recorded these amounts as of December 31, 2004 on the assumption that we will execute an agreement with terms substantially the same as those we have agreed to in principle.

Historical Information Necessary to Understand our Business

We began our operations in January 1993 and, prior to April 1, 2003, we were a development stage company. Accordingly, we have a limited operating history. Since our inception, substantially all of our resources have been dedicated to:

- the development, patenting, preclinical testing and clinical trials of our drug candidates, Fuzeon and T-1249,

- the development of a manufacturing process for Fuzeon and T-1249,
- production of drug material for future clinical trials of Fuzeon and T-1249,
- preparation of materials for regulatory filings for Fuzeon,
- pre-marketing and marketing activities for the commercial launch of Fuzeon, and
- research and development and preclinical testing of other potential product candidates.

We have lost money since inception and, as of December 31, 2004, have an accumulated deficit of approximately \$370.4 million. We may never generate significant revenue from product sales or royalties.

Development of current and future drug candidates will require additional, time-consuming and costly research and development, preclinical testing and extensive clinical trials prior to submission of any regulatory application for commercial use. We expect to incur losses for the foreseeable future and these losses may increase if our research and development, preclinical testing, drug production and clinical trial efforts expand. The amount and timing of our operating expenses will depend on many factors, including:

- the sales levels and market acceptance achieved by Fuzeon,
- the production levels for Fuzeon, which affect the economies of scale in the production process and our cost of goods sold,
- the status of our research and development activities,
- product candidate discovery and development efforts, including preclinical testing and clinical trials,
- the timing of regulatory actions,
- the costs involved in preparing, filing, prosecuting, maintaining, protecting and enforcing patent claims and other proprietary rights,
- our ability to work with Roche to manufacture, develop, sell, market and distribute Fuzeon,
- technological and other changes in the competitive landscape,
- changes in our existing or future research and development relationships and strategic alliances,
- development of any future research and development relationships or strategic alliances,
- evaluation of the commercial viability of potential product candidates, and
- other factors, many of which are outside of our control.

As a result, we believe that period-to-period comparisons of our financial results are not necessarily meaningful. The past results of operations and results of previous clinical trials should not be relied on as an indication of future performance. If we fail to meet the clinical and financial expectations of securities analysts and investors, it could have a material adverse effect on the market price of our common stock. Our ability to achieve profitability will depend, in part, on our own or Roche's ability to successfully develop and obtain and maintain regulatory approval for Fuzeon or other drug candidates, and our ability to develop the capacity, either internally or through relationships with third parties, to manufacture, sell, market and distribute approved products, if any. We may never achieve profitable operations, even if Roche achieves increased Fuzeon sales levels.

Research and Development

The following discussion highlights certain aspects of our on going and planned research and development programs and commercialization efforts. The results of our previous clinical trials are not necessarily indicative of the results of future clinical trials.

Fuzeon[®], enfuvirtide (formerly known as T-20)

Fuzeon is our first-generation HIV fusion inhibitor, a new class of anti-HIV drugs. The FDA has approved the use of Fuzeon in combination with other anti-HIV drugs for the treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. Anti-HIV drugs are referred to as

antiretroviral agents. The standard approach to treating HIV infection has been to lower viral loads by using a combination of drugs other than fusion inhibitors that inhibit one of two of the viral enzymes that are necessary for the virus to replicate: reverse transcriptase and protease. There are currently three classes of drugs that inhibit these two enzymes: nucleoside reverse transcriptase inhibitors, or NRTIs, non-nucleoside reverse transcriptase inhibitors, or NNRTIs, and protease inhibitors, or PIs. We refer to NRTIs and NNRTIs collectively as RTIs. There are eleven FDA-approved RTIs and nine FDA-approved PIs.

In March 2003, the FDA granted accelerated approval for the commercial sale of Fuzeon, and commercial sales of Fuzeon began in March 2003. Roche received accelerated FDA approval of Fuzeon based on 24-week clinical data from two Phase III pivotal trials for Fuzeon. In October 2004, the FDA granted full approval based on results from Phase III clinical trials over 48 weeks.

Roche filed an application for European marketing approval in September 2002. Roche received marketing approval under exceptional circumstances from the European Medicines Evaluation Agency, or EMEA, for use of Fuzeon in the European Union in May 2003. Roche submitted a full analysis of 48-week clinical data to the Committee for Human Medicinal Products, or CHMP, in December 2003 seeking a label change for Fuzeon. In April 2004, the CHMP recommended inclusion of the 48 week data in the label. This was followed by approval by the EMEA for this label change in June 2004. Outside the United States and the European Union, Roche has received approval and reimbursement for Fuzeon in over thirty-five countries, and is in the process of negotiating reimbursement from additional countries in which they plan to market Fuzeon.

Manufacturing

Roche manufactures the bulk drug substance of Fuzeon. Based on our progress and experience to date, we believe that Roche will be able to produce supply of Fuzeon sufficient to meet anticipated demand. If Fuzeon sales levels do not meet Roche and our expectations, the resulting production volumes may not allow Roche to achieve their anticipated economies of scale for Fuzeon. If Roche does not achieve these economies of scale, the costs of goods for Fuzeon could be higher than our current expectations.

Distribution

On April 26, 2004, Fuzeon became available through retail and specialty pharmacies across the U.S. This development enhanced and simplified access to Fuzeon for patients and their healthcare providers. Physicians can write prescriptions for Fuzeon from their own prescription pads and patients can get Fuzeon from the pharmacy of their choice, including Chronimed, Inc. ("Chronimed"). Prior to April 26, 2004, Fuzeon was only available in the U.S. exclusively through Chronimed.

Next Generation Peptides and T-1249

We, together with our partner Roche, are currently researching several promising HIV gp41 peptide inhibitors, with the hope of selecting one of these peptides for advanced pre-clinical studies. In the near-future we plan to select a lead candidate and back-up candidate that will proceed to advanced formulation studies. The results of these studies will determine how rapidly we move towards naming a clinical candidate.

T-1249 is a second-generation HIV fusion inhibitor that has been investigated successfully in four separate clinical trials. Phase I/II trials of T-1249 demonstrated satisfactory efficacy and safety, including in patients who had previously failed on and had developed resistance to Fuzeon. In January 2004, Roche and Trimeris announced that further clinical development of T-1249 was being put on hold due to technical challenges in achieving a formulation capable of delivering a once daily injection. The compound's safety, efficacy and tolerability were not factors affecting the decision. The clinical trial, T1249-105, was ongoing when the decision was made to put the development of T-1249 on hold. T1249-105 is now a compassionate use protocol for patients that were already receiving T-1249, as these patients have exhausted all treatment options. To date, 26 patients have completed 96 weeks of treatment with T-1249. Although in January 2005, we put further clinical development of T-1249 on hold indefinitely, T-1249 remains one of our next-generation drug candidates having established the proof-of-concept in overcoming Fuzeon resistant virus in the clinic. However, our focus will be to continue the pursuit of new formulations of T-1249 or future peptide fusion inhibitors that will allow significantly less frequent dosing.

Other Research Programs

On June 3, 2004, we announced the renewal of an agreement with Array Biopharma Inc., or Array, to discover small molecule entry inhibitors directed against HIV. As part of this renewed agreement, Trimeris will screen small molecule compounds created by Array against HIV entry inhibitor targets. The terms of the agreement are substantially similar to those of the initial agreement, signed in August 2001. Array will be entitled to receive research funding as well as milestone payments and royalties based on the success of this program.

In 2002, we entered into an agreement with Neokimia Inc., or Neokimia, to discover and develop small molecule HIV fusion inhibitors. We will initially screen a library of small molecule compounds provided by Neokimia. Neokimia will use its proprietary drug discovery platform to optimize lead compounds. We will collaborate with Neokimia to identify preclinical drug candidates. Neokimia will provide the initial library of compounds on a non-exclusive basis and will work exclusively with us on the HIV gp41 fusion protein target during the term of the collaboration. We exercised our option to select an additional target to add to the collaboration related to HIV fusion. We will work with Neokimia on a non-exclusive basis on these targets. We, with Neokimia, will equally fund all research activities through the declaration of a development candidate. We will be responsible for all future clinical development, regulatory and commercial activities on a worldwide basis. Neokimia will be entitled to receive payments and royalties on net product sales based on achievement of certain developmental and commercial milestones. Neokimia also has an option to co-fund clinical development activities for development compounds through the end of Phase I human clinical trials, in exchange for increased royalties on net product sales.

The following table summarizes our research expenses since inception (in thousands):

<u>Project</u>	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>1993-2001</u>	<u>Cumulative</u>
Fuzeon	\$12,916	\$21,842	\$39,060	\$142,244	\$216,062
T-1249	2,039	9,386	5,597	13,446	30,468
3rd Generation	3,933	3,208	3,887	—	11,028
Other	2,425	2,387	2,682	—	7,494
All Projects	\$21,313	\$36,823	\$51,226	\$155,690	\$265,052

LIQUIDITY AND CAPITAL RESOURCES

The table below presents our cash flows for the years ended December 31, 2004, 2003 and 2002.

	<u>Years ended December 31,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
	(in thousands)		
Net cash used in operating activities	\$(42,628)	\$(56,720)	\$(72,972)
Net cash (used) provided by investing activities	25,033	(19,707)	21,443
Net cash provided by financing activities	411	1,983	148,970
Net increase (decrease) in cash and cash equivalents	(17,184)	(74,444)	97,441
Cash and cash equivalents, beginning of period	45,285	119,729	22,288
Cash and cash equivalents, end of period	<u>\$ 28,101</u>	<u>\$ 45,285</u>	<u>\$119,729</u>

Operating Activities: Since inception, we have financed our operations primarily through private placements and public offerings of common stock, equipment lease financing and payments received from Roche under our collaboration agreement with Roche.

In 2004, the cash used by operating activities was used primarily to fund research and development relating to Fuzeon, T-1249 and other product candidates and marketing costs for the commercialization of Fuzeon. The amount used decreased for the year ended December 31, 2004, compared to 2003 primarily due to the reduced net loss and accrued marketing costs offset in part by the advance payments made to Roche for our share of the cost of the capital improvements made at Roche's Boulder facility where Fuzeon drug substance is produced.

In 2003 and 2002, the cash used in operating activities was primarily to fund research and development relating to Fuzeon, T-1249 and other product candidates and marketing costs for the commercialization of Fuzeon. The amount used decreased for the year ended December 31, 2003, compared to 2002 primarily due to milestone payments received from Roche and reduced research and development expenses for the development of Fuzeon.

Investing Activities: In 2004, cash provided by investing activities was due to net maturities of investment securities—available-for-sale of \$26.6 million, offset in part by purchases of property, furniture and equipment of \$1.2 million and patent costs of \$406,000.

In 2003, cash used by investing activities was due to net purchases of investment securities—available-for-sale of \$17.4 million, purchases of property, furniture and equipment of \$1.4 million and patent costs of \$900,000.

In 2002, cash provided by investing activities was due to net maturities and sales of investment securities—available-for-sale of \$22.8 million, purchases of property, furniture and equipment of \$949,000 and patent costs of \$445,000.

Financing Activities: During 2004 and 2003, the cash provided was primarily due to the exercise of employee stock options and purchases of our stock under the employee stock purchase plan offset, in part, by payments under capital lease obligations. During 2002, the cash provided was primarily the result of the sale of our common stock offset, in part, by payments under capital lease obligations.

Total Cash, Cash Equivalents and Investment securities—available-for-sale. As of December 31, 2004, we had \$48.4 million in cash and cash equivalents and investment securities—available-for-sale, compared to \$92.2 million as of December 31, 2003. The decrease is primarily a result of cash used by operating activities during the year ended December 31, 2004.

Future Capital Requirements. We have experienced negative cash flows from operations since our inception and do not anticipate generating sufficient positive cash flows to fund our operations in the foreseeable future. Although we expect to share the future development costs for Fuzeon and any other potential drug candidates covered by our collaboration for the United States and Canada with Roche, we have expended, and expect to continue to expend in the future, substantial funds to pursue our drug candidates and compound discovery and development efforts, including:

- expenditures for marketing activities related to Fuzeon,
- research and development and preclinical testing of other product candidates, and
- the development of our proprietary technology platform.

We and Roche share profits equally from the sale of Fuzeon in the United States and Canada and we receive a royalty on the net sales of Fuzeon outside of these two countries. Under provisions of this agreement, our actual cash contribution to the selling and marketing expenses for Fuzeon in 2004 was limited to approximately \$10 million, even though Roche spent significantly more on these expenses. If certain cumulative levels of sales for Fuzeon in the United States and Canada are achieved, our share of any additional expenses incurred by Roche during 2004 will be payable to Roche beginning at a future date over several years from that future date. Although our 2005 contribution to selling and marketing expenses will be higher as compared to 2004, we are currently in negotiations with Roche to finalize the 2005 budget for selling and marketing expenses and the amount of our contribution.

Under the current operating environment, excluding any extraordinary items, based on current sales levels of Fuzeon, we expect that our existing capital resources, together with the interest earned thereon, will be adequate to fund our current programs for at least the next 24 months. However, any reduction in Fuzeon sales below current levels or increase in expenditures beyond currently expected levels would increase our capital requirements substantially beyond our current expectations. If we require additional funds and such funds are not available through debt or equity financings, or collaboration arrangements, we will be required to delay, scale-back or eliminate certain preclinical testing, clinical trials and research and development programs, including our collaborative efforts with Roche. In the event Roche becomes unable or unwilling to share future development expenses for Fuzeon, T-1249 or our other potential drug candidates, our capital requirements would increase substantially beyond our current expectations.

Our future capital requirements and the adequacy of available funds will depend on many factors, including the level of market acceptance and sales levels achieved by Fuzeon; expenses related to the sale of Fuzeon; the condition of the capital markets; the progress and scope of our product development programs; the magnitude of these programs; the results of preclinical testing and clinical trials; the need for additional facilities based on the results of these clinical trials and other product development programs; changes in the focus and direction of our product development programs; the costs involved in preparing, filing, processing, maintaining, protecting and enforcing patent claims and other intellectual property rights; competitive factors and technological advances; the cost, timing and outcome of regulatory reviews; changes in the requirements of the FDA; administrative and legal expenses; evaluation of the commercial viability of potential product candidates and compounds; the establishment of capacity, either internally or through relationships with third parties, for manufacturing, sales, marketing and distribution functions; the results of our business development activities, including in-licensing and merger and acquisition opportunities; and other factors, many of which are outside of our control.

Since our initial public offering in 1997, we have obtained the majority of our funding through public or private offerings of our common stock. We expect to continue to obtain our funding through public or private offerings of our common stock or other equity like instruments, like convertible preferred stock or convertible debt, until such time, if ever, as we are able to generate significant funds from operations.

We may have difficulty raising additional funds by selling equity. If we fail to meet the clinical and financial expectations of securities analysts and investors, it could have a material adverse effect on the market price of our common stock and restrict or eliminate our ability to raise additional funds by selling equity. The public capital markets in which shares of our common stock are traded have been extremely volatile. Therefore, even if we do achieve positive clinical or financial results that meet or exceed the expectations of securities analysts and investors, the state of the public equity markets in general and particularly the public equity market for biotechnology companies may prohibit us from raising funds in the equity markets on acceptable terms or at all. Even if we are able to obtain additional funding through an equity financing, the terms of this financing could be highly dilutive to current shareholders.

We may also attempt to obtain additional funding through debt and debt-like financings such as convertible debt and/or arrangements with new or existing collaborative partners. Any debt financings may contain restrictive terms that limit our operating flexibility. Arrangements with collaborative partners may require us to relinquish rights to our technologies or product candidates or to reduce our share of potential profits. This could have a material adverse effect on our business, financial condition or results of operations.

Contractual Obligations. The following table summarizes our material contractual commitments at December 31, 2004.

<u>Contractual Obligation</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>Thereafter</u>	<u>Total</u>
	(in thousands)						
Operating leases*	\$1,549	\$1,508	\$1,508	\$1,538	\$1,569	\$ 8,473	\$16,145
Other contractual obligations**	3,025	2,112	2,000	2,000	1,000	—	10,137
Other long-term liabilities reflected on the Balance Sheet***	—	—	—	—	—	15,761	15,761
Total	<u>\$4,574</u>	<u>\$3,620</u>	<u>\$3,508</u>	<u>\$3,538</u>	<u>\$2,569</u>	<u>\$24,234</u>	<u>\$42,043</u>

* Includes payments due under a sublease signed during June 2004, that commenced on January 1, 2005, on an existing office and laboratory building.

** We are making advance payments to Roche for our share of the cost of the capital improvements made at Roche's Boulder facility where Fuzeon drug substance is produced. Through a series of negotiations, we reached an understanding in principle with Roche whereby we will pay Roche for our share of the capital invested in Roche's manufacturing facility over a seven-year period. We are in the process of formalizing these terms in a written agreement. Our anticipated share of this capital investment is approximately \$14.0 million. At December 31, 2004, we have paid \$4.5 million and accrued \$500,000 (netted in our receivable from Roche) and expect to pay approximately \$500,000 per quarter through June 2009. This amount, net of charges to cost of goods sold, is

recorded as an asset on our Balance Sheet under the caption "Advanced payment—Roche." In the event our collaboration agreement is terminated, we would not be obligated for any unpaid amounts for capital investment. This amount also includes \$1.0 million in 2005 and \$112,000 in 2006 for contracts to purchase product candidate material and fund various clinical studies contingent on delivery of the materials or performance of the services. Substantially all of these costs will be shared equally with Roche.

*** Our actual cash contribution to the selling and marketing expenses for Fuzeon in 2004 is limited to approximately \$10 million, even though Roche spent significantly more on these expenses. If certain cumulative levels of sales for Fuzeon in the United States and Canada are achieved, our share of any additional expenses incurred by Roche during 2004 will be payable to Roche beginning at a future date over several years from that future date. We currently estimate this date to be in 2011. During the year ended December 31, 2004, we reached our \$10 million limitation for the year. We recorded a liability of approximately \$15.8 million as part of collaboration loss during the year ended December 31, 2004. This represents the net present value of our estimated share of the additional expenses, discounted at a risk-free interest rate from the expected payment date based on achievement of the sales milestones in the agreement.

RESULTS OF OPERATIONS

Comparison Of Years Ended December 31, 2004, 2003 and 2002

Revenues

The table below presents our revenue sources for the years ended December 31, 2004, 2003 and 2002.

	Years ended December 31,				
	2004	2003	2002	2004 to 2003 Increase (Decrease)	2003 to 2002 Increase (Decrease)
	(in thousands)				
Milestone revenue	\$ 2,152	\$ 2,964	\$1,133	\$ (812)	\$ 1,831
Royalty revenue	4,556	755	—	3,801	755
Collaboration loss	(16,125)	(25,515)	—	9,390	(25,515)
Total revenue and collaboration loss	<u>\$ (9,417)</u>	<u>\$(21,796)</u>	<u>\$1,133</u>	<u>\$12,379</u>	<u>\$(22,929)</u>

Milestone revenue: Total milestone revenue represents the amortization of achieved milestones under our collaboration with Roche.

The table below presents our achieved milestones from Roche as of December 31, 2004. We are recognizing these milestones on a straight-line basis.

Milestone Total	Date Achieved	Total Revenue Recognized Through December 31, 2004	Revenue for the year ended December 31, 2004	End of Recognition Period
		(in thousands)		
\$ 4,600*	July 1999	\$3,413	\$ 198	December 2010
2,000	October 2000	1,331	112	December 2010
8,000	March 2003	2,408	932	December 2010
5,000	May 2003	1,338	610	December 2010
2,500	June 2003	388	250	June 2013
750**	June 2004	51	50	June 2013
Total		<u>\$8,929</u>	<u>\$2,152</u>	

* Roche made a nonrefundable initial cash payment to the Company of \$10 million during 1999. In July 1999, the Company granted Roche a warrant to purchase 362,000 shares of common stock at a purchase price of \$20.72 per share. The fair value of the warrant of \$5.4 million was credited to additional paid-in capital in 1999, and as a reduction of the \$10 million up-front payment received from Roche. We have deferred \$4.6 million, the net of the \$10 million up-front payment and the \$5.4 million in warrants, over the research and development period.

** We are in the process of finalizing an amendment to our collaboration agreement with Roche. In its present form the proposed amendment resolves issues related to the performance of certain milestones. As of June 2004, the parties had agreed that certain performance targets had been met and that payment of this milestone was appropriate. We have recorded these amounts as of December 31, 2004 in anticipation that we will reach a final agreement with terms substantially the same as those we have agreed to in principle.

In January 2005, based on our current evaluation of our research and development programs, we placed further clinical development of T-1249 on hold indefinitely due to challenges in achieving an extended release formulation that would allow significantly less dosing frequency. In the near future we will select a lead peptide candidate to conduct pre-clinical and advanced formulation research with the goal of less frequent delivery. Taking into account the additional research that will be required to achieve these new formulation goals, in 2005 we changed our estimate of the end of the research and development period from December 2010 to December 2012; as a result we will recognize approximately \$500,000 less revenue in 2005 compared to 2004.

Royalty revenue: Royalty revenue represents the royalty payment earned from Roche based on total net sales of Fuzeon outside the United States and Canada. Sales of Fuzeon outside the United States and Canada began in June 2003. To calculate the royalty revenue an 8% distribution charge is deducted from Roche's reported net sales, from which Trimeris receives a 10% royalty.

The table below presents net sales outside the United States and Canada for the years ended December 31, 2004 and 2003. Fuzeon was launched in June 2003 in the EU.

	Years ended December 31		
	2004	2003	Increase (Decrease)
	(in thousands)		
Total net sales outside the United States and Canada (as recorded by Roche)	\$49,523	\$8,210	\$41,313

Collaboration Loss: The table below presents our collaboration loss for the year ended December 31, 2004 compared to the year ended December 31, 2003. Collaboration loss is reported on our Statement of Operations as a component of revenue. Under our collaboration agreement with Roche, we share profits equally from the sale of Fuzeon in the United States and Canada. Fuzeon was launched in March 2003.

	Years ended December 31,		
	2004	2003	Increase (Decrease)
	(in thousands)		
Gross Fuzeon sales by Roche	\$ 99,908	\$ 32,246	\$ 67,662
Less sales adjustments	(14,215)	(3,901)	10,314
Net sales	85,693	28,345	57,348
Cost of goods sold	(51,766)	(11,864)	39,902
Gross margin	33,927	16,481	17,446
Selling and marketing expenses	(22,311)	(57,628)	35,317
Other costs	(11,504)	(9,526)	(1,978)
Total shared profit & loss	112	(50,673)	50,785
Trimeris share (50%)	56	(25,337)	25,393
Costs exclusive to Trimeris Inc.	(16,181)	(178)	(16,003)
Net collaboration loss	\$(16,125)	\$(25,515)	\$ 9,390

Gross Fuzeon sales by Roche: Gross Fuzeon sales are recorded by Roche. Prior to April 26, 2004, Roche had an exclusive distribution arrangement with Chronimed to distribute Fuzeon in the United States during the initial commercial launch in 2003, which terminated on April 26, 2004. Effective April 26, 2004, Fuzeon became available through retail and specialty pharmacies across the U.S. Prior to April 26, 2004, revenue from product sales was recognized when title and risk of loss has passed to Chronimed, which was when Chronimed allocated drug for shipment to a patient. Beginning April 26, 2004, revenue is recognized when Roche ships drug and title and risk of loss passes to wholesalers.

The table below presents the number of kits shipped to wholesalers in the U.S. and Canada during 2004 and 2003.

<u>Kits Shipped</u>	<u>2004</u>	<u>2003</u>
Q1	11,000	—
Q2	16,200*	3,000
Q3	14,600	7,000
Q4	17,200	9,000
Total	<u>59,000</u>	<u>19,000</u>

* Includes an estimated 3,000 kits as a result of inventory build up at wholesalers.

Sales adjustments: Sales adjustments are recorded by Roche based on their experience with selling Fuzeon. Sales adjustments increased for the year ended December 31, 2004 as compared to the year ended December 31, 2003 due to increased kit sales as presented above. There were no material revisions to Roche's recorded estimates of sales adjustments for the years ended December 31, 2004 and 2003.

Cost of goods sold: Cost of goods sold increased for the year ended December 31, 2004 as compared to the year ended December 31, 2003 due to increased kit sales as described above.

Cost of goods sold for the year ended December 31, 2004 includes approximately \$6.8 million relating to unabsorbed costs that were the result of unexpectedly low initial manufacturing volumes when Fuzeon was launched and various costs associated with the development of the Fuzeon manufacturing process.

These costs were disclosed to us during the second quarter of 2004 by Roche. Previously, we inquired about manufacturing variances and were provided amounts by Roche which we previously recorded. After a series of discussions and negotiations during the second quarter with Roche and notwithstanding our contractual agreement, we agreed in principle on an amount subject to some additional due diligence. We recorded the above amount during the second quarter. We are currently in the process of formalizing an amendment to our collaboration agreement with respect to the variance calculation.

Gross Margin: Gross margin as a percentage of net sales for the year ended December 31, 2004 was 40% compared to 58% for the year ended December 31, 2003. The gross margin for the year ended December 31, 2004 declined compared to December 31, 2003 primarily as a result of unabsorbed manufacturing costs described in the immediately preceding two paragraphs. Excluding these costs, gross margin from the collaboration for the year ended December 31, 2004 is approximately 47% compared to 34% for the year ended December 31, 2003.

Selling and marketing expenses: Our actual cash contribution to certain selling and marketing expenses for Fuzeon in 2004 is limited to approximately \$10 million, even though Roche spent significantly more on these expenses. If certain cumulative levels of sales for Fuzeon in the United States and Canada are achieved, our share of any additional expenses incurred by Roche during 2004 will be payable to Roche beginning at a future date over several years from that future date. During the year ended December 31, 2004, we reached our \$10 million limitation for the year. Although our 2005 contribution to selling and marketing expenses will be higher as compared to 2004, we are currently in negotiations with Roche to finalize the 2005 budget for selling and marketing expenses and the amount of our contribution. Selling and marketing expenses excludes incremental selling and marketing costs included in "Costs exclusive to Trimeris," below.

Other costs: Other costs for the year ended December 31, 2004 comprises net inventory write offs, a supply contract penalty and charges for the Boulder manufacturing facility. Also included in other costs are general and administrative and distribution charges. Trimeris is responsible for 50% of these costs under the collaboration agreement.

Costs exclusive to Trimeris: Costs exclusive to Trimeris includes the net present value of the Company's estimated share of certain marketing expenses in excess of approximately \$10 million, based on expected timing and terms of payment under the agreement. The marketing limit is discussed above. Also included in the costs exclusive to Trimeris is approximately \$575,000 related to license fees for certain technology paid to a third party.

Research And Development Expenses

The table below presents our research and development expenses for the years ended December 31, 2004, 2003 and 2002.

	Years ended December 31,			2004 to 2003 Increase (Decrease)	2003 to 2002 Increase (Decrease)
	2004	2003	2002		
	(in thousands)				
Non-cash compensation	\$ 159	\$ (1)	\$ 250	\$ 160	\$ (251)
Other research and development expense	21,154	36,824	50,976	(15,670)	(14,152)
Total research and development expense	<u>\$21,313</u>	<u>\$36,823</u>	<u>\$51,226</u>	<u>\$(15,510)</u>	<u>\$(14,403)</u>

Total research and development expenses include gross research and development expenses less Roche's share of such costs for Fuzeon and T-1249. Under our collaboration agreement, Roche and we shared equally the development costs incurred during the period from July 1, 1999 to December 31, 2004 for Fuzeon, T-1249 and other potential candidates.

Non-cash compensation: Non-cash compensation expense for the year ended December 31, 2004 is primarily comprised of amortization expense for restricted stock issued to employees in June 2004. This restricted stock grant vests 100% after the third year of service and is being amortized on a straight-line basis over the three-year period. Non-cash compensation expense in 2003 and 2002 comprises expense calculated under EITF 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." The change in expense resulted because the cumulative expense calculated under EITF 96-18 for stock options previously granted to non-employees was less at December 31, 2003 compared to December 31, 2002, primarily because of the decrease in the market price of our stock from \$43.17 at December 31, 2002 to \$20.94 at December 31, 2003, and the fact that a significant number of the options previously granted to non-employees became vested during 2002. At December 31, 2003, the majority of these options were vested.

Other research and development expense: Other research and development expense decreased for the year ended December 31, 2004 compared to the year ended December 31, 2003 as a result of:

- decreased costs associated with ongoing clinical trials for Fuzeon,
- decreased costs associated with our clinical trials for T-1249, whose clinical development was put on hold in January 2004,
- decrease in the purchase of drug material for future clinical trials,
- decrease in the costs in connection with a potential building project, and
- decreased personnel expenses, due to a headcount reduction in workforce implemented in January 2004

Other research and development expense decreased for the year ended December 31, 2003 compared to the year ended December 31, 2002 as a result of reduced expenses related to the following:

- production of drug material for Fuzeon clinical trials,
- our two Phase III clinical trials for Fuzeon which were initiated in late 2000, and the data accumulation and compilation process for clinical data from these trials,
- our Phase II clinical trials for Fuzeon which were substantially completed in 2002.
- during 2003, we extended the term of our research agreement with Roche to December 2005. We also recognized reimbursement from Roche for their 50% share of certain research and development expenses, incurred by Trimeris, during the year ended December 31, 2003. We did not recognize a similar reimbursement for the year ended December 31, 2002 because the research agreement was not renewed until December 2003.

Total research personnel were 62, 91 and 88 at December 31, 2004, 2003 and 2002, respectively. We expect research and development expenses, net of the reimbursements for Fuzeon and next generation development costs from Roche, to be lower during 2005 as compared to 2004, barring any unforeseen changes, as a result of reduced post marketing commitment expenses for Fuzeon due to the fact that we received accelerated FDA approval, and submitted 48 week data for full FDA approval during 2003 and received approval in October of 2004.

In 2004, Roche and Trimeris conducted research pursuant to an agreed upon research plan, in furtherance of our goals under our joint research agreement. In 2005, we believe that the total cost to be shared by the parties under the research plan will be significantly less than in 2004. Although, the research agreement itself does not require that a specific amount be spent on any annual research plan, at their discretion, either party has the option to supplement the budgeted research plan at their own additional expense. At present we are still in discussions with Roche to define the research plan and budget for 2005.

General and Administrative Expenses

The table below presents our general and administrative expenses for the years ended December 31, 2004, 2003 and 2002.

	Years ended December 31,			2004 to 2003 Increase (Decrease)	2003 to 2002 Increase (Decrease)
	2004	2003	2002		
			(in thousands)		
Non-cash compensation	\$ 311	\$ 767	\$ 1,645	\$ (456)	\$ (878)
Other general and administrative expense	9,840	7,810	9,340	2,030	(1,530)
Total general and administrative expense	<u>\$10,151</u>	<u>\$8,577</u>	<u>\$10,985</u>	<u>\$1,574</u>	<u>\$(2,408)</u>

Non-cash compensation: Non-cash compensation expense for the year ended December 31, 2004 is comprised of amortization expense for restricted stock issued to employees in June 2004. This restricted stock grant vests 100% after the third year of service and is being amortized on a straight-line basis over the three-year period. Non-cash compensation expense in 2003 and 2002 comprises expense calculated under EITF 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." The decrease from 2002 to 2003 is primarily due to the fact that some of the options previously granted to a former consultant who became an employee during 2001 became vested during 2002, and the remaining options granted to this individual became vested during 2003.

Other general and administrative expense: Other general and administrative expense increased for the year ended December 31, 2004 compared to the year ended December 31, 2003 as a result of :

- increased costs to meet new requirements placed on public companies by The Sarbanes-Oxley Act of 2002 and related regulations issued by the SEC and new Nasdaq listing standards,
- increased incentive compensation payments to our executives. In 2003, we did not pay bonuses to our three top executives,
- increased premiums for directors and officers' insurance and
- increased recruitment costs.

Other general and administrative expense decreased for the year ended December 31, 2003 compared to the year ended December 31, 2002 as a result of:

- decreased professional fees related to a legal dispute with a former consultant that was settled in 2002, and
- decreased bonuses as we did not pay bonuses to our three top executives for 2003.

These decreases were partially offset by increases in the following expenses:

- increased premiums for directors and officers' insurance, and
- additional professional fees due to new requirements placed on public companies by The Sarbanes-Oxley Act of 2002.

Total general and administrative employees were 35, 41 and 40 at December 31, 2004, 2003 and 2002, respectively. We expect other general and administrative expenses to increase in the future due to increased costs to meet new requirements placed on public companies by The Sarbanes-Oxley Act of 2002 and related regulations issued by the SEC and new Nasdaq listing standards.

Other Income (Expense)

The table below presents our other income (expense) for the years ended December 31, 2004, 2003 and 2002.

	<u>Years ended December 31,</u>			<u>2004 to 2003 Increase (Decrease)</u>	<u>2003 to 2002 Increase (Decrease)</u>
	<u>2004</u>	<u>2003</u>	<u>2002</u>		
			(in thousands)		
Interest income	\$ 953	\$1,534	\$2,230	\$(581)	\$(696)
Interest expenses	(160)	(41)	(108)	(119)	67
Total other income (expense)	<u>\$ 793</u>	<u>\$1,493</u>	<u>\$2,122</u>	<u>\$(700)</u>	<u>\$(629)</u>

Other income (expense) consists of interest income and expense. Interest income decreased across all periods as a result of decreasing average investment balances. Interest expense increased in 2004 compared to 2003 as a result of accreting the excess marketing expenses recorded on the balance sheet as "Accrued marketing costs." Our actual cash contribution to certain selling and marketing expenses for Fuzeon in 2004 is limited to approximately \$10 million, even though Roche spent significantly more on these expenses. If certain cumulative levels of sales for Fuzeon in the United States and Canada are achieved, our share of any additional expenses incurred by Roche during 2004 will be payable to Roche beginning at a future date over several years from that future date. During the year ended December 31, 2004, we reached our \$10 million limitation for the year. We recorded a liability of approximately \$15.8 million as part of collaboration loss during the year ended December 31, 2004. This represents the net present value of our estimated share of the additional expenses, discounted at a risk-free interest rate from the expected payment date based on achievement of the sales milestones in the agreement. Interest expense in 2003 and 2002 is related to interest payments on capital leases during those periods. All capital leases were paid off during 2003.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements other than operating leases for our properties. In the past we have entered into derivative transactions that represented call options sold on our stock to a third party financial institution and were entered into in order to generate cash from the option premiums and provide us with the opportunity to raise capital at prices significantly in excess of the market price at the time of the transaction. All of these options have expired unexercised. In the event these options were exercised, we expect they would have been settled by issuing shares of our stock. We may enter into similar transactions in the future, subject to market conditions. We enter into these transactions as a potential method to raise capital and not to speculate on the future market price of our stock. We have no subsidiaries or other unconsolidated limited purpose entities, and we have not guaranteed or otherwise supported the obligations of any other entity.

In April 2002, we entered into a set of derivative transactions with a financial institution that could have been settled by selling up to 200,000 shares of our stock to the financial institution at prices significantly higher than the market price per share of our stock at the inception of the transaction. Alternatively, we had the option to settle this contract by making a cash payment to the financial institution for the underlying value of the derivative contract to the financial institution on the settlement date. This contract was expected to be settled by issuing shares of our stock in the event the option was exercised. This agreement expired unexercised. In 2002, we received approximately \$388,000 in proceeds for the sale of this call option that was accounted for as an increase to additional paid-in capital in accordance with EITF 00-19. We may enter into similar transactions in the future, subject to market conditions. We enter into these transactions as a potential method to raise capital and not to speculate on the future market price of our stock.

Critical Accounting Policies

We believe the following accounting policies are the most critical to our financial statements. We believe they are important to the presentation of our financial condition, and require the highest degree of management judgment to make the estimates necessary to ensure their fair presentation. Actual results could differ from those estimates.

Revenue Recognition Under Staff Accounting Bulletin No. 104

Staff Accounting Bulletin (“SAB”) No. 104, “Revenue Recognition” summarizes the SEC’s views in applying generally accepted accounting principles to revenue recognition in financial statements. SAB No. 104 establishes the SEC’s view that it is not appropriate to recognize revenue until all of the following criteria are met: persuasive evidence that an arrangement exists; delivery has occurred or services have been rendered; the seller’s price to the buyer is fixed or determinable; and collectability is reasonably assured. Further, SAB No. 104 requires that both title and the risks and rewards of ownership be transferred to the buyer before revenue can be recognized. We believe that our revenue recognition policies are in compliance with SAB No. 104.

Milestone Revenue and Deferred Revenue—Roche

SAB No. 104 provides guidance that it is appropriate to recognize revenue related to license and milestone payments over the research and development term of a collaboration agreement. The primary estimates we make in connection with the application of this policy are the length of the period of the research and development under our collaboration agreement with Roche and the estimated commercial life of Fuzeon. In the event our judgment of the length of these terms changes, the milestone revenue to be recognized under our collaboration with Roche would change prospectively in accordance with Accounting Principles Board Opinion (“APB”) No. 20, “Accounting Changes.” If either term were expected to be longer, the amount of revenue recognized would be less per quarter than currently being recognized. If either term were expected to be shorter, the amount of revenue recognized would be more per quarter than currently being recognized.

To date, the Company has received a \$10 million license fee, research milestone payments of \$15 million and has achieved \$3.3 million in manufacturing milestones. The license fee and research milestones were recorded as deferred revenue and are being recognized ratably over the research and development period. The manufacturing milestones were also recorded as deferred revenue and are being recognized ratably through June 2013, which is the current expected commercial life of Fuzeon.

At the time of the license fee payment, Roche was granted a warrant to purchase Trimeris stock. The fair value of the warrant, \$5.4 million, was credited to additional paid-in capital in 1999, and as a reduction of the \$10 million license fee payment.

Over the course of the collaboration, our estimate of the end of the research and development period has changed:

- During the fourth quarter of 2002, we changed our estimate of the end of this research and development period to 2007 based on the expected development schedule of T-1249 or a replacement compound, the final compound covered by our collaboration agreement with Roche.
- During the first quarter of 2004, we changed our estimate of the end of the research and development period to 2010 from 2007. This change was due to a change in estimate of the development period for T-1249 or a replacement compound as further clinical development of T-1249 has been placed on hold. We recognized approximately \$800,000 less of milestone revenue for the year ended December 31, 2004 compared to the year ended December 31, 2003 due largely in part to this change in estimate.
- In January 2005, based on our current evaluation of our research and development programs, we placed further clinical development of T-1249 on hold indefinitely due to challenges in achieving an extended release formulation that would allow significantly less dosing frequency. Taking into account the additional research that will be required to achieve our goals for formulation, in January 2005, we changed our estimate of the end of the research and development period from December 2010 to December 2012; as a result we will recognize approximately \$500,000 less milestone revenue in 2005 compared to 2004.

Collaboration Income/Loss

Product sales of Fuzeon began in the United States on March 27, 2003 and are recorded by Roche. Under the collaboration agreement with Roche, the Company shares profits equally from the sale of Fuzeon in the United States and Canada with Roche, which is reported as collaboration income (loss) in the Statements of Operations as a component of revenue. Collaboration income (loss) is calculated as follows: Total gross sales of Fuzeon in the United

States and Canada is reduced by any estimated discounts, rebates or returns resulting in total net sales. Net sales are reduced by costs of goods sold resulting in gross margin. Gross margin is reduced by selling and marketing expenses and other costs related to the sale of Fuzeon, resulting in operating income or loss. The Company's 50% share of the operating income or loss is reported as collaboration income or loss as a component of revenue. Roche previously had an exclusive distribution arrangement with Chronimed to distribute Fuzeon in the United States. This exclusive arrangement terminated on April 26, 2004. Effective April 26, 2004, Fuzeon became available through retail and specialty pharmacies across the U.S. Prior to April 26, 2004, revenue from product sales was recognized when title and risk of loss has passed to Chronimed, which is when Chronimed allocates drug for shipment to a patient. We do not believe there were any shipments that were as a result of incentives and/or in excess of the wholesaler's ordinary course of business inventory level. Beginning April 26, 2004, revenue is recognized when Roche ships drug and title and risk of loss passes to wholesalers. Roche prepares its estimates for sales returns and allowances, discounts and rebates based primarily on their historical experience with Fuzeon and other anti-HIV drugs and their estimates of the payor mix for Fuzeon, updated for changes in facts and circumstances on a quarterly basis. If actual results differ from these estimates, these estimates will be adjusted which could have an effect on results from operations in the period of adjustment.

We recognize 50% of the total Collaboration income/loss which includes estimates made by and recorded by Roche for reductions to gross sales for expected returns of expired products, government rebate programs, such as Medicaid reimbursements, and customer incentives, such as cash discounts for prompt payment. Estimates for government rebate programs and cash discounts are determined by Roche based on contractual terms, historical information from Roche's anti-HIV drug portfolio, and Roche's expectations regarding future utilization rates for these programs. Estimates for product returns are based on an on-going analysis of industry return patterns and historical return patterns by Roche for its anti-HIV drug portfolio. This includes the purchase of third-party data by Roche to assist Roche and us in monitoring channel inventory levels and subsequent prescriptions for Fuzeon. We also monitor the activities and clinical trials of our key competitors and assess the potential impact on future Fuzeon sales and return expectations where necessary. Expected returns for Fuzeon are generally low as Fuzeon has a high Wholesale Acquisition Cost, or WAC, compared to other anti-HIV drugs, and requires significantly more storage space than other anti-HIV drugs due to the size of a monthly kit because Fuzeon requires twice daily injections. Consequently wholesalers tend to stock only the necessary volumes of Fuzeon inventory. We believe that wholesalers hold less than a month of Fuzeon inventory. The current shelf life of Fuzeon is 36 months. Roche reviews the estimates discussed above on a quarterly basis and revises estimates as appropriate for changes in facts or circumstances. These estimates reduce our share of collaboration income or loss under our collaboration agreement.

Calculation of Compensation Costs for Stock Options Granted to Non-Employees

Compensation costs for stock options granted to non-employees are accounted for in accordance with Statement of Financial Accounting Standards ("SFAS") No. 123 and Emerging Issues Task Force ("EITF") Issue No. 96-18, which require that such compensation costs be measured at the end of each reporting period to account for changes in the fair value of the Company's common stock until the options are vested. These costs are non-cash charges resulting from stock option grants to non-employees. The primary estimate we make in connection with the calculation of this expense is the future volatility of our stock price used to calculate the value of the stock options in the Black-Scholes option-pricing model. At December 31, 2004, we estimated the future volatility at 50% based on the implied future volatility for call options in our stock quoted on the Chicago Board Options Exchange in January 2005. A higher volatility would result in greater compensation costs, and a lower volatility would result in lower compensation costs for these stock options.

In addition, the closing market price per share of our stock at the end of each reporting period has a significant effect on the value of the stock options calculated using the Black-Scholes option-pricing model. A higher market price per share of our stock would result in greater compensation costs, and a lower market price per share of our stock would result in lower compensation costs for these stock options. At December 31, 2004, there were options to purchase approximately 21,000 shares of common stock granted to non-employees outstanding that were not fully vested that could result in additional changes in compensation costs under EITF 96-18.

Capitalization of Patent Costs

The costs of patents are capitalized and are amortized using the straight-line method over the estimated remaining lives of the patents, either 17 years from the date the patent is granted or 20 years from the initial filing of the patent, depending on the patent. These costs are primarily legal fees and filing fees related to the prosecution of patent filings. We perform a continuous evaluation of the carrying value and remaining amortization periods of these costs. The primary estimate we make is the expected cash flows to be derived from the patents. In the event future expected cash flows derived from any patents are less than their carrying value, the related costs would be expensed at that time.

Accrued Marketing Costs

In 2004 we reached an agreement with Roche whereby our actual cash contribution to certain selling and marketing expenses for Fuzeon in 2004 is limited to approximately \$10 million, even though Roche spent significantly more on these expenses. If certain cumulative levels of sales for Fuzeon in the United States and Canada are achieved, our share of any additional expenses incurred by Roche during 2004 will be payable to Roche beginning at a future date over several years from that future date. We currently estimate this date to be in 2011. During the year ended December 31, 2004, we reached our \$10 million limitation for the year. We recorded an expense, and associated liability, of approximately \$15.6 million as part of collaboration loss during the year ended December 31, 2004. This represents the net present value of our estimated share of the additional expenses, discounted at a risk free interest rate from the expected payment date based on achievement of the sales milestones in the agreement. We are increasing the liability over time to the expected payment amount. In 2004 we increased this liability by \$154,000, for accretion of interest. The total liability of \$15.8 million is reflected on our balance sheet under the caption "Accrued marketing costs."

Advanced Payment—Roche

We are making advance payments to Roche for our share of the cost of the capital improvements made at Roche's Boulder facility where Fuzeon drug substance is produced. Through a series of negotiations, we reached an understanding in principle with Roche whereby we will pay Roche for our share of the capital invested in Roche's manufacturing facility over a seven-year period. We are in the process of formalizing these terms in a written agreement. Our anticipated share of this capital investment is approximately \$14.0 million. At December 31, 2004, we have paid \$4.5 million and accrued \$500,000 and expect to pay approximately \$500,000 per quarter through June 2009. This amount, net of charges to cost of goods sold, is recorded as an asset on our Balance Sheet under the caption "Advanced payment—Roche." This asset will be amortized to cost of goods sold based on the units of Fuzeon sold during the collaboration period. We estimate that as of December 31, 2004, this asset has a remaining useful life of approximately 12 years. In the event our collaboration agreement is terminated, we would not be obligated for any unpaid amounts for capital investment. In addition, other peptide drug candidates discovered under our collaboration with Roche, including T-1249, can be manufactured using this same Roche facility. The carrying value of this asset will be evaluated annually for impairment or if a triggering event occurs.

Accounting and Other Matters

In November 2002, the Financial Accounting Standards Board Emerging Issues Task Force issued its consensus concerning Revenue Arrangements with Multiple Deliverables ("EITF 00-21"). EITF 00-21 addresses how to determine whether a revenue arrangement involving multiple deliverables should be divided into separate units of accounting, and if separation is appropriate, how the consideration should be measured and allocated to the identified accounting units. EITF 00-21 is effective prospectively for arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF 00-21 had no impact on our financial statements.

In December 2003, SFAS No. 132 (revised), "Employers' Disclosures about Pensions and Other Postretirement Benefits," was issued. SFAS No. 132 (revised) prescribes employers' disclosures about pension plans and other postretirement benefit plans; it does not change the measurement or recognition of those plans. SFAS No. 132 (revised) retains and revises the disclosure requirements contained in the original SFAS 132. It also requires additional disclosures about the assets, obligations, cash flows, and net periodic benefit cost of defined benefit pension plans and other postretirement benefit plans. SFAS 132 (revised) generally is effective for fiscal years ending after December 15, 2003. Our disclosures in note 8 incorporate the requirements of SFAS No. 132 (revised).

In November 2004, SFAS No. 151, "Inventory Costs an amendment of ARB No. 43, Chapter 4," was issued. SFAS No. 151 amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that ". . . under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and re-handling costs may be so abnormal as to require treatment as current period charges. . . ." This statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal." In addition, this statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 generally is effective for fiscal years ending after June 15, 2005. We are assessing the impact of this statement on our financial statements.

In December 2004, SFAS No. 123 (revised), "Share-Based Payment," was issued. SFAS No. 123 (revised) requires that the cost resulting from all share-based payment transactions be recognized as a charge in the financial statements. This statement establishes fair value as the measurement objective in accounting for share-based payment arrangements and requires all entities to apply a fair-value-based measurement method in accounting for share-based payment transactions with employees except for equity instruments held by employee share ownership plans. This statement also establishes fair value as the measurement objective for transactions in which an entity acquires goods or services from non-employees in share-based payment transactions. This statement amends FASB Statement No. 95, Statement of Cash Flows, to require that excess tax benefits be reported as a financing cash inflow rather than as a reduction of taxes paid. This Statement replaces FASB Statement No. 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees. SFAS No. 123 (revised) is effective—as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. We are assessing the impact of this statement on our financial statements.

The FASB also issues exposure drafts for proposed statements of financial accounting standards. Such exposure drafts are subject to comment from the public, to revisions by the FASB and to final issuance by the FASB as statements of financial accounting standards. Management considers the effect of the proposed statements on our financial statements and monitors the status of changes to issued exposure drafts and to proposed effective dates.

Corporate Code of Ethics

We have a code of ethics for our employees and officers. This document is available on our website at the following address: http://trimeris.com/about/trimeris_code_of_ethics.pdf.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE OF MARKET RISK

Our exposure to market risk is primarily in our investment portfolio. We do not use derivative financial instruments for speculative or trading purposes. Substantially all of our contracts are denominated in US dollars; therefore, we have no material foreign currency risk. We have an investment policy that sets minimum credit quality standards for our investments. The policy also limits the amount of money we can invest in any one issue, issuer or type of instrument. We have not experienced any material loss in our investment portfolio, and we believe the market risk exposure in our investment portfolio has remained consistent over this period.

The table below presents the carrying value, which is approximately equal to fair market value, and related weighted-average interest rates for our investment portfolio at December 31, 2004. Fair market value is based on actively quoted market prices. Our investments are generally most vulnerable to changes in short-term interest rates in the United States. Substantially all of our investments mature in twelve months or less, and have been given a rating of A1 or higher by a nationally recognized statistical rating organization or are the debt obligations of a federal agency and, therefore, we believe that the risk of material loss of principal due to changes in interest rates is minimal.

	<u>Carrying Amount</u>	<u>Average Interest Rate</u>
	(thousands)	
Cash equivalents—fixed rate	\$27,353	2.09%
Investment securities—available-for-sale—fixed rate	20,301	2.24%
Overnight cash investments—fixed rate	748	1.28%
Total investment securities	<u>\$48,402</u>	<u>2.14%</u>

In April 2002, we entered into a set of call transactions with respect to 200,000 shares of our common stock. This transaction is described in detail under Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Off Balance Sheet Transactions.” The derivative transactions relating to these 200,000 shares expired unexercised in April 2003.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by Item 8 is included in Item 15 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

There have been no changes in or disagreements with the Company’s independent auditors, KPMG LLP.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. We maintain “disclosure controls and procedures,” as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective.

Management’s Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) of the Securities Exchange Act of 1934. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of the company’s internal control over financial reporting as of December 31, 2004. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in Internal Control - Integrated Framework. As a result of this assessment, management believes that, as of December 31, 2004, our internal control over financial reporting is effective based on those criteria.

Our management’s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report which appears on page F-1 of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting. There was no change in our internal control over financial reporting that occurred during the quarter ending December 31, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

No information was required to be disclosed in a report on Form 8-K in the fourth quarter that was not so disclosed.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by Item 10 is incorporated by reference from the Company's Proxy Statement to be filed by the Company with the Securities and Exchange Commission within 120 days after the end of the fiscal year.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is incorporated by reference from the Company's Proxy Statement to be filed by the Company with the Securities and Exchange Commission within 120 days after the end of the fiscal year.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by Item 12 is incorporated by reference from the Company's Proxy Statement to be filed by the Company with the Securities and Exchange Commission within 120 days after the end of the fiscal year.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by Item 13 is incorporated by reference from the Company's Proxy Statement to be filed by the Company with the Securities and Exchange Commission within 120 days after the end of the fiscal year.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by Item 14 as to principal accounting fees and services is incorporated by reference from the Company's Proxy Statement to be filed by the Company with the Securities and Exchange Commission within 120 days after the end of the fiscal year.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

	<u>Page Number</u>
(a)1. Financial Statements	
Reports of Independent Registered Public Accounting Firm	F-1
Balance Sheets as of December 31, 2004 and 2003	F-3
Statements of Operations for the Years Ended December 31, 2004, 2003 and 2002	F-4
Statements of Stockholders' Equity for the Years Ended December 31, 2002, 2003 and 2004	F-5
Statements of Cash Flows for the Years Ended December 31 2004, 2003 and 2002	F-6
Notes to Financial Statements	F-7

(a)2. Financial Statement Schedules

All financial statement schedules required under Regulation S-X are omitted as the required information is not applicable.

(a)3. Exhibits

The Exhibits filed as part of this Form 10-K are listed on the Exhibit Index immediately preceding such Exhibits and are incorporated by reference. The Company has identified in the Exhibit Index each management contract and compensation plan filed as an exhibit to this Annual Report on Form 10-K in response to Item 15(a) of Form 10-K.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Trimeris, Inc.:

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that Trimeris, Inc. (the Company) maintained effective internal control over financial reporting as of December 31, 2004, based on, criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Trimeris, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in COSO. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Trimeris, Inc. as of December 31, 2004 and 2003, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004, and our report dated March 9, 2005, expressed an unqualified opinion on those financial statements.

/s/ KPMG LLP

Raleigh, North Carolina
March 9, 2005

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Trimeris, Inc:

We have audited the accompanying balance sheets of Trimeris, Inc. (the Company) as of December 31, 2004 and 2003, and the related statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Trimeris, Inc. as of December 31, 2004 and 2003, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 9, 2005 expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

/s/ KPMG LLP

Raleigh, North Carolina
March 9, 2005

TRIMERIS, INC.
BALANCE SHEETS
(in thousands, except par value)

	As of December 31,	
	2004	2003
Assets		
Current assets:		
Cash and cash equivalents	\$ 28,101	\$ 45,285
Investment securities—available-for-sale	20,301	46,913
Recoverable franchise taxes	144	—
Accounts receivable—Roche	5,878	—
Prepaid expenses	1,630	2,106
Total current assets	56,054	94,304
Property, furniture and equipment, net of accumulated depreciation and amortization of \$11,646 and \$10,306 at December 31, 2004 and 2003, respectively	2,408	2,578
Other assets:		
Patent costs, net of accumulated amortization of \$200 and \$196 at December 31, 2004 and 2003, respectively	1,829	1,650
Advanced payment—Roche	4,498	—
Deposits	31	68
Total other assets	6,358	1,718
Total assets	\$ 64,820	\$ 98,600
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,424	\$ 893
Accounts payable—Roche	—	11,029
Current installments of obligations under capital leases	—	274
Accrued compensation	2,981	1,739
Deferred revenue—Roche	2,185	3,954
Accrued expenses	260	674
Total current liabilities	6,850	18,563
Deferred revenue—Roche	11,736	11,369
Accrued marketing costs	15,761	—
Other liabilities	127	—
Total liabilities	34,474	29,932
Stockholders' equity:		
Preferred Stock at \$0.001 par value per share, authorized 10,000 shares; issued and outstanding zero shares at December 31, 2004 and 2003	—	—
Common Stock at \$0.001 par value per share, authorized 60,000 shares; issued and outstanding 21,917 and 21,573 shares at December 31, 2004 and 2003, respectively ..	22	22
Additional paid-in capital	403,307	398,925
Accumulated deficit	(370,364)	(330,276)
Deferred compensation	(2,613)	—
Accumulated other comprehensive income (loss)	(6)	(3)
Total stockholders' equity	30,346	68,668
Commitments and contingencies		
Total liabilities and stockholders' equity	\$ 64,820	\$ 98,600

See accompanying notes to financial statements.

TRIMERIS, INC.

STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	For the Years Ended December 31,		
	2004	2003	2002
Revenue:			
Milestone revenue	\$ 2,152	\$ 2,964	\$ 1,133
Royalty revenue	4,556	755	—
Collaboration loss	(16,125)	(25,515)	—
Total revenue and collaboration loss	(9,417)	(21,796)	1,133
Operating expenses:			
Marketing expense	—	—	16,722
Research and development:			
Non-cash compensation	159	(1)	250
Other research and development expense	21,154	36,824	50,976
Total research and development expense	21,313	36,823	51,226
General and administrative:			
Non-cash compensation	311	767	1,645
Other general and administrative expense	9,840	7,810	9,340
Total general and administrative expense	10,151	8,577	10,985
Total operating expenses	31,464	45,400	78,933
Operating loss	(40,881)	(67,196)	(77,800)
Other income (expense):			
Interest income	953	1,534	2,230
Interest expense	(160)	(41)	(108)
Total other income (expense)	793	1,493	2,122
Net loss	\$(40,088)	\$(65,703)	\$(75,678)
Basic and diluted net loss per share	\$ (1.86)	\$ (3.06)	\$ (3.93)
Weighted average shares used in per share computations	21,608	21,460	19,272

See accompanying notes to financial statements.

TRIMERIS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2002, 2003, and 2004
(in thousands)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Notes receivable from stockholders	Net Stockholders' Equity
	Number of shares	Par Value	Number of Shares	Par Value						
Balance as of December 31, 2001		\$	17,414	\$17	\$244,725	\$(188,895)	\$(2,533)	\$ 189	\$ (9)	\$ 53,494
Loss for the year						(75,678)				(75,678)
Unrealized loss on available-for-sale securities								(222)		(222)
Comprehensive (loss) income for period										(75,900)
Issuance of shares in private placement, net			1,258	1	40,764					40,765
Issuance of shares in public offering, net			2,505	3	106,723					106,726
Exercise of stock options			155		1,508					1,508
Issuance of stock for 401 (K) match			15		662					662
Issuance of stock under Employee Stock Purchase Plan			14		501					501
Proceeds from sale of call options					388					388
Amortization of deferred compensation					22		1,873			1,895
Restricted stock donation			2		79		(164)			79
Restricted stock grant			3		164					
Repayment of notes receivable from stockholders									9	9
Balance as of December 31, 2002		\$	21,366	\$21	\$395,536	\$(264,573)	\$(824)	\$ (33)	\$	\$130,127
Loss for the year						(65,703)				(65,703)
Unrealized gain on available-for-sale securities								30		30
Comprehensive (loss) income for period										(65,673)
Exercise of stock options			156	1	2,243					2,244
Issuance of stock for 401 (K) match			35		724					724
Issuance of stock under Employee Stock Purchase Plan			16		480					480
Amortization of deferred compensation (reversal of compensation expense)					(58)		824			766
Balance as of December 31, 2003		\$	21,573	\$22	\$398,925	\$(330,276)	\$	\$ (3)	\$	\$ 68,668
Loss for the year						(40,088)				(40,088)
Unrealized loss on available-for-sale securities								(3)		(3)
Comprehensive (loss) income for period										(40,091)
Exercise of stock options			56		505					505
Issuance of stock for 401 (K) match			43		614					614
Issuance of stock under Employee Stock Purchase Plan			15		180					180
Amortization of deferred compensation (reversal of compensation expense)					(27)					(27)
Restricted stock grant(s)			242		3,283		(3,283)			
Restricted stock forfeited			(12)		(173)		173			
Restricted stock amortization							497			497
Balance as of December 31, 2004		\$	21,917	\$22	\$403,307	\$(370,364)	\$(2,613)	\$ (6)	\$	\$ 30,346

See accompanying notes to financial statements.

TRIMERIS, INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	For the years ended December 31,		
	2004	2003	2002
Cash flows from operating activities:			
Net loss	\$(40,088)	\$(65,703)	\$(75,678)
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation and amortization of property, furniture and equipment	1,340	1,615	1,912
Non-cash compensation expense	470	766	1,895
Amortization of deferred revenue—Roche	(2,152)	(2,964)	(1,133)
Other amortization	64	71	37
401 (K) plan stock match	614	724	662
Restricted stock donation	—	—	79
Patent costs expensed	163	424	677
Decrease (increase) in assets:			
Recoverable franchise taxes	(144)	1	1
Accounts receivable—Roche	(5,878)	—	—
Prepaid expenses	476	(976)	(776)
Advanced payment—Roche, net	(4,498)	—	—
Other assets	37	97	30
Increase (decrease) in liabilities:			
Accounts payable	531	(599)	(1,202)
Accounts payable—Roche	(11,029)	(4,220)	2,380
Accrued compensation	1,242	(1,228)	919
Accrued expenses	(414)	(228)	(2,775)
Accrued marketing costs	15,761	—	—
Other liabilities	127	—	—
Deferred revenue—Roche	750	15,500	—
Net cash used by operating activities	<u>(42,628)</u>	<u>(56,720)</u>	<u>(72,972)</u>
Cash flows from investing activities:			
Purchase of property, furniture and equipment	(1,170)	(1,377)	(949)
Sales of investment securities—available-for-sale	—	—	1,100
Purchases of investment securities—available-for-sale	(40,149)	(53,154)	(67,991)
Maturities of investment securities—available-for-sale	66,758	35,724	89,728
Patent costs	(406)	(900)	(445)
Net cash provided (used) by investing activities	<u>25,033</u>	<u>(19,707)</u>	<u>21,443</u>
Cash flows from financing activities:			
Principal payments under capital lease obligations	(274)	(741)	(927)
Proceeds from issuance of Common Stock, net	—	—	147,491
Proceeds from sale of call options	—	—	388
Proceeds from exercise of stock options	505	2,244	1,508
Employee stock purchase plan stock issuance	180	480	501
Repayment of notes receivable from stockholders	—	—	9
Net cash provided by financing activities	<u>411</u>	<u>1,983</u>	<u>148,970</u>
Net increase (decrease) in cash and cash equivalents	(17,184)	(74,444)	97,441
Cash and cash equivalents at beginning of year	45,285	119,729	22,288
Cash and cash equivalents at end of year	<u>\$ 28,101</u>	<u>\$ 45,285</u>	<u>\$ 119,729</u>
Supplemental disclosure of cash flow information:			
Cash paid during the period for interest	<u>\$ 6</u>	<u>\$ 41</u>	<u>\$ 108</u>

See accompanying notes to financial statements.

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Trimeris, Inc. (the "Company") was incorporated on January 7, 1993 in Delaware, to discover and develop novel therapeutic agents that block viral infection by inhibiting viral fusion with host cells. Prior to April 1, 2003, the financial statements were prepared in accordance with Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises," to recognize the fact that the Company was devoting substantially all of its efforts to establishing a new business. Principal operations commenced with the commercial launch of Fuzeon® on March 27, 2003, and revenue was recognized from the sale of Fuzeon beginning in 2003. As a result, beginning on April 1, 2003, the Company no longer prepares its financial statements in accordance with SFAS No. 7.

The Company has a worldwide agreement with F. Hoffmann-La Roche Ltd., or Roche, to develop and market T-20, currently known as Fuzeon, whose generic name is enfuvirtide, and T-1249, or a replacement compound. Fuzeon is manufactured and distributed by Roche through Roche's sales and distribution network throughout the world in countries where regulatory approval has been received. The Company shares profits equally from the sale of Fuzeon in the United States and Canada with Roche, and receives a royalty based on net sales of Fuzeon outside the United States and Canada.

Liquidity

We have experienced negative cash flows from operations since our inception and do not anticipate generating sufficient positive cash flows to fund our operations in the foreseeable future. Although we expect to share the future development costs for Fuzeon and our other potential peptide drug candidates covered under the collaboration agreement, for the United States and Canada equally with Roche, we have expended, and expect to continue to expend in the future, substantial funds to pursue our drug candidate and compound discovery and development efforts, including:

- expenditures for marketing activities related to Fuzeon,
- research and development and preclinical testing of other products candidates, and
- the development of our proprietary technology platform.

Under the current operating environment, based on current sales levels of Fuzeon, we expect that our existing capital resources, together with the interest earned thereon, will be adequate to fund our current programs based on current expectations. However, any reduction in Fuzeon sales below current levels or increase in expenditures beyond currently expected levels would increase our capital requirements substantially beyond our current expectations. If we require additional funds and such funds are not available through debt or equity financing, or collaboration arrangements, we will be required to delay, scale-back or eliminate certain preclinical testing, clinical trials and research and development programs, including our collaborative efforts with Roche. In the event Roche becomes unable or unwilling to share future development expenses for Fuzeon, T-1249 or our other potential drug candidates, our capital requirements would increase substantially beyond our current expectations.

Since our initial public offering in 1997, we have obtained the majority of our funding through public or private offerings of our common stock. We expect to continue to obtain our funding through public or private offerings of our common stock or other equity-like instruments (including convertible preferred stock or convertible debt) until such time, if ever, as we are able to generate significant funds from operations.

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments with an original maturity of three months or less to be cash equivalents. Cash and cash equivalents of \$28.1 million and \$45.3 million at December 31, 2004 and 2003,

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS—CONTINUED

respectively, are stated at cost and consist primarily of overnight commercial paper, variable rate demand notes, commercial paper, short-term debt securities and mutual funds that hold these securities. The carrying amount of cash and cash equivalents approximates fair value.

Investment Securities—Available-For-Sale

Investment securities, which consist of short-term debt securities, short-term corporate securities, municipal bonds, commercial paper and federal agency securities, are classified as available-for-sale, and are reported at fair value based on quoted market prices. The cost of securities sold is determined using the specific identification method when computing realized gains and losses. Unrealized gains and losses are included as a component of stockholders' equity until realized.

In accordance with its investment policy, the Company limits the amount of credit exposure with any one issuer. These investments are generally not collateralized and typically mature within one year.

Financial Instruments

SFAS No. 107, "Disclosures about Fair Value of Financial Instruments," as amended, requires disclosure of fair value information about financial instruments, whether or not recognized in the balance sheet, for which it is practicable to estimate fair value. Fair value is defined in the SFAS as the amount at which the instruments could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale. Fair value is determined using available market information.

Financial instruments other than investment securities—available-for-sale held by the Company include accounts receivable, notes receivable, accrued marketing costs, accounts payable and obligations under capital leases. The Company believes that the carrying amount of these financial instruments approximates their fair value. The Company also has commitments of approximately \$1.1 million as described in note 11. The Company believes this amount reflects the approximate fair value of these commitments.

Property, Furniture and Equipment

Property, furniture and equipment are recorded at cost. Property, furniture and equipment under capital leases are initially recorded at the present value of minimum lease payments at the inception of the lease.

Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. Property, furniture and equipment held under capital leases and leasehold improvements are amortized using the straight-line method over the lesser of the lease term or estimated useful life of the asset, generally three years.

Intangible Assets

Management performs a continuing evaluation of the carrying value and remaining amortization periods of unamortized amounts of intangible assets. Any impairments would be recognized when the expected future operating cash flows derived from such intangible assets are less than their carrying value. During 2004 and 2003, \$163,000 and \$424,000 respectively, of patent costs were expensed in other research and development expense because the expected future operating cash flows from these patents was less than their carrying value.

The costs of patents are capitalized and are amortized using the straight-line method over the estimated remaining lives of the patents, the longer of 17 years from the date the patent is granted or 20 years from the initial filing of the patent. Financing costs were incurred as part of the Company's capital lease agreements and are amortized straight-line over the lease term.

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS—CONTINUED

Accrued Marketing Costs

In 2004 the Company reached an agreement with Roche whereby cash contribution to certain selling and marketing expenses for Fuzeon in 2004 is limited to approximately \$10 million, even though Roche spent significantly more on these expenses. If certain cumulative levels of sales for Fuzeon in the United States and Canada are achieved, the Company's share of any additional expenses incurred by Roche during 2004 will be payable to Roche beginning at a future date over several years from that future date. We currently estimate this date to be in 2011. During the year ended December 31, 2004, the Company reached the \$10 million limitation for the year. As a result the Company recorded a liability of approximately \$15.6 million as part of collaboration loss during the year ended December 31, 2004. This represents the net present value of the additional selling and marketing expenses, discounted at a risk free interest rate from the expected payment date based on achievement of the sales milestones in the agreement. The Company is increasing the liability over time to the expected payment amount. In 2004 the Company increased the initial recorded liability by \$154,000 for accretion of interest. The total liability of \$15.8 million is reflected on our balance sheet under the caption "Accrued marketing costs."

Advanced Payment—Roche

The Company is making advance payments to Roche for the cost of the capital improvements made at Roche's Boulder facility where Fuzeon drug substance is produced. Through a series of negotiations, the Company has reached an understanding in principle with Roche whereby the Company will pay for its share of the capital invested in Roche's manufacturing facility over a seven-year period. The Company is in the process of formalizing these terms in a written agreement. The Company's anticipated share of this capital investment is approximately \$14.0 million. At December 31, 2004, the Company has paid \$4.5 million and accrued \$500,000 and expects to pay approximately \$500,000 per quarter through June 2009. This amount, net of charges to cost of goods sold, of \$502,000 in 2004, is recorded as an asset on the Balance Sheet under the caption "Advanced payment-Roche." This asset will be amortized to cost of goods sold based on the units of Fuzeon sold during the collaboration period. The Company estimates that this asset has a remaining useful life of approximately 12 years. In the event the collaboration agreement is terminated, the Company would not be obligated for any unpaid amounts for capital investment. In addition, other peptide drug candidates discovered under our collaboration with Roche, including T-1249, can be manufactured using this same Roche facility. The carrying value of this asset will be evaluated annually for impairment or if a triggering event occurs.

Milestone Revenue and Deferred Revenue—Roche

To date, the Company has received a \$10 million license fee, research milestone payments of \$15 million and has achieved \$3.3 million in manufacturing milestones. The license fee and research milestones were recorded as deferred revenue and are being recognized ratably over the research and development period. The manufacturing milestones were also recorded as deferred revenue and are being recognized ratably over the commercial life of Fuzeon or through June 2013.

At the time of the license fee payment, Roche was granted a warrant to purchase Trimeris stock. The fair value of the warrant, \$5.4 million, was credited to additional paid-in capital in 1999, and as a reduction of the \$10 million license fee payment.

Over the course of the collaboration our estimate of the end of the research and development period has changed:

- During the fourth quarter of 2002, we changed our estimate of the end of this research and development period to 2007 based on the expected development schedule of T-1249 or a replacement compound, the final compound covered by our collaboration agreement with Roche.
- During the first quarter of 2004, we changed our estimate of the end of the research and development period to 2010 from 2007. This change was due to a change in estimate of the development period for T-1249 or a replacement compound as further clinical development of T-1249 has been placed on hold. We recognized approximately \$800,000 less of milestone revenue for the year ended December 31, 2004 compared to the year ended December 31, 2003 due largely in part to this change in estimate.

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS—CONTINUED

- In January 2005, based on our current evaluation of our research and development programs, we placed further clinical development of T-1249 on hold indefinitely due to challenges in achieving an extended release formulation that would allow significantly less dosing frequency. Taking into account the additional research that will be required to achieve our goals for formulation, in January 2005, we changed our estimate of the end of the research and development period from December 2010 to December 2012; as a result we will recognize approximately \$500,000 less revenue in 2005 compared to 2004.

Royalty Revenue

Under our collaboration agreement with Roche, we receive a royalty based on net sales of Fuzeon outside the United States and Canada. These royalties are recognized as revenue when the sales are earned. Royalties of \$4,556,000 and \$755,000 were recognized as revenue during the year ended December 31, 2004 and 2003, respectively.

Collaboration Loss

Product sales of Fuzeon began in the United States on March 27, 2003. Under the collaboration agreement with Roche, the Company shares profits equally from the sale of Fuzeon in the United States and Canada with Roche, which is reported as collaboration loss in the Statements of Operations as a component of revenue. Collaboration income/loss is calculated as follows: Total gross sales of Fuzeon in the United States and Canada is reduced by any discounts, returns or rebates resulting in total net sales. Net sales is reduced by costs of goods sold resulting in gross margin. Gross margin is reduced by selling and marketing expenses and other costs related to the sale of Fuzeon, resulting in operating income or loss. The Company's 50% share of the operating income or loss is reported as collaboration income or loss. Total net sales of Fuzeon in the United States and Canada were \$85.7 and \$28.3 million during the year ended December 31, 2004 and 2003, respectively. During the years ended December 31, 2004 and 2003, sales and marketing expenses exceeded the gross margin from the sale of Fuzeon resulting in the Company's 50% share of operating loss from the sale of Fuzeon in the United States of \$16.1 and \$25.5 million, respectively. Roche previously had an exclusive distribution arrangement with Chronimed, Inc. ("Chronimed") to distribute Fuzeon in the United States during 2003. This exclusive arrangement terminated on April 26, 2004. Effective April 26, 2004, Fuzeon became available through retail and specialty pharmacies across the U.S. Prior to April 26, 2004, revenue from product sales had been recognized when title and risk of loss had passed to Chronimed, which was when Chronimed allocated drug for shipment to a patient. Beginning April 26, 2004, revenue is recognized when Roche ships drug and title and risk of loss passes to wholesalers.

Roche prepares estimates for sales returns and allowances, discounts and rebates based primarily on their historical experience with Fuzeon and other anti-HIV drugs and their estimates of the payor mix for Fuzeon, updated for changes in facts and circumstances on a quarterly basis. If actual results differ from these estimates, these estimates will be adjusted which could have an effect on results from operations in the period of adjustment.

Concentrations

The Company has a collaboration agreement with Roche, which accounted for 100% of the Company's royalty revenue for the years ended December 31, 2004 and 2003. The collaboration agreement with Roche also accounts for 100% of our collaboration loss. All of the accounts receivable at December 2004, is comprised of receivables from Roche.

Research and Development

Research and development costs, including the cost of producing drug material for clinical trials, are charged to operations as incurred.

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS—CONTINUED

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities, and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company has established a valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The most significant estimates made by the Company in the preparation of its financial statements are: the estimate of the length of the research and development period for our Roche collaboration; the estimate of the future volatility of our stock price used to calculate the value of stock options granted to non-employees; the estimate(s) of sales returns and allowances, discounts and rebates related to sales of Fuzeon; the estimate of losses incurred related to unusable product and supplies; the estimate of the period when our liability for accrued marketing costs comes due; the estimate of the patent life of Fuzeon; and the estimate of the expected future operating cash flows from our intangible patent assets.

Net Loss Per Share

In accordance with SFAS No. 128, "Earnings Per Share" ("SFAS No. 128"), basic loss per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding for the period after certain adjustments described below. Diluted net income per common share reflects the maximum dilutive effect of common stock issuable upon exercise of stock options, stock warrants, and conversion of preferred stock. Diluted net loss per common share is not shown, as common equivalent shares from stock options, restricted stock, and stock warrants, would have an anti-dilutive effect. At December 31, 2004, 2003 and 2002, there were 3,244,000, 2,701,000 and 2,484,000 options to purchase common stock outstanding, respectively. At December 31, 2004, 2003 and 2002, there was a warrant outstanding with Roche to purchase 362,000 shares of common stock. At December 31, 2002, there were 3,000 shares of unvested restricted stock outstanding, which became fully vested during 2003. At December 31, 2004, there were 179,000 restricted stock grants, which become fully vested in 2007 and 50,000 restricted stock grants, which become fully vested in 2008.

Stock-Based Compensation

SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123"), encourages, but does not require companies to record compensation cost for stock-based employee compensation plans at fair value. The Company has chosen to continue to account for employee stock-based compensation using the method prescribed in Accounting Principles Board Opinion ("APB") No. 25, "Accounting for Stock Issued to Employees," and related interpretations. Accordingly, compensation cost for stock options is measured as the excess, if any, of the quoted market price of the Company's stock at the date of the grant over the amount an employee must pay to acquire the stock.

Compensation costs for stock options granted to non-employees are accounted for in accordance with SFAS No. 123 and Emerging Issues Task Force ("EITF") 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," which require that compensation be measured at the end of each reporting period for changes in the fair value of the Company's common stock until the options are vested.

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS—CONTINUED

SFAS No. 123 permits entities to recognize as expense over the vesting period the fair value of all stock-based awards on the date of grant. Alternatively, SFAS No. 123 also allows entities to continue to apply the provisions of APB Opinion No. 25 and provide pro forma net income and pro forma earnings per share disclosures for employee stock option grants as if the fair-value-based method defined in SFAS No. 123 had been applied. The Company has elected to continue to apply the provisions of APB Opinion No. 25. Had the Company determined compensation expense based on the fair value at the grant date for its stock-based plans under SFAS No. 123, the Company's net loss and basic loss per share would have been increased to the pro forma amounts indicated below for the years ended December 31 (in thousands, except per share data):

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Net loss:			
As reported	\$(40,088)	\$(65,703)	\$(75,678)
Add back: Compensation cost recorded under APB 25	497	824	1,873
Compensation cost resulting from common stock options, restricted stock and employee stock purchase plan	<u>(9,284)</u>	<u>(13,813)</u>	<u>(11,833)</u>
Pro forma	<u>\$(48,875)</u>	<u>\$(78,692)</u>	<u>\$(85,638)</u>
Basic and diluted loss per share:			
As reported	\$ (1.86)	\$ (3.06)	\$ (3.93)
Pro forma	\$ (2.26)	\$ (3.67)	\$ (4.44)

The fair value of common stock options is estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions used:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Estimated dividend yield	0.00%	0.00%	0.00%
Expected stock price volatility	50.0%	50.0%	45.0%
Risk-free interest rate	3.50%	3.50%	4.00%
Expected life of options	5 years	5 years	5 years
Expected life of employee stock purchase plan options	2 years	2 years	2 years

Comprehensive Income

Comprehensive income (loss) includes all non-owner changes in equity during a period and is divided into two broad classifications: net income (loss) and other comprehensive income ("OCI"). OCI includes revenue, expenses, gains, and losses that are excluded from earnings under generally accepted accounting principles. For the Company, OCI consists of unrealized gains or losses on securities available-for-sale.

Segment Reporting

SFAS No. 131, "Disclosure about Segments of an Enterprise and Related Information," establishes standards for reporting information about the Company's operating segments. The Company operates in one business segment, the business of discovery, development and commercialization of novel pharmaceuticals.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation. These reclassifications had no impact on net loss or stockholders' equity as previously reported. The Company reclassified \$40.4 million of auction rate securities from cash and cash equivalents to investment securities—available-for-sale, as of December 31, 2003 and, accordingly, reflected additional purchases of investment securities—available-for-sale of \$40.4 million in the 2003 statement of cash flows.

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS—CONTINUED

2. INVESTMENT SECURITIES—AVAILABLE-FOR-SALE

The following is a summary of available-for-sale securities. Estimated fair values of available-for-sale securities are based generally on quoted market prices (in thousands).

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value
December 31, 2004				
Federal agency securities maturing within 1 year	\$ 1,506	\$—	\$ 3	\$ 1,503
Federal agency securities maturing after 1 year through 5 years	501	—	1	500
Corporate debt securities maturing within 1 year	1,007	—	1	1,006
Corporate debt securities maturing after 10 years	1,000	—	—	1,000
Other debt securities maturing after 1 year through 5 years	730	—	1	729
Other debt securities maturing after 5 years through 10 years	1,637	—	—	1,637
Other debt securities maturing after 10 years	10,235	—	—	10,235
Municipal bonds maturing after 10 years	3,691	—	—	3,691
	<u>\$20,307</u>	<u>\$—</u>	<u>\$ 6</u>	<u>\$20,301</u>
December 31, 2003				
Equity securities maturing within 1 year	\$18,425	\$—	\$—	\$18,425
Corporate debt securities, maturing within 1 year	6,488	1	4	6,485
Corporate debt securities maturing after 1 year through 5 years	600	—	—	600
Corporate debt securities maturing after 10 years	2,316	—	—	2,316
Other debt securities maturing after 10 years	15,156	—	—	15,156
Municipal bonds maturing after 10 years	3,931	—	—	3,931
	<u>\$46,916</u>	<u>\$ 1</u>	<u>\$ 4</u>	<u>\$46,913</u>

There were no sales of these investments or realized gains or losses during 2004 or 2003. All unrealized losses on investment securities are considered to be temporary given the credit ratings on these investment securities and the short durations of the unrealized losses.

3. LEASES

The gross amount of furniture and equipment and related accumulated amortization recorded under capital leases and included in property, furniture and equipment were as follows at December 31, 2003 (in thousands):

	<u>2003</u>
Furniture and equipment	\$ 1,268
Less accumulated amortization	(1,173)
	<u>\$ 95</u>

The Company had no property, furniture or equipment under capital leases at December 31, 2004.

The Company also has several non-cancelable operating leases, primarily for office space and office equipment, that extend through January 2015. Rental expense, including maintenance charges, for operating leases during 2004, 2003 and 2002 was \$1.9 million, \$1.7 million, and \$1.7 million respectively.

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS—CONTINUED

Future minimum lease payments under non-cancelable operating leases (with initial or remaining lease terms in excess of one year) of December 31, 2004 (in thousands) are:

	<u>OPERATING LEASES</u>
Year ending December 31:	
2005	\$ 1,549
2006	1,508
2007	1,508
2008	1,538
2009	1,569
Thereafter	<u>8,473</u>
Total minimum lease payments	<u>\$16,145</u>

4. PROPERTIES, FURNITURE AND EQUIPMENT

Property, furniture and equipment consists of the following at December 31, 2004 and 2003 (in thousands):

	<u>2004</u>	<u>2003</u>
Furniture and equipment	\$ 12,896	\$ 10,733
Leasehold improvements	1,158	883
Furniture and equipment under capital lease	—	1,268
	<u>14,054</u>	<u>12,884</u>
Less accumulated depreciation and amortization	<u>(11,646)</u>	<u>(10,306)</u>
	<u>\$ 2,408</u>	<u>\$ 2,578</u>

The depreciable lives of our property, furniture and equipment are as follows:

Equipment and furniture	3.5 years
Computer / software	3 years
Leasehold improvements	Lesser of useful life or life of lease

5. STOCKHOLDERS' EQUITY

Offerings of Common Stock

In January 2002, the Company closed a private placement of approximately 1.3 million shares of common stock at \$34.00 per share. The net proceeds of the offering were approximately \$40.8 million after deducting applicable issuance costs and expenses of approximately \$2.0 million.

In October 2002, the Company closed a public offering of approximately 2.5 million shares of common stock at \$45.25 per share. The net proceeds of the offering, including the proceeds received in connection with the exercise of the underwriters' over-allotment option, were approximately \$106.7 million after deducting applicable issuance costs and expenses of approximately \$6.6 million.

Derivative Transactions

In April 2002, the Company entered into a set of derivative transactions with a financial institution that could have been settled by selling up to a total of 200,000 shares of its stock to the financial institution at prices significantly

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS—CONTINUED

higher than the market price per share of the Company's stock at the inception of the transaction. The Company received approximately \$388,000 in proceeds that were accounted for as an increase to additional paid-in capital in accordance with EITF Issue No. 00-19, "Determination of Whether Share Settlement Is within the Control of the Company for Purposes of Applying EITF Issue No. 96-13, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock." Alternatively, the Company had the option to settle these contracts by making a cash payment to the financial institution for the underlying value of the derivative contracts to the financial institution on the settlement date. The Company intended to settle the contracts by issuing shares. The derivative transactions relating to these 200,000 shares expired unexercised in April 2003.

Warrant

In July 1999, the Company granted Roche a warrant to purchase 362,000 shares of common stock at a purchase price of \$20.72 per share. The warrant is exercisable prior to the tenth annual anniversary of the grant date and was not exercised as of December 31, 2004. The fair value of the warrant of \$5.4 million was credited to additional paid-in capital in 1999, and as a reduction of the \$10 million up-front payment received from Roche. We deferred \$4.6 million, the net of the \$10 million up-front payment and the \$5.4 million in warrants, over the research and development period. The value was calculated using the Black-Scholes option-pricing model using the following assumptions: estimated dividend yield of 0%; expected stock price volatility of 86.00%; risk-free interest rate of 5.20%; and expected option life of ten years.

Preferred Stock

The Board of Directors has the authority to issue shares of preferred stock and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, without any further vote or action by the stockholders.

6. STOCK OPTION PLAN

In 1993, the Company adopted a stock option plan which allows for the issuance of non-qualified and incentive stock options. During 1996, the Trimeris, Inc. New Stock Option Plan (the "Stock Option Plan") was implemented and replaced the 1993 plan. Under the Stock Option Plan, as amended, the Company may grant non-qualified or incentive stock options for up to 4,102,941 shares of common stock. The exercise price of each incentive stock option shall not be less than the fair market value of the Company's common stock on the date of grant and an option's maximum term is ten years. Outstanding incentive stock options have been issued at prices ranging from \$0.34 to \$78.50 per share. The vesting period generally occurs ratably over four years. At December 31, 2004, there were approximately 785,000 options remaining available for grant. All incentive stock options which had been granted under the 1993 plan were cancelled at inception of the Stock Option Plan while the non-qualified stock options remain outstanding at an exercise price of \$0.43. No more grants will be made under the 1993 plan.

Stock option transactions for the years ended December 31, 2004, 2003 and 2002 are as follows:

	2004	Weighted Average Exercise Price	2003	Weighted Average Exercise Price	2002	Weighted Average Exercise Price
Options outstanding at January 1	2,701,000	\$33.38	2,484,000	\$31.32	2,161,000	\$27.12
Granted	945,000	14.18	472,000	40.74	499,000	43.30
Exercised	(56,000)	9.02	(156,000)	14.35	(155,000)	9.75
Cancelled	(346,000)	43.79	(99,000)	47.01	(21,000)	42.07
Options outstanding at end of period	<u>3,244,000</u>	<u>\$27.09</u>	<u>2,701,000</u>	<u>\$33.38</u>	<u>2,484,000</u>	<u>\$31.32</u>

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS—CONTINUED

The following summarizes information about stock options outstanding as of December 31, 2004:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number Outstanding as of December 31, 2004	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.34-1.00	91,000	1.68	\$.48	91,000	\$.48
\$1.01-8.00	179,000	3.31	\$ 7.86	179,000	\$ 7.86
\$9.00-11.625	778,000	6.74	\$11.57	448,000	\$11.62
\$11.626-20.00	657,000	8.31	\$15.26	175,000	\$16.41
\$20.01-40.00	343,000	7.55	\$28.26	199,000	\$31.08
\$40.00-45.11	628,000	7.25	\$42.84	521,000	\$42.99
\$45.12-50.00	317,000	7.61	\$47.14	273,000	\$47.42
\$50.00-78.50	251,000	5.55	\$63.25	196,000	\$63.63
\$0.34-78.50	<u>3,244,000</u>	<u>6.90</u>	<u>\$27.09</u>	<u>2,082,000</u>	<u>\$30.50</u>

The Company applies APB Opinion No. 25 and related interpretations in accounting for its plans. Accordingly, compensation cost related to stock options issued to employees would be recorded on the date of grant only if the current market price of the underlying stock exceeded the exercise price. The Company recorded deferred charges of \$3.3 million in 2004, \$0 in 2003 and \$164,000 in 2002, representing the fair value of restricted common stock granted to employees.

Compensation expense for employee stock options was approximately \$0, \$767,000 and \$1.9 million for 2004, 2003 and 2002, respectively.

Compensation costs for stock options granted to non-employees are accounted for in accordance with SFAS No. 123 and EITF 96-18 over the service period that generally coincides with vesting, generally four years. The measurement date for the calculation of compensation expense is considered to be the date when all services have been rendered or the date that options are fully vested. Compensation expense is recognized during interim periods up to the measurement date based on changes in the fair value of the Company's common stock. Compensation expense for non-employee stock options of \$22,000 for the year ended December 31, 2002, was recorded as an increase to additional paid-in capital. Compensation expense reversal of \$27,000 and \$58,000 for the years ended December 31, 2004 and 2003, respectively, was recorded as a decrease to additional paid-in capital.

7. INCOME TAXES

At December 31, 2004, the Company has net operating loss carryforwards (NOLs) for federal tax purposes of approximately \$333.4 million which expire in varying amounts between 2008 and 2024. The Company has state net economic losses of approximately \$258.1 million which expire in varying amounts between 2008 and 2019. The Company has research and development credits of \$9.2 million which expire in varying amounts between 2008 and 2024.

The Tax Reform Act of 1986 contains provisions which limit the ability to utilize net operating loss carryforwards and tax credit carryforwards in the case of certain events including significant changes in ownership interests. If the Company's NOLs and/or tax credits are limited, and the Company has taxable income which exceeds the permissible yearly NOL, the Company would incur a federal income and/or state tax liability even though NOLs would be available in future years.

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS—CONTINUED

The components of deferred tax assets and deferred tax liabilities as of December 31, 2004 and 2003 are as follows (in thousands):

	<u>2004</u>	<u>2003</u>
Deferred tax assets:		
Tax loss carryforwards	\$ 125,119	\$ 119,906
Tax credits	9,167	8,242
Deferred revenue	4,764	5,918
Reserves and accruals	<u>8,902</u>	<u>3,527</u>
Total gross deferred tax assets	147,952	137,593
Valuation allowance	<u>(147,952)</u>	<u>(137,593)</u>
Net deferred asset	—	—
Deferred tax liabilities:		
Deferred tax liability	<u>—</u>	<u>—</u>
Net deferred tax assets (liability)	<u>\$ —</u>	<u>\$ —</u>

The Company has established a valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets. The valuation allowance represents the amount necessary to reduce the Company's gross deferred tax assets to the amount that is more likely than not to be realized. The increase in the valuation allowance was approximately \$10.4 million, \$28.2 million, and \$32.6 million for the years ended December 31, 2004, 2003 and 2002, respectively. The valuation allowance includes deferred tax assets that when realized, may increase equity rather than reduce tax expense. The Company will evaluate this amount when the criteria for recognizing the deferred tax asset relating to these amounts are met.

The reasons for the difference between the actual income tax benefit for the years ended December 31, 2004, 2003 and 2002 and the amount computed by applying the statutory federal income tax rate to losses before income tax benefit are as follows (in thousands):

	<u>2004</u>	<u>% of Pre-tax Loss</u>	<u>2003</u>	<u>% of Pre-tax Loss</u>	<u>2002</u>	<u>% of Pre-tax Loss</u>
Income tax benefit at statutory rate	\$(13,630)	(34.00)%	\$(22,339)	(34.00)%	\$(25,730)	(34.00)%
State income taxes, net of federal benefit	3,599	8.98%	—	—	—	—
Non-deductible meals and entertainment expenses and other	303	0.75%	14	0.02%	14	0.02%
Non-deductible compensation	—	—%	261	0.40%	600	0.79%
Generation of research credit	(631)	(1.57)%	(1,597)	(2.43)%	(2,280)	(3.01)%
Change in federal portion of valuation allowance	<u>10,359</u>	<u>25.84%</u>	<u>23,661</u>	<u>36.01%</u>	<u>27,396</u>	<u>36.20%</u>
Income tax benefit	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>—</u>

8. EMPLOYEE BENEFIT PLANS

401 (K) Plan

The Company sponsors a 401(k) Profit Sharing Plan (the "401k Plan") under Section 401 (k) of the Internal Revenue Code covering all qualified employees. Participants may elect a salary reduction from 1% to 75% as a contribution to the 401k Plan, up to the annual Internal Revenue Service allowable contribution limit. Modifications of the salary reductions may be made quarterly. The 401k Plan permits the Company to match participants' contributions. Beginning in 1998, the Company matched up to 100% of a participant's contributions with Company stock, provided

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS—CONTINUED

the participant was employed on the last day of the year. The number of shares issued is based on the contributions to be matched divided by the closing price of the Company's stock on the last trading day of the year. During 2004, 43,000 shares were issued, and compensation expense of \$614,000 was recognized. During 2003, 35,000 shares were issued, and compensation expense of \$724,000 was recognized. During 2002, 15,000 shares were issued, and compensation expense of \$662,000, was recognized. These shares vest ratably based on a participant's years of service and are fully vested after four years of service.

The normal retirement age shall be the later of a participant's 65th birthday or the fifth anniversary of the first day of the 401k Plan year in which participation commenced. The 401k Plan does not have an early retirement provision.

Employee Stock Purchase Plan

The Company has an Employee Stock Purchase Plan, which permits eligible employees to purchase newly issued common stock of the Company up to an aggregate of 250,000 shares. Under this plan, employees may purchase from the Company a designated number of shares through payroll deductions at a price per share equal to 85% of the lesser of the fair market value of the Company's common stock as of the date of the grant or the date the right to purchase is exercised. A total of 15,000, 16,000, and 14,000 shares were issued under this plan in 2004, 2003, and 2002, respectively. At December 31, 2004 there were 96,000 shares remaining available for issuance.

Post-Retirement Health Insurance Continuation Plan

In June 2001, the Company adopted a post-retirement health insurance continuation plan ("the Plan"). Employees who have achieved the eligibility requirements of 60 years of age and 10 years of service are eligible to participate in the Plan. The Plan provides participants the opportunity to continue participating in the Company's group health plan after their date of retirement. Participants will pay the cost of health insurance premiums for this coverage, less any contributions by the Company; this amount was previously capped at \$300 per month per participant. In November 2003, the Plan was amended and the limit on contributions by the Company was changed to 50% of the health insurance premium for the employee and his or her spouse.

The components of net periodic post-retirement benefits cost and the significant assumptions of the Plan for 2004, 2003 and 2002 consisted of the following (in thousands):

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Service cost	\$135	\$29	\$17
Interest cost	30	6	3
Recognized net actuarial loss	—	1	—
Amortization of prior service costs	24	3	3
Total	<u>\$189</u>	<u>\$39</u>	<u>\$23</u>

The Plan's status as of December 31 was as follows:

	<u>2004</u>	<u>2003</u>
Accumulated post-retirement benefit obligation (APBO)	\$(674)	\$(137)
Unrecognized prior service cost	371	29
Unrecognized net loss	42	36
Accrued post-retirement benefit cost	<u>\$(261)</u>	<u>\$ (72)</u>

The accumulated post-retirement benefit obligation, or APBO, was determined using a discount rate of 6.00% and 6.25% at December 31, 2004 and 2003, respectively. A 1% increase in the trend factors would increase the projected

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS—CONTINUED

APBO by approximately \$160,000 and would increase the service and interest cost components by approximately \$56,000. A 1% decrease in the trend factors would decrease the projected APBO by approximately \$120,000 and would decrease the service and interest cost components by approximately \$42,000.

The expected future benefit payments under the plan (in thousands) are as follows:

<u>Year(s) ending</u>	<u>Amount</u>
2005	\$—
2006	—
2007	—
2008	1
2009	3
2010 to 2014	<u>84</u>
Total	\$88

9. ROCHE COLLABORATION

In July 1999, the Company announced a worldwide agreement with F. Hoffmann-La Roche Ltd., or Roche, to develop and market T-20, currently known as Fuzeon, whose generic name is enfuvirtide, and T-1249, or a replacement compound. In the United States and Canada, the Company and Roche will share development expenses and profits for Fuzeon and T-1249, or a replacement compound equally. Outside of these two countries, Roche will fund all development costs and pay the Company royalties on net sales of these products. Roche made a nonrefundable initial cash payment to the Company of \$10 million during 1999, and a milestone payment of \$2 million in 2000. The Company recorded a \$8 million milestone in March 2003, a \$5 million milestone in May 2003, a \$2.5 million milestone in June 2003 and a \$750,000 milestone in June 2004. The June 2004 milestone has been recorded as the parties have agreed that certain performance has been met and that payment is appropriate. We have recorded this amount as of December 31, 2004 in anticipation that we will reach a final agreement with terms substantially the same as those we have agreed to in principle. Roche will provide up to an additional \$33 million in cash upon achievement of developmental, regulatory and commercial milestones. This agreement with Roche grants them an exclusive, worldwide license for Fuzeon and T-1249, and certain other compounds. Under this agreement with Roche, a joint management committee consisting of members from Trimeris and Roche oversees the strategy for the collaboration. Roche may terminate its license for a particular country in its sole discretion with advance notice. This agreement with Roche gives Roche significant control over important aspects of the commercialization of Fuzeon and our other drug candidates, including but not limited to pricing, sales force activities, and promotional activities.

Roche is manufacturing Fuzeon bulk drug substance in its Boulder, Colorado facility. Roche's manufacturing facility in Basel, Switzerland and another third party facility are producing the finished drug product from such bulk drug substance. Fuzeon is distributed and sold by Roche through Roche's sales and distribution network throughout the world in countries where regulatory approval has been received.

The Company and Roche agreed to limit the Company's actual cash contribution to the Fuzeon selling and marketing expenses in 2004 to approximately \$10 million, even though Roche has spent significantly more on these expenses. If certain cumulative levels of sales for Fuzeon in the United States and Canada are achieved, our share of any additional expenses incurred by Roche during 2004 will be payable to Roche beginning at a future date over several years from that future date. We currently estimate this date to be in 2011. During the year ended December 31, 2004, the Company's share of selling and marketing expenses exceeded \$10 million. In addition to the \$10 million included in collaboration loss, the Company recorded a liability of \$15.8 million as part of collaboration loss, which represents the net present value of the Company's estimated share of these expenses in excess of approximately \$10 million, based on the expected timing and terms of payment under the agreement. At present, Trimeris and Roche have not yet agreed what limit, if any, will be placed on Trimeris' contribution to Fuzeon selling and marketing expenses for 2005 and beyond.

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS—CONTINUED

In July 1999, the Company granted Roche a warrant to purchase 362,000 shares of common stock at a purchase price of \$20.72 per share. The warrant is exercisable prior to the tenth annual anniversary of the grant date and was not exercised as of December 31, 2004. The fair value of the warrant of \$5.4 million was credited to additional paid-in capital in 1999, and as a reduction of the \$10 million up-front payment received from Roche. We deferred \$4.6 million, the net of the \$10 million up-front payment and the \$5.4 million in warrants, over the research and development period. The value was calculated using the Black-Scholes option-pricing model using the following assumptions: estimated dividend yield of 0%; expected stock price volatility of 86.00%; risk-free interest rate of 5.20%; and expected option life of ten years.

In 2001, the Company executed a research agreement with Roche to discover, develop and commercialize novel generations of HIV fusion inhibitor peptides. Roche and Trimeris will fund worldwide research, development and commercialization costs, and share profits from worldwide sales of new HIV fusion inhibitor peptides discovered after July 1, 1999. The joint research obligations under the agreement are renewable thereafter on an annual basis. The term of this agreement was extended to December 2005 during 2003.

Product sales of Fuzeon began in the United States on March 27, 2003 and are recorded by Roche. Under the collaboration agreement with Roche, the Company shares profits equally from the sale of Fuzeon in the United States and Canada with Roche, which is reported as collaboration loss in the Statements of Operations as a component of revenue. Collaboration income or loss is calculated as follows: Total gross sales of Fuzeon in the United States and Canada is reduced by any discounts, returns or rebates resulting in total net sales. Net sales is reduced by costs of goods sold resulting in gross margin. Gross margin is reduced by selling, marketing and other expenses related to the sale of Fuzeon, resulting in operating income or loss. The Company's 50% share of the operating income or loss is reported as collaboration income or loss. Total net sales of Fuzeon in the United States and Canada were \$85.7 million and \$28.3 million during the year ended December 31, 2004 and 2003, respectively. During the year ended December 31, 2004 and 2003, sales, marketing and other expenses exceeded the gross margin from the sale of Fuzeon resulting in the Company's 50% share of operating loss from the sale of Fuzeon in the United States of \$16.1 million and \$25.5 million, respectively. Roche previously had an exclusive distribution arrangement with Chronimed, Inc. ("Chronimed") to distribute Fuzeon in the United States during 2003. This exclusive arrangement terminated on April 26, 2004. Effective April 26, 2004, Fuzeon became available through retail and specialty pharmacies across the U.S. Prior to April 26, 2004, revenue from product sales had been recognized when title and risk of loss had passed to Chronimed, which was when Chronimed allocated drug for shipment to a patient. Beginning April 26, 2004, revenue is recognized when Roche ships drug and title and risk of loss passes to wholesalers.

Our share of the collaboration loss for the year ended December 31, 2004 includes approximately \$4.7 million of a net charge comprised of our share of a supply contract penalty, and charges for the Boulder manufacturing facility partially off-set by an adjustment to Roche's inventory.

Under our collaboration agreement with Roche, the Company contributes towards a share of the capital invested in Roche's manufacturing facility through the depreciation charged to cost of goods sold as the products are sold. Through a series of negotiations, we have reached an understanding in principle with Roche whereby we will pay Roche for our share of the capital invested in Roche's manufacturing facility over a seven-year period. We are in the process of formalizing these terms in a written agreement. Our anticipated share of this capital investment is approximately \$14 million. As a result, we accrued an initial payment of \$4 million at June 2004 and expect to pay approximately \$500,000 per quarter through June 2009. As a result, Roche will no longer include the depreciation related to the manufacturing facility in the cost of goods sold. In the event our collaboration agreement is terminated, we would not be obligated for any unpaid amounts for capital investment.

These payments, net of the portion allocated to cost of goods sold, are recorded as an asset presented as "Advanced payment—Roche". This asset will be amortized based on the units of Fuzeon sold during the collaboration period, in order to properly allocate the capital investment to cost of goods sold in future periods. Assuming all

TRIMERIS, INC.

NOTES TO FINANCIAL STATEMENTS—CONTINUED

payments are made and sales of Fuzeon continue, the Company estimates that this asset has a remaining useful life of approximately 12 years. In addition, other peptide drug candidates discovered under our collaboration with Roche, including T-1249, can be manufactured using the same Roche facility. The carrying value of this asset will be evaluated annually for impairment or if a triggering event occurs.

10. OTHER COLLABORATIONS

In July 2001, the Company entered into a non-exclusive agreement with Array BioPharma, Inc. ("Array") to discover orally-available small molecule fusion inhibitors of HIV and respiratory syncytial virus, or RSV. In April 2002, the Company entered into a non-exclusive agreement with Neokimia, Inc. ("Neokimia") to discover and develop small molecule HIV fusion inhibitors. Array and Neokimia will be entitled to receive payments and royalties based on achievement of certain developmental and commercial milestones. In June 2004, Trimeris and Array announced the renewal of their research agreement. As part of this renewed agreement, Trimeris will screen small molecule compounds created by Array against HIV entry inhibitor targets. The terms of the agreement are substantially similar to those of the initial agreement, signed in 2001.

In September 1997, the Company obtained an exclusive, worldwide, royalty-bearing license from the New York Blood Center under certain U.S. and foreign patents and patent applications relating to certain HIV peptides. Under this license we are required to pay to the New York Blood Center a royalty equal to one-half of one percent of the net sales of Fuzeon up to \$100 million, and one-quarter of one percent of net sales in excess of \$100 million. Royalties of \$575,000 were expensed during 2004.

11. COMMITMENTS AND CONTINGENCIES

The Company is involved in certain claims arising in the ordinary course of business. In the opinion of management, the ultimate disposition of these matters will not have a material adverse effect on the financial position or results of operations of the Company.

As of December 31, 2004, the Company had commitments of approximately \$1.1 million to purchase product candidate materials and fund various clinical studies over the next twenty-four months contingent on delivery of the materials or performance of the services. Substantially all of these expenditures will be shared equally by Roche under the Company's collaboration agreement with Roche. Under this collaboration agreement, Trimeris and Roche are obligated to share the future development expenses for Fuzeon and T-1249 for the United States and Canada.

In 2004, the Company entered into a sublease agreement for its office and laboratory space in Morrisville, North Carolina. The sublease calls for the payment of a security deposit of \$754,000 in 2005.

12. REDUCTION IN WORKFORCE

During January of 2004, we put further clinical development of T-1249 on hold. In connection with this programmatic change, the Company reduced its workforce by approximately 25%. In January 2004 we initially estimated approximately \$600,000 in severance and other related costs; actual costs were approximately \$450,000. This expense was charged to the Statement of Operations under "Other research and development expense" and "Other general and administrative expense," in the first quarter of 2004. At December 31, 2004 there was no remaining liability related to the reduction in workforce.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Trimeris, Inc.
(Registrant)

March 10, 2005

/s/ STEVEN D. SKOLSKY

Steven D. Skolsky
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ STEVEN D. SKOLSKY</u> Steven D. Skolsky	Chief Executive Officer	March 10, 2005
<u>/s/ DANI P. BOLOGNESI</u> Dani P. Bolognesi, Ph.D.	Chief Scientific Officer and Vice Chairman of the Board of Directors	March 10, 2005
<u>/s/ ROBERT R. BONCZEK</u> Robert R. Bonczek	Chief Financial Officer and General Counsel (principal financial officer)	March 10, 2005
<u>/s/ ANDREW L. GRAHAM</u> Andrew L. Graham	Director of Finance and Secretary (principal accounting officer)	March 10, 2005
<u>/s/ JEFFREY M. LIPTON</u> Jeffrey M. Lipton	Chairman of the Board of Directors	March 10, 2005
<u>/s/ E. GARY COOK</u> E. Gary Cook, Ph.D.	Director	March 10, 2005
<u>/s/ FELIX J. BAKER</u> Felix J. Baker	Director	March 10, 2005
<u>/s/ JULIAN C. BAKER</u> Julian C. Baker	Director	March 10, 2005
<u>/s/ CHARLES A. SANDERS</u> Charles A. Sanders, M.D.	Director	March 10, 2005
<u>/s/ J. RICHARD CROUT</u> J. Richard Crout, M.D.	Director	March 10, 2005
<u>/s/ KEVIN C. TANG</u> Kevin C. Tang	Director	March 10, 2005

EXHIBIT INDEX

(a) Exhibits

- 3.1 * Amended and Restated Bylaws of the Registrant.
- 3.2^(d) Fourth Amended and Restated Certificate of Incorporation of the Registrant
- 4.1 * Specimen certificate for shares of Common Stock.
- 4.2 * Description of Capital Stock (contained in the Fourth Amended and Restated Certificate of Incorporation of the Corporation of the Registrant, filed as Exhibit 3.2).
- 10.1 * License Agreement dated February 3, 1993, between the Registrant and Duke University.
- 10.2 Trimeris, Inc. Amended and Restated Stock Incentive Plan. †
- 10.3 * Trimeris, Inc. Employee Stock Purchase Plan. †
- 10.4 * Sixth Amended and Restated Registration Rights Agreement dated June 27, 1997, by and among the Registrant and certain stockholders of the Registrant.
- 10.5 * Form of Indemnification Agreements.
- 10.6 * License Agreement dated September 9, 1997 between the Registrant and The New York Blood Center.
- 10.7⁽ⁱ⁾ Poyner & Spruill, L.L.P. Defined Contribution Prototype Plan and Trust for the Trimeris, Inc. Employee 401(k) Plan. †
- 10.8^(j) Adoption Agreement for the Trimeris, Inc. Employee 401(k) Plan. †
- 10.9^(a) Chief Executive Employment Agreement between Trimeris and Dani P. Bolognesi dated April 21, 1999. †
- 10.10^(m) Executive Employment Agreement between Trimeris, Inc. and George W. Koszalka dated June 21, 2004. †
- 10.11⁽ⁿ⁾ Executive Employment Agreement by and between Trimeris, Inc. and Steven Skolsky dated September 8, 2004. †
- 10.12⁽ⁿ⁾ Incentive Stock Option Agreement by and between Trimeris, Inc. and Steven Skolsky dated September 9, 2004. †
- 10.13⁽ⁿ⁾ Restricted Stock Agreement by and between Trimeris, Inc. and Steven Skolsky dated September 9, 2004. †
- 10.14^(b) Development and License Agreement between Trimeris and Hoffmann-La Roche dated July 1, 1999 (Portions of this exhibit have been omitted pursuant to an order of the Commission granting confidential treatment.).
- 10.15^(b) Financing Agreement between Trimeris, Inc. and Roche Finance Ltd. dated as of July 9, 1999.
- 10.16^(b) Registration Rights Agreement between Trimeris, Inc. and Roche Finance Ltd. dated as of July 9, 1999.
- 10.17^(b) Lease between Trimeris, Inc. and University Place Associates dated April 14, 1999.
- 10.18^(m) Sublease Agreement between Trimeris, Inc. and PPD Development, LP dated June 30, 2004
- 10.19^(m) Lease Agreement and Amendments between PPD Development, LP (formerly PPD Pharmaco, Inc.) and Weeks Realty, LP relating to Sublease Agreement filed as Exhibit 10.17 hereto
- 10.20 Executive Agreement between Trimeris and Robert R. Bonczek dated January 7, 2000. †
- 10.21^(c) Employment Agreement between Trimeris, Inc. and M. Nixon Ellis dated March 31, 2000. †
- 10.22^(m) Settlement Agreement and Release between Trimeris, Inc. and M. Nixon Ellis dated July 1, 2004. †

- 10.23^(e) Research Agreement between Trimeris, Inc., F. Hoffmann-La Roche Ltd, and Hoffmann-La Roche, Inc. dated January 1, 2000 (Portions of this exhibit have been omitted pursuant to an order of the Commission granting confidential treatment.).
- 10.24^(f) Form of Purchase Agreement dated as of May 7, 2001 by and between Trimeris, Inc. and the purchasers set forth on the signature page thereto.
- 10.25⁽ⁱ⁾ Sublease Agreement dated as of December 14, 2001 between Trimeris, Inc. and Triangle Pharmaceuticals, Inc.
- 10.26⁽ⁱ⁾ Second Amendment dated as of January 21, 2002 between University Place Properties, LLC and Trimeris, Inc.
- 10.27^(g) Form of Equity Option Confirmation for Call Transaction.
- 10.28^(o) First Amendment to the Research Agreement by and between Trimeris, Inc. and F. Hoffmann-La Roche Ltd. And Hoffmann-La Roche Inc. dated November 13, 2003. (Portions of this exhibit have been omitted pursuant to a request for confidential treatment filed with the Commission.)
- 10.29^(h) Form of Purchase Agreement dated as of January 23, 2002 by and between Trimeris, Inc. and the purchasers set forth on the signature page thereto.
- 10.30^(m) Rescission of the Amendment to the Development and License Agreement dated July 12, 2004.
- 10.31^(p) Amendment to the Development and License Agreement between Trimeris, Inc. and Hoffman-La Roche dated on July 12, 2004. (Portions of this exhibit have been omitted pursuant to a request for confidential treatment filed with the Commission.)
- 10.32^(k) Third Amendment of Lease between University Place Properties, LLC and Trimeris, Inc. dated May 28, 2003.
- 10.33^(l) Agreement of Sublease by and between Gilead Sciences, Inc. and Trimeris, Inc.
- 10.34 Description of compensation arrangement for Andrew L. Graham. †
- 10.35 Description of non-management director compensation arrangements. †
- 23 Consent of KPMG LLP.
- 31.1 Rule 13a-14(a) Certification by Steven D. Skolsky as Chief Executive Officer.
- 31.2 Rule 13a-14(a) Certification by Robert R. Bonczek as Chief Financial Officer.
- 32.1 Section 1350 Certification by Steven D. Skolsky as Chief Executive Officer.
- 32.2 Section 1350 Certification by Robert R. Bonczek as Chief Financial Officer.

† Management contract or compensatory plan or arrangement required to be filed as an exhibit to this form pursuant to Item 15(a) of this report.

* *Incorporated by reference to Trimeris' Registration Statement on Form S-1, as amended (File No. 333-31109) initially filed with the Commission on July 11, 1997.*

- (a) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended March 31, 1999.
- (b) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended June 30, 1999.
- (c) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended March 31, 2000.
- (d) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.
- (e) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.
- (f) Incorporated by reference to Trimeris' Current Report on Form 8-K filed on May 11, 2001.
- (g) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.
- (h) Incorporated by reference to Trimeris' Current Report on Form 8-K filed with the Commission on January 30, 2002.
- (i) Incorporated by reference to Trimeris' Annual Report on Form 10-K for the year ended December 31, 2001 filed with the Commission on March 25, 2002.

- (j) Incorporated by reference to Trimeris' Annual Report on Form 10-K for the year ended December 31, 2002 filed with the Commission on March 27, 2003.
- (k) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended June 30, 2003.
- (l) Incorporated by reference to Trimeris' Annual Report on Form 10-K for the year ended December 31, 2004 filed with the Commission on March 12, 2004.
- (m) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.
- (n) Incorporated by reference to Trimeris' Current Report on Form 8-K filed with the Commission on September 10, 2004.
- (o) Incorporated by reference to Trimeris' Annual Report on Form 10-K/A for the year ended December 31, 2003, filed with the Commission on October 15, 2004.
- (p) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q/A for the quarter ended June 30, 2004, filed with the Commission on October 15, 2004.

All financial statement schedules have been omitted because either they are not required, are not applicable or the information is otherwise set forth in the Financial Statements and Notes thereto.

CERTIFICATION

I, Steven D. Skolsky, certify that:

1. I have reviewed this annual report on Form 10-K of Trimeris, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

- (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the company's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
- (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date : March 10, 2005

/s/ STEVEN D. SKOLSKY

Steven D. Skolsky
Chief Executive Officer

CERTIFICATION

I, Robert R. Bonczek, certify that:

1. I have reviewed this annual report on Form 10-K of Trimeris, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the company's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date : March 10, 2005

/s/ ROBERT R. BONCZEK

Robert R. Bonczek
Chief Financial Officer and General Counsel

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

In connection with the Annual Report on Form 10-K of Trimeris, Inc. (the "Company") for the period ending December 31, 2004 as filed with Securities and Exchange Commission on the date hereof (the "Report"), I, Steven D. Skolsky, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ STEVEN D. SKOLSKY

Steven D. Skolsky

Chief Executive Officer
March 10, 2005

The foregoing certification is being furnished solely pursuant to § 18 U.S.C. 1350 and is not being filed as part of the Report or as a separate disclosure document.

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

In connection with the Annual Report on Form 10-K of Trimeris, Inc. (the "Company") for the period ending December 31, 2004 as filed with Securities and Exchange Commission on the date hereof (the "Report"), I, Robert R. Bonczek, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ ROBERT R. BONCZEK

Robert R. Bonczek

Chief Financial Officer

March 10, 2005

The foregoing certification is being furnished solely pursuant to § 18 U.S.C. 1350 and is not being filed as part of the Report or as a separate disclosure document.



Independent Auditors

KPMG LLP
150 Fayetteville Street Mall, Suite 1200
Raleigh, North Carolina 27601

Transfer Agent

EquiServe Trust Company, N.A.
P.O. Box 43010
Providence, Rhode Island 02940-3010
877-282-1168
www.equiserve.com

Legal Counsel

Wilmer Cutler Pickering Hale and Dorr LLP
2445 M Street, N.W.
Washington, D.C. 20037

Financial and Other Information

The Company's Annual Report filed with the Securities and Exchange Commission on Form 10-K, periodic filings and press releases are available to shareholders without charge. To obtain copies contact:

Investor Relations
Trimeris, Inc.
3500 Paramount Parkway
Morrisville, North Carolina 27560
Phone: 919-419-6050
Fax: 919-419-1816
Email: info@trimeris.com

Electronic copies of these reports are also available at: www.trimeris.com

Trimeris' common stock is traded on the Nasdaq National Market System under the symbol: TRMS

Board of Directors

Jeffrey M. Lipton
Chairman of the Board of Directors
President and Chief Executive Officer, NOVA Chemicals Corporation

Steven D. Skolsky
Chief Executive Officer, Trimeris, Inc.

Dani P. Bolognesi, Ph.D.
Chief Scientific Officer, Trimeris, Inc.

Felix J. Baker, Ph.D.
Managing Member
Baker Bros. Advisors, LLC

Julian C. Baker
Managing Member
Baker Bros. Advisors, LLC

E. Gary Cook, Ph.D.
Retired Chairman, President, and Chief Executive Officer,
Witco Corporation

J. Richard Crout, M.D.
President, Crout Consulting, Former Director, Bureau of Drugs,
U.S. Food and Drug Administration

Charles A. Sanders, M.D.
Retired Chairman and Chief Executive Officer, Glaxo Inc.

Kevin C. Tang
Founder and Managing Director of Tang Capital Management, LLC

Senior Management

Steven D. Skolsky
Chief Executive Officer

Dani P. Bolognesi, Ph.D.
Chief Scientific Officer

Robert R. Bonczek, J.D.
Chief Financial Officer, General Counsel

Andrew L. Graham
Corporate Secretary, Director of Finance

M. Lynn Smiley, M.D.
Senior Vice President, Clinical Research

George W. Koszalka, Ph.D.
Executive Vice President, Scientific Operations

Trademarks

FUZEON® is a registered trademark of Hoffmann-LaRoche Inc. Trimeris and the Trimeris logo are registered trademarks of Trimeris, Inc. Epivir® (3TC®) and Combivir® are registered trademarks of Glaxo Group Limited UK Biojector® is a registered trademark of Bioject Medical Technologies, Inc.

This document and any attachments may contain forward-looking information about the Company's financial results and business prospects that involve substantial risks and uncertainties. These statements can be identified by the fact that they use words such as "expect," "project," "intend," "plan," "believe" and other words and terms of similar meaning. Among the factors that could cause actual results to differ materially are the following: there is uncertainty regarding the success of research and development activities, regulatory authorizations and product commercializations; the results of our previous clinical trials are not necessarily indicative of future clinical trials; and, our drug candidates are based upon novel technology, are difficult and expensive to manufacture, and may cause unexpected side effects. For a detailed description of these factors, see Trimeris' Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 11, 2005, and its periodic reports filed with the SEC.

Trimeris, Inc.
3500 Paramount Parkway
Morrisville, NC 27560
Phone: 919-419-6050
Fax: 919-419-1816
Toll Free: 1-877-652-4027
www.trimeris.com
info@trimeris.com

Research • Innovation • Patient Support • Treatment Options • Resistance Profiles • Novel Antiviral Therapies • Scientific Expertise • Extra-Cellular Activity • GP-41 Protein Target • **FUZEON®** • Blocking Viral Entry • Strategic Marketing • Clinical Candidate • GP-120 Protein Target • Sustained Release • Alignment • Execution • FDA Full Approval • Fusion Inhibition • Discovery • Development • Unprecedented Efficacy • New Treatment Paradigm • Research • Innovation • Patient Support • Treatment Options • Resistance Profiles • Novel Antiviral Therapies • Scientific Expertise • Extra-Cellular Activity • **FIRST IN CLASS** • GP-41 Protein Target • Blocking Viral Entry • Strategic Marketing • **COMMERCIALIZATION** • Clinical Candidate • GP-120 Protein Target • Sustained Release • Alignment • Execution • FDA Full Approval • Fusion Inhibition • Discovery • Development • Unprecedented Efficacy • New Treatment Paradigm • Research • Innovation • Patient Support • Treatment Options • Resistance Profiles • Novel Antiviral Therapies • Scientific Expertise • Extra-Cellular Activity • GP-41 Protein Target • Blocking Viral Entry • Strategic Marketing • Clinical Candidate • GP-120 Protein Target • Sustained Release • Alignment • Execution • **FOCUS IS THE FUTURE** • FDA Full Approval • Fusion Inhibition • Discovery • Development • Unprecedented Efficacy • New Treatment Paradigm • Research • Innovation • Patient Support • Treatment Options • Resistance Profiles • Novel Antiviral Therapies • Scientific Expertise • Extra-Cellular Activity • **SAVE AND IMPROVE LIVES** • GP-41 Protein Target • Blocking Viral Entry • Strategic Marketing • Clinical Candidate • GP-120 Protein Target • Sustained Release • Alignment • Execution • **CREATIVITY** • FDA Full Approval • Fusion Inhibition • Discovery • Development • Unprecedented Efficacy • New Treatment Paradigm • Research • Innovation • Patient Support • Treatment Options • **ACHIEVEMENT** • Resistance Profiles • Novel Antiviral Therapies • Scientific Expertise • Extra-Cellular Activity • GP-41 Protein Target • Blocking Viral Entry • Strategic Marketing • Clinical Candidate • GP-120 Protein Target • Sustained Release • Alignment • Execution • FDA Full Approval • **TEAMWORK** • Fusion Inhibition • Discovery • Development • **INTEGRITY** • Unprecedented Efficacy • New Treatment Paradigm • Research • Innovation • Patient Support • Treatment Options • Resistance Profiles • Novel Antiviral Therapies • Scientific Expertise • Extra-Cellular Activity • GP-41 Protein Target • Blocking Viral Entry • Strategic Marketing • Clinical Candidate • GP-120 Protein Target • Sustained Release • Alignment • Execution • FDA Full Approval • Fusion Inhibition • **EXCELLENCE** • Discovery • Development • Unprecedented Efficacy • New Treatment Paradigm • Research • Innovation • Patient Support • Treatment Options • Resistance Profiles • Novel

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for Injection
Single Use Vial

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

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

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE
SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

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 0-23155

TRIMERIS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of
incorporation or organization)

56-1808663
(I.R.S. Employer
Identification No.)

3500 PARAMOUNT PARKWAY
MORRISVILLE, NORTH CAROLINA 27560
(Address of principal executive offices, including zip code)

(919) 419-6050

Registrant's telephone number, including area code:

SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT:

None

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT:

Common Stock, \$.001 par value (Title of Class)

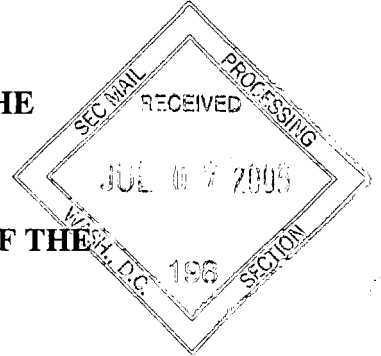
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Annual Report on Form 10-K or any amendment to this Annual Report on Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 30, 2004 was approximately \$259,050,000 (based on the last sale price of such stock as reported by the Nasdaq National Market System on June 30, 2004).

The number of shares of the registrant's common stock outstanding as of April 26, 2005 was 21,949,847.



Explanatory Note

This Amendment No. 1 on Form 10-K/A, or Amendment No. 1, is being filed by Trimeris, Inc. to amend our Annual Report on Form 10-K for the fiscal year ended December 31, 2004 filed with the Securities and Exchange Commission, or SEC, on March 11, 2005, or the Initial Report, to include the information originally intended to be incorporated by reference from our Definitive Proxy Statement for our 2005 annual meeting of stockholders pursuant to Regulation 14A of the Securities Act of 1934, as amended.

Since we will not be filing our Definitive Proxy Statement by the end of 120 days following our fiscal year end as originally intended, we are hereby filing this Amendment No. 1, to add the information required by Part III of Form 10-K. Pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended, Part III of the Initial Report is hereby deleted in its entirety and replaced with the following Part III as set forth below. As a result of this Amendment No. 1, the certifications pursuant to Sections 302 of the Sarbanes-Oxley Act of 2002, filed as exhibits to the original filing, have been re-executed and re-filed as of the date of this Amendment No. 1.

Other than as set forth in this Amendment No. 1, no information included in the Initial Report has been amended by this Amendment No. 1. This Amendment No. 1 does not reflect events occurring after the filing of the Initial Report and does not modify or update the disclosures therein in any other way than as required to reflect this Amendment No. 1.

As used in this Amendment No. 1, the terms "we," "us," "our," "the Company" and "Trimeris" refer to Trimeris Inc., unless the context indicates otherwise.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The following table sets forth the name, age and position of our executive officers, directors and key employees as of April 28, 2005:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Steven D. Skolsky	48	Chief Executive Officer and Director
Dani P. Bolognesi, Ph.D.	64	Chief Scientific Officer and Vice Chairman of the Board of Directors
Robert R. Bonczek	60	Chief Financial Officer and General Counsel
M. Lynn Smiley, M.D.	52	Senior Vice President of Clinical Research
George Koszalka, Ph.D.	54	Executive Vice President of Scientific Operations
Andrew Graham	35	Director of Finance (Principal Accounting Officer) and Secretary
Jeffrey M. Lipton (1)(2)(3)	62	Chairman of the Board of Directors
Felix J. Baker, Ph.D. (2)	36	Director
Julian C. Baker (3)	38	Director
E. Gary Cook, Ph.D. (2)(3)	60	Director
J. Richard Crout, M.D. (1)	75	Director
Charles A. Sanders, M.D. (1)(2)	73	Director
Kevin C. Tang (2)(3)	38	Director

- (1) Member of the Audit and Finance Committee.
- (2) Member of the Compensation Committee.
- (3) Member of the Nomination and Governance Committee.

Steven D. Skolsky, was named Chief Executive Officer in September 2004. Prior to joining the Company, Mr. Skolsky was employed with GlaxoSmithKline (“GSK”), where he most recently managed product strategy and world wide clinical development for the GSK portfolio as Senior Vice President, Global Commercial Strategy. Mr. Skolsky previously served as Managing Director of GSK’s operations in New Zealand from 2000 to 2001 and in Australia from 1999 to 2000. Mr. Skolsky received his B.A. degree from the University of North Carolina at Chapel Hill.

Dani P. Bolognesi, Ph.D., a founder of Trimeris, has been a director since its inception and served as Chief Executive Officer of the Company from 1999 through August 2005. Dr. Bolognesi currently serves as Chief Scientific Officer and Vice-chairman of the Board of Directors. Dr. Bolognesi held a number of positions at Duke University from 1971 to March 1999, including, James B. Duke Professor of Surgery, Professor of Microbiology/Immunology, Vice Chairman of the Department of Surgery for Research and Development and Director of the Duke University Center for AIDS Research from 1989 to March 1999. From 1988 to March 1999, Dr. Bolognesi was the Director of the Central Laboratory Network that supports all HIV vaccine clinical trials sponsored by the National Institutes of Health. Dr. Bolognesi received his Ph.D. degree in Virology from Duke University and a B.S. degree from Rensselaer Polytechnic Institute.

Robert R. Bonczek joined Trimeris as a consultant in March 1997. He was named Acting Chief Administrative Officer and Acting Chief Financial Officer in September 1999, was named Chief Financial Officer in March 2000 and was named General Counsel in April 2000. From 1991 until 2001, Mr. Bonczek acted in a consulting capacity for Donaldson, Lufkin & Jenrette, an investment bank, and for Wilmer Cutler Pickering Hale and Dorr LLP (formerly Wilmer Cutler & Pickering), a law firm. Since 1991, Mr. Bonczek has served as President of AspenTree Capital, a financial services and investment management company. Prior to 1991, Mr. Bonczek was with E.I. Du Pont de Nemours & Co., a chemical company, for 24 years, holding a number of senior management positions, including Corporate Counsel. Mr. Bonczek received his J.D. degree from the University of North Carolina at Chapel Hill, his M.B.A. from The Wharton School at the University of Pennsylvania and a B.A. degree from the University of North Carolina at Chapel Hill.

M. Lynn Smiley, M.D. joined Trimeris as Senior Vice President of Clinical Research in January 2001. From January 1997 until January 2001, Dr. Smiley served as Vice President of HIV and Opportunistic Infections Clinical

Development at Glaxo Wellcome, Inc., now GlaxoSmithKline plc. From March 1988 to December 1996, Dr. Smiley held several positions in research and development at Burroughs Wellcome Co. and Glaxo Wellcome, Inc., including Director of the Infectious Diseases and Immunology Department. Dr. Smiley has also held teaching positions at the University of North Carolina at Chapel Hill School of Medicine since 1984, and has served as Clinical Professor of Medicine since 1994. Dr. Smiley received her M.D. from Duke University Medical School and a B.A. degree from the University of Kansas.

George Koszalka, Ph.D. joined Trimeris as Senior Vice President of Corporate Strategy in June 2002 and has served as Executive Vice President of Scientific Operations since July 2004. Dr. Koszalka served as Division Director of Virology at GlaxoSmithKline from January 2001 to June 2002, with global responsibilities for Research and Clinical Virology and serving as a liaison between the commercial, clinical development and research areas in the antiviral franchise. From 1973 until 2001, Dr. Koszalka held positions of increasing responsibility within Research and Development with Burroughs Wellcome and Glaxo Wellcome. Dr. Koszalka holds an M.S degree and a Ph.D. in Biochemistry from North Carolina State University and received a B.S. degree from Bethany College.

Andrew L. Graham, C.P.A. joined Trimeris as Director of Finance and Secretary in September 2004. From 2002 to 2004, Mr. Graham served as Chief Accounting Officer at Paradigm Genetics, Inc. From 1999 to 2002, Mr. Graham served as Comptroller and later as Director of Finance at Paradigm Genetics, Inc. Mr. Graham received his B.A and M.A. degrees in accounting from North Carolina State University and his M.B.A. from the University of North Carolina at Chapel Hill.

Jeffrey M. Lipton has been a director of Trimeris since June 1998 and has been Chairman of the Board since June 1999. Since July 1998, Mr. Lipton has been President and Chief Executive Officer of NOVA Chemicals Corporation. Previously, Mr. Lipton served as Senior Vice President and Chief Financial Officer of NOVA Corporation from February 1994 until September 1994. From September 1994 to July 1998 he was President of NOVA Corporation. Prior to NOVA, Mr. Lipton worked with E.I. Du Pont de Nemours & Co. for almost three decades, where he held a number of senior management positions. Mr. Lipton serves on the Board of Directors of NOVA Chemicals Corporation, and is a Director of Hercules Incorporated. Mr. Lipton is a Director, a member of the Executive Committee, and Chairman of the Finance and Membership Committee of the American Chemistry Council. He is a member of the Executive Committee and Honorary Secretary of the Society of Chemical Industry and is a member of the Canadian Council of Chief Executives. Mr. Lipton received his M.B.A. from Harvard University and a B.S. degree from Rensselaer Polytechnic Institute.

Felix J. Baker, Ph.D. has served as a director of Trimeris, Inc. since April 2004. Dr. Baker is a Managing Member of Baker Bros. Advisors, LLC, which he and his brother, Julian Baker, founded in 2000. Dr. Baker's firm manages Baker Brothers Investments, a family of long-term investment funds for university endowments and foundations, which are focused on publicly traded life sciences companies. In 1994, Dr. Baker co-founded a biotechnology investing partnership with the Tisch Family, which led to the establishment in 2000 of Baker/Tisch Advisors, LLC. Dr. Baker is currently a Managing Member of Baker/Tisch Advisors. Dr. Baker holds a B.S. and a Ph.D. in Immunology from Stanford University, where he also completed two years of medical school. He is also a director of Neurogen Corporation, Conjuchem Inc., Seattle Genetics, Inc., and AnorMED Inc.

Julian C. Baker has served as a director of Trimeris, Inc since April 2004. Mr. Baker is a Managing Member of Baker Bros. Advisors, LLC, which he and his brother, Felix Baker, Ph.D., founded in 2000. Mr. Baker's firm manages Baker Brothers Investments, a family of long-term investment funds for university endowments and foundations, which are focused on publicly traded life sciences companies. In 1994, Mr. Baker co-founded a biotechnology investing partnership with the Tisch Family, which led to the establishment in 2000 of Baker/Tisch Advisors, LLC. Mr. Baker is currently a Managing Member of Baker/Tisch Advisors. Previously, Mr. Baker was employed from 1988 to 1993 by the private equity investment arm of Credit Suisse First Boston Corporation. He is also a director of Incyte Corporation, Neurogen Corporation, and Theravance, Inc. Mr. Baker holds an A.B. *magna cum laude* from Harvard University.

E. Gary Cook, Ph.D. has been a director of Trimeris since February 2000. Since May 2002, Dr. Cook has served as Chairman of Integrated Environmental Technologies. From 1996 to 1999, Dr. Cook was Chairman of the Board of

Directors, President and Chief Executive Officer of Witco Corporation, a global specialty chemicals corporation. From 1994 to 1996, Dr. Cook was President and Chief Operating Officer of Albemarle Corporation, a global specialty chemicals corporation. From 1992 to 1994, Dr. Cook was Senior Vice President, President—Chemicals, and member of the Board of Directors of Ethyl Corporation. Prior to Ethyl, Dr. Cook was with E.I. Du Pont de Nemours & Co. for 23 years, holding a number of senior management positions, including Vice President, Printing and Publishing, Vice President, Medical Products, and Vice President, Corporate Plans. Dr. Cook serves on the Boards of Directors of Louisiana-Pacific Corporation and Envirokare Tech, Inc. Dr. Cook received his Ph.D. degree in Chemistry from The Virginia Polytechnic Institute and University and a B.S. degree from the University of Virginia.

J. Richard Crout, M.D. has been a director of Trimeris since November 1998. Since 1994, Dr. Crout has been President of Crout Consulting, a firm that provides consulting advice to pharmaceutical and biotechnology companies on the development of new products. From 1984 to 1993, Dr. Crout was Vice President, Medical and Scientific Affairs with Boehringer Mannheim Pharmaceuticals Corp. From 1973 to 1982, Dr. Crout was Director of the Bureau of Drugs, now known as the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. Dr. Crout received his M.D. degree from Northwestern University Medical School and an A.B. degree from Oberlin College.

Charles A. Sanders, M.D. has been a director of Trimeris since October 1996. From 1989 to May 1995, Dr. Sanders was Chairman of the Board of Directors and Chief Executive Officer of Glaxo Inc. and a member of the Board of Directors of Glaxo plc. Dr. Sanders is currently retired. Prior to joining Glaxo, Dr. Sanders held a number of positions at Squibb Corporation, a multinational pharmaceutical corporation, including Vice Chairman, Chief Executive Officer of the Science and Technology Group and Chairman of the Science and Technology Committee of the Board. Dr. Sanders serves on the Boards of Directors of Vertex Pharmaceuticals Incorporated, Genentech, Inc., Biopure Corporation, Fisher Scientific International, Icagen Incorporated and Cephalon, Inc. Dr. Sanders received his M.D. degree from Southwestern Medical College of the University of Texas.

Kevin C. Tang has been a director of Trimeris since August 2001. Mr. Tang is the Managing Director of Tang Capital Management, LLC, a Life Sciences-focused investment company he founded in August 2002. From September 1993 to July 2001, Mr. Tang held various positions at Deutsche Banc Alex Brown, Inc., an investment banking firm, most recently serving as Managing Director and head of the firm's Life Sciences research group. Mr. Tang currently serves as a director of IntraBiotics Pharmaceuticals, Inc. Mr. Tang received a B.S. from Duke University.

Audit Committee

The Board of Directors has a standing Audit and Finance Committee, which assists the Board in executing its responsibilities. The Audit and Finance Committee's responsibilities include providing oversight of the quality and integrity of the Company's regulatory and financial accounting and reporting, risk management, legal and regulatory compliance, the internal and external audit functions and the preparation of this Audit and Finance Committee report. The Audit and Finance Committee is composed of three non-employee directors, each of whom is independent as defined in Nasdaq listing standards and is chaired by Dr. Crout. The other members of the committee are Mr. Lipton and Dr. Sanders. Although each of the members of the Audit and Finance Committee is financially literate, the Board has determined that Mr. Lipton is an audit committee financial expert as defined by the SEC. Our Board of Directors has adopted a written charter for the Audit and Finance Committee, a copy of which is available on-line at www.trimeris.com.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our officers and directors, and persons who own more than 10% of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC and the Nasdaq National Market ("Nasdaq"). Officers, directors and greater than 10% stockholders are required by SEC regulations to furnish us with copies of all reports they file pursuant to Section 16(a).

Based solely on a review of the copies of such reports furnished to us, or written representations from certain reporting persons that no other reports were required for those persons, we believe that, during the year ended December 31, 2004, all Section 16(a) filing requirements applicable to our officers, directors and greater than 10% stockholders were satisfied.

Code of Ethics

The Board of Directors has adopted a Code of Ethics which outlines the principles, policies and laws that govern the activities of our personnel and establishes guidelines for professional conduct in the workplace. The Code of Ethics applies to all of our employees, officers and directors. A copy of our Code of Ethics is available on our website at www.trimeris.com or you may request a free copy from our Compliance Officer at the following address: 3500 Paramount Parkway, Morrisville, NC 27560.

To date, there have been no waivers under our Code of Business Conduct and Ethics. We intend to disclose any amendments to our Code of Ethics and any waiver granted from the Code on a Form 8-K filed with the SEC within four business days following such amendment or waiver or on our website at www.trimeris.com within four business days following such amendment or waiver. The information contained or connected to our website is not incorporated by reference into this report and should not be considered a part of this or any other report that we file or furnish to the SEC.

ITEM 11. EXECUTIVE COMPENSATION

Executive Compensation

The following table sets forth certain information with respect to the annual and long-term compensation paid by us during the fiscal years ended December 31, 2004, 2003, and 2002 to Messrs. Skolsky, Bolognesi, Ellis (resigned effective June 27, 2004), Bonczek, Koszalka, Creech (resigned effective October 25, 2004), and Graham (collectively, the "Named Executive Officers").

Summary Compensation Table

Name And Principal Position	Year	Annual Compensation		Long Term Compensation		
		Salary	Bonus (2)	Restricted Stock Awards (\$)	Securities Underlying Options (#)	All Other Compensation
Steven D. Skolsky Chief Executive Officer	2004	\$142,381(1)	\$ 70,000	\$575,500(3)	350,000(5)	(11)
	2003	—	—	—	—	—
	2002	—	—	—	—	—
Dani P. Bolognesi Chief Scientific Officer	2004	\$438,263	\$167,000	\$442,582(4)	94,000(6)	(11)
	2003	437,304	—	—	54,000(7)	(11)
	2002	417,300	313,000	—	69,000(8)	(11)
M. Nixon Ellis President (resigned)	2004	\$157,522	\$ —	—	—	\$166,793(12)
	2003	314,304	—	—	26,000(7)	—
	2002	294,876	180,000	—	34,500(8)	—
Robert R. Bonczek Chief Financial Officer and General Counsel	2004	\$292,040	\$ 89,000	\$221,998(4)	47,200(6)	(11)
	2003	291,300	—	—	26,000(7)	(11)
	2002	278,604	127,000	—	34,500(8)	(11)
Barney Koszalka Executive Vice President of Scientific Operations	2004	\$222,768	\$ 49,000	\$155,540(4)	32,800(6)	(11)
	2003	196,308	53,000	—	14,000(7)	(11)
	2002	111,013	51,000	—	10,000(9)	(11)
Timothy J. Creech Vice President of Finance (Principal Accounting Officer) (resigned)	2004	\$147,027	\$ —	\$ 98,980(4)	20,800(6)(10)	—
	2003	165,300	42,000	—	12,000(7)	(11)
	2002	149,304	57,000	—	9,500(8)	(11)
Andrew L. Graham Director of Finance (Principal Accounting Officer)	2004	\$ 45,454(1)	\$ 7,000	—	5,000(9)	—
	2003	—	—	—	—	—
	2002	—	—	—	—	—

(1) Mr. Skolsky and Mr. Graham each commenced employment with Trimeris in September 2004.

- (2) In February 2003, 2002 bonuses were awarded and paid to the Named Executive Officers for achievement in 2002; however, such bonuses are reported with the 2002 compensation. In February 2004, a 2003 bonus was awarded and paid to Mr. Creech for achievement in 2003; however, such bonus was reported with the 2003 compensation. The other Named Executive Officers that were present in 2003 did not receive a bonus for that year. In February 2005, 2004 bonuses were awarded and paid to the Named Executive Officers for achievement in 2004; however, such bonuses are reported with the 2004 compensation.
- (3) These shares of restricted stock were granted to Mr. Skolsky pursuant to the Amended and Restated Stock Incentive Plan in connection with his initial employment agreement with Trimeris. The dollar value of the grant was calculated using \$11.51, the closing price of our stock on the date of grant. These restricted shares vest 100% in September 2008. In the event that Mr. Skolsky's employment is terminated because of death, disability, without Cause, or for Good Reason (as these terms are defined in Mr. Skolsky's employment agreement), Mr. Skolsky is entitled to receive a pro rata number of the shares granted (but in no event, other than termination for Cause, shall Mr. Skolsky be entitled to receive less than 50% of the shares granted).
- (4) On June 22, 2004, the Compensation Committee approved an aggregate number of shares of restricted stock to be granted to all eligible employees, including the Named Executive Officers pursuant to our Amended and Restated Stock Incentive Plan. The dollar value of the grant was calculated using \$14.14, the closing price of our stock on the date of grant. These restricted shares vest 100% in June 2007 and are cancelled in the event that employment is terminated prior to vesting.
- (5) These options to purchase shares of stock were granted to Mr. Skolsky pursuant to the Amended and Restated Stock Incentive Plan in connection with his initial employment agreement with Trimeris. The options vest monthly over four years (100% vesting in September 2008). In the event that Mr. Skolsky's employment is terminated because of death, disability, without Cause, or for Good Reason (as these terms are defined in Mr. Skolsky's employment agreement), prior to September 2006, Mr. Skolsky will automatically vest in 50% of the options granted.
- (6) On June 22, 2004, the Compensation Committee approved an aggregate number of options to purchase shares of our common stock to be granted on a quarterly basis over four quarters to all eligible employees, including the Named Executive Officers pursuant to our Amended and Restated Stock Incentive Plan. These option grants were designed to be awarded at the fair market value of our common stock on the date of that particular quarterly grant. These quarterly option grants began in June 2004 and continued thereafter until April 2005, as long as the employee was employed by us on the date of grant. Once granted, the aggregate number of options become exercisable over a four-year period, with the first grant in June 2004 exercisable in full in June 2005 and the remainder of the grants exercisable ratably over a three-year period beginning in June 2005. The number in this column represents the total number of options to purchase shares of our common stock that the Named Executive Officer received pursuant to such grants on a quarterly basis in June 2004, October 2004, January 2005 and April 2005.
- (7) On June 18, 2003, the Compensation Committee approved an aggregate number of options to purchase shares of our common stock to be granted on a quarterly basis over four quarters to all eligible employees, including the Named Executive Officers pursuant to our Amended and Restated Stock Incentive Plan. These option grants were designed to be awarded at the fair market value of our common stock on the date of that particular quarterly grant. These quarterly option grants began in June 2003 and continued thereafter until April 2004, as long as the employee was employed by us on the date of grant. Once granted, the aggregate number of options become exercisable over a four-year period, with the first grant in June 2003 exercisable in full in June 2004 and the remainder of the grants exercisable ratably over a three-year period beginning in June 2004. The number in this column represents the total number of options to purchase shares of our common stock that the Named Executive Officer received pursuant to such grants on a quarterly basis in June 2003, October 2003, January 2004 and April 2004.
- (8) On June 26, 2002, the Compensation Committee approved an aggregate number of options to purchase shares of our common stock to be granted on a quarterly basis over four quarters to all eligible employees, including the Named Executive Officers pursuant to our Amended and Restated Stock Incentive Plan. These option grants were designed to be awarded at the fair market value of our common stock on the date of that particular quarterly grant. These quarterly option grants began in June 2002 and continued thereafter until April 2003, as long as the employee was employed by us on the date of grant. Once granted, the aggregate number of options become exercisable over a four-year period, with the first grant in June 2002 exercisable in full in June 2003 and the remainder of the grants exercisable ratably over a three-year period beginning in June 2003. The number in this

column represents the total number of options to purchase shares of our common stock that the Named Executive Officer received pursuant to such grants on a quarterly basis in June 2002, October 2002, January 2003 and April 2003.

- (9) These options to purchase shares of stock were granted pursuant to the Amended and Restated Stock Incentive Plan in connection with the executive officer's commencement of employment with Trimeris. The options vest monthly over four years from the date of commencement of employment.
- (10) This number represents the total number of options approved by the Compensation Committee to be granted to Mr. Creech beginning in June 2004. Mr. Creech received 10,400 of these options prior to his departure, however these options expired unexercised following his termination of employment with the Company.
- (11) Beginning in 1998, we matched up to 100% of a participant's annual contributions to the Trimeris Employee 401(k) Plan with common stock, provided the participant was employed on the last day of the year. The number of shares issued is based on the annual contributions to be matched divided by the closing price of the common stock on the last trading day of the year. The dollar amount of matching contributions were calculated using the closing stock price on the date of grant. On December 31, 2002, December 31, 2003 and December 31, 2004, the closing price was \$43.17, \$20.94 and \$14.17, respectively. On December 31, 2004, Mr. Skolsky received 635 shares of stock. Based on the closing price that day the value of the Company's 401(k) contribution to Mr. Skolsky for 2004 was approximately \$9,000. Mr. Skolsky is not yet vested in any of these shares. On December 31, 2002, December 31, 2003 and December 31, 2004, Dr. Bolognesi received 254, 540 and 917 shares of stock, respectively, and as of April 23, 2005, is vested in all of those shares of stock. Based upon the closing price of the Company's common stock on the date of grant, the value of the Company's 401(k) contributions to Dr. Bolognesi for years 2002, 2003 and 2004 was approximately \$11,000, \$11,300 and \$13,000, respectively. On December 31, 2002, December 31, 2003 and December 31, 2004, Mr. Bonczek received 277, 630 and 1,129 shares of stock, respectively, and as of April 23, 2004, is vested in all of those shares of stock. Based upon the closing price of the Company's common stock on the date of grant, the value of the Company's 401(k) contributions to Mr. Bonczek for years 2002, 2003 and 2004 were approximately \$12,000, \$13,200 and \$16,000, respectively. On December 31, 2002, December 31, 2003 and December 31, 2004, Dr. Koszalka received 170, 631 and 1,129 shares of stock, respectively, and as of April 23, 2005, is vested in 50% of those shares of stock. Based upon the closing price of the Company's common stock on the date of grant, the value of the Company's 401(k) contributions to Dr. Koszalka for years 2002, 2003 and 2004 were approximately \$7,300, \$13,200 and \$16,000, respectively. On December 31, 2002, December 31, 2003 and December 31, 2004, Mr. Creech received 254, 540 and 0 shares of stock, respectively, and as of April 23, 2004, is vested in all of those shares of stock. Based upon the closing price of the Company's common stock on the date of grant, the value of the Company's 401(k) contributions to Mr. Creech for years 2002 and 2003 were approximately \$11,000 and \$11,300, respectively. On December 31, 2004, Mr. Graham received 381 shares of stock. Based upon the closing price of the Company's common stock on the date of grant, the value of the Company's 401(k) contribution to Mr. Graham for 2004 was approximately \$5,400. Mr. Graham is not yet vested in any of these shares.
- (12) In connection with his Separation and Severance Agreement with the Company, Dr. Ellis is entitled to continue receiving his monthly base salary as of the date of termination of his employment for a period of two years following termination (up to a total of \$628,000). The amount reported for 2004 includes approximately \$10,000 owed to Dr. Ellis as a result of unused vacation time.

Stock Option Grants

The following table sets forth the stock options we granted during the year ended December 31, 2004 to each of our Named Executive Officers. We have never granted any stock appreciation rights.

Amounts shown as potential realizable values are based on compounded annual rates of share price appreciation of five and ten percent over the 10-year term of the options, as mandated by rules of the SEC, and are not indicative of expected share price performance. Actual gains, if any, on share option exercises are dependent on future performance of the overall market conditions, as well as the option holder's continued employment through the vesting period. The amounts reflected in this table may not necessarily be achieved or may be exceeded. The indicated amounts are net of the option exercise price but before taxes that may be payable upon exercise.

OPTIONS GRANTED IN THE YEAR ENDED DECEMBER 31, 2004

Name	Individual Grants				Potential Realizable Value At Assumed Annual Rates Of Stock Price Appreciation For Option Term (6)	
	Number Of Securities Underlying Options	Percent Of Total Options Granted To Employees In 2004	Exercise Price Per Share	Expiration Date	5%	10%
Steven D. Skolsky	350,000(2)	37.0%	\$11.51	9/08/2014	\$2,377,264	\$5,945,442
Dani P. Bolognesi	13,500(3)	1.4%	21.01	6/18/2013	167,376	418,601
	13,500(3)	1.4%	14.96	6/18/2013	115,263	286,156
	23,500(4)	2.5%	14.14	6/22/2014	208,975	529,585
	23,500(4)	2.5%	15.95	6/22/2014	228,457	575,279
M. Nixon Ellis (1)	6,500(3)	0.7%	21.01	6/18/2013	80,589	201,549
	6,500(3)	0.7%	14.96	6/18/2013	57,382	143,511
Robert R. Bonczek	6,500(3)	0.7%	21.01	6/18/2013	80,589	201,549
	6,500(3)	0.7%	14.96	6/18/2013	55,497	137,779
	11,800(4)	1.2%	14.14	6/22/2014	104,932	236,412
	11,800(4)	1.2%	15.95	6/22/2014	114,715	288,864
Barney Koszalka	3,500(3)	0.4%	21.01	6/18/2013	43,394	108,526
	3,500(3)	0.4%	14.96	6/18/2013	30,898	77,275
	8,200(4)	0.9%	14.14	6/22/2014	68,422	171,121
	8,200(4)	0.9%	15.95	6/22/2014	77,181	193,026
Timothy J. Creech (1)	3,000(3)	0.3%	21.01	6/18/2013	37,195	93,023
	3,000(3)	0.3%	14.96	6/18/2013	26,484	66,236
	5,200(4)	0.6%	14.14	6/22/2014	43,390	108,516
	5,200(4)	0.6%	15.95	6/22/2014	48,944	122,407
Andrew L. Graham	5,000(5)	0.5%	11.95	9/01/2014	35,259	88,182

(1) This table represents the total number of options approved by the Compensation Committee to be granted to named executive officer for 2004. In the case of both Dr. Ellis and Mr. Creech, these options expired unexercised following termination of their employment with the Company.

(2) These options to purchase shares of stock were granted to Mr. Skolsky pursuant to the Amended and Restated Stock Incentive Plan in connection with his initial employment agreement with Trimeris. The options vest monthly over four years (100% vesting in September 2008). In the event that Mr. Skolsky's employment is terminated because of death, disability, without Cause, or for Good Reason (as these terms are defined in Mr. Skolsky's employment agreement), prior to September 2006, Mr. Skolsky will automatically vest in 50% of the options granted.

(3) Each option represents the right to purchase one share of common stock. The options shown in this row were all granted pursuant to the Amended and Restated Stock Incentive Plan. These options were granted in January 2004 and April 2004 based upon an aggregate option number determined in June 2003 that was designed to be granted

on a quarterly basis over four quarters at the fair market value of our common stock on the date of grant. These January 2004 and April 2004 options become exercisable ratably over a three-year period that began in June 2004. Upon the occurrence of certain events that result in a change of control, all outstanding options granted to all employees, including executive officers, will become fully exercisable.

- (4) Each option represents the right to purchase one share of common stock. The options shown in this row were all granted pursuant to the Amended and Restated Stock Incentive Plan. These options were granted in June 2004 and October 2004 and collectively become exercisable over a four-year period. The June 2004 grant is exercisable in full in June 2005. The October 2004 grant is exercisable ratably over a three-year period that begins in June 2006. The number of option shares granted in each instance was based upon an aggregate option number that was determined in June 2004 and that was designed to be granted on a quarterly basis over four quarters at the fair market value of our common stock on the date of grant. Upon the occurrence of certain events that result in a change of control, all outstanding options granted to all employees, including executive officers, will become fully exercisable.
- (5) These options to purchase shares of stock were granted to Mr. Graham pursuant to the Amended and Restated Stock Incentive Plan in connection with his initial employment agreement with Trimeris. The options vest monthly over four years (100% vesting in September 2008).
- (6) Amounts represent hypothetical gains that could be achieved for the respective options if exercised at the end of the option term. The 5% and 10% assumed annual rates of compounded stock price appreciation are mandated by the rules of the SEC and do not represent an estimate or projection of our future common stock prices. These amounts represent certain assumed rates of appreciation in the value of our common stock from the fair market value on the date of grant. Actual gains, if any, on stock option exercises are dependent on the future performance of the common stock and overall stock market conditions. The amounts reflected in the table may not necessarily be achieved.

Year-End Option Table

The following table contains information regarding stock options held by our named executive officers, and the number of and value of any unexercised in-the-money options, as of December 31, 2004. The value of unexercised in-the-money options at December 31, 2004 is based on a value of \$14.17 per share, the fair market value of our common stock as reflected by the closing price on the Nasdaq National Market on December 31, 2004, less the per share exercise price, multiplied by the number of shares issuable upon exercise of the option.

AGGREGATED OPTION EXERCISES IN THE YEAR ENDED DECEMBER 31, 2004 AND YEAR-END OPTION VALUES

Name	Shares Acquired on Exercise (#)	Value Realized (1)	Number of Securities underlying Unexercised Options as of December 31, 2004 (#)		Value of Unexercised In-the-Money Options at December 31, 2004	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Steven D. Skolsky	—	—	21,875	328,125	\$ 58,188	\$872,813
Dani P. Bolognesi	—	—	524,352	114,890	1,323,584	705
M. Nixon Ellis (2)	—	—	0	0	0	0
Robert R. Bonczek	—	—	303,800	56,930	562,870	354
Timothy J. Creech (3)	20,487(4)	62,485	54,334	22,766	50,900	156
Barney Koszalka	—	—	11,499	28,901	0	246
Andrew L. Graham	—	—	416	4,584	924	10,176

- (1) Value realized is calculated as the fair market value of our common stock as reflected by the closing price on the Nasdaq National Market on the date of exercise, less the per share exercise price, multiplied by the number of shares issuable upon exercise of the option.
- (2) Mr. Ellis resigned from the Company, effective June 27, 2004.
- (3) Mr. Creech resigned from the Company, effective October 25, 2004.
- (4) At the time of exercise, Mr. Creech was not an employee of the Company.

Employment Agreements

We have entered into employment agreements with some of our Named Executive Officers as described below. In addition to the specific rights set forth in any agreement, in the event of any change in control, options and restricted stock granted pursuant to the Amended and Restated Stock Incentive Plan contain a change in control provision, which provides for the immediate vesting in full of all grants or lapse of all restrictions for all grantees.

In April 1999, we entered into an employment agreement with Dr. Bolognesi to serve as our Chief Executive Officer and Chief Scientific Officer. Under this agreement, Dr. Bolognesi is entitled to receive minimum annual compensation of \$285,000, an annual bonus based upon the achievement of certain milestones and all health insurance and other benefits generally made available to our employees. He also received in 1999 a one-time payment of \$40,000 for replacement of lost income. In connection with the agreement, Dr. Bolognesi received a grant of options to purchase 235,000 shares of common stock at \$11.625 per share. If Dr. Bolognesi's employment is terminated for any reason other than for cause, Dr. Bolognesi's employment agreement provides that he is entitled to his base salary and benefits for two years from the date of termination. In April 2003, Dr. Bolognesi's employment agreement was automatically renewed until April 2005, unless terminated earlier in accordance with its terms. In September 2004, Dr. Bolognesi stopped serving as Chief Executive Officer but continues to serve as Chief Scientific Officer. The Company is currently in negotiations with Dr. Bolognesi with respect to the terms of a new contract.

In March 2000, we entered into an employment agreement with Dr. Ellis, our former President. Under this agreement, Dr. Ellis is entitled to receive minimum annual compensation of \$220,000, an annual bonus based upon the achievement of certain milestones and all health insurance and other benefits generally made available to our employees. In June 2004, the Company terminated its employment agreement with Dr. Ellis. According to the terms of the Separation and Severance Agreement between Dr. Ellis and the Company, Dr. Ellis is entitled to receive his monthly base salary as of the date of termination of his employment for a period of two years following termination. The Company will contribute towards medical and dental coverage for Dr. Ellis and his wife through December 2005 as part of the Separation and Severance Agreement.

In January 2000, we entered into an employment agreement with Mr. Bonczek, our Chief Financial Officer and General Counsel. Under this agreement, Mr. Bonczek is entitled to receive minimum annual compensation of \$210,000 and an annual bonus based upon the achievement of certain milestones. Pursuant to his agreement, he also received in 2000 a one-time payment of \$16,000 for replacement of lost income and in 2001 a one-time payment of \$19,790 for reimbursement for moving and miscellaneous expenses. In October 1999, Mr. Bonczek received a grant of options to purchase 100,000 shares of common stock at \$17.625 per share. If Mr. Bonczek's employment is terminated for any reason other than for cause, Mr. Bonczek's agreement provides that he is entitled to his base salary and benefits for two years from the date of such termination. In January 2004, Mr. Bonczek's employment agreement was automatically renewed until January 2006, unless terminated earlier in accordance with its terms.

In February 2004, we entered into an employment agreement with Mr. Creech, our former Vice President of Finance. Under this agreement, Mr. Creech is entitled to receive minimum annual compensation of \$172,000, an annual bonus based upon the achievement of certain milestones and all health insurance and other benefits generally made available to our employees. If Mr. Creech's employment is terminated by the Company for any reason other than for cause, Mr. Creech's employment arrangement provides that he is entitled to his base salary and benefits from the date of such termination until February 2005. This agreement expired according to its terms upon Mr. Creech's termination of employment in November 2004 with no further obligations on the part of the Company.

In June 2004, we entered into an employment agreement with Dr. Koszalka, our Executive Vice President of Commercial Operations. Under this agreement, Dr. Koszalka is entitled to receive minimum annual compensation of \$235,000, an annual bonus based upon the achievement of certain milestones and all health insurance and other benefits generally made available to our employees. If Dr. Koszalka's employment is terminated for any reason other than for cause, Dr. Koszalka's employment arrangement provides that he is entitled to his base salary and benefits for one year from the date of such termination. The agreement is set to expire in June 2006 and shall automatically renew for a one-year period unless terminated earlier in accordance with its terms.

In September 2004, we entered into an employment agreement with Mr. Skolsky, our Chief Executive Officer. The employment agreement has an initial term of two years and thereafter will automatically be extended for two year periods unless notice of non-renewal is given by either party no later than 90 days prior to the end of the expiration of

each term. Under the agreement, Mr. Skolsky will receive an annual salary of \$450,000, as well as other compensation, including bonus opportunities based upon the achievement of financial and other performance criteria. In addition, under the agreement, Mr. Skolsky received a grant of an option to purchase 350,000 shares of the Company's common stock and a grant of 50,000 shares of restricted stock. Both the option grant and the restricted stock grant are subject to the terms of the Company's Amended and Restated Stock Incentive Plan. In the event that Mr. Skolsky's employment is terminated other than for Cause, death or Disability or upon his resignation for Good Reason (as these terms are defined in the agreement), Mr. Skolsky will be entitled to certain severance payments and benefits, including two times his base salary plus his Target Bonus (as defined in the Employment Agreement). Mr. Skolsky will also be entitled to a pro rata bonus for the year of termination based on actual results for such year if he is terminated due to death, Disability, termination without Cause, or upon resignation for Good Reason. Mr. Skolsky is subject to non-competition restrictions during the term of his employment and for one year thereafter. In the event that the payment of benefits is due as a result of a Change of Control, the Company is required to pay any excise taxes that may apply to such benefits. Mr. Skolsky is entitled to receive reimbursement for financial planning and tax preparation (including a gross-up for any taxes incurred on payment for these services) up to a maximum of \$10,000 per year.

401(k) Plan

The Company sponsors a 401(k) Profit Sharing Plan (the "401(k) Plan") under Section 401(k) of the Internal Revenue Code covering all qualified employees. Participants may elect a salary reduction from 1% to 75% as a contribution to the 401(k) Plan, up to the annual Internal Revenue Service allowable contribution limit. Modifications of the salary reductions may be made quarterly. The 401(k) Plan permits the Company to match participants' contributions. Beginning in 1998, the Company matched up to 100% of a participant's contributions with Company stock, provided the participant was employed on the last day of the year. Matching contribution shares vest ratably based on a participant's years of service and are fully vested after four years of service.

Compensation Committee Interlocks and Insider Participation

Our Board of Directors' Compensation Committee is responsible for determining the salaries and incentive compensation of the executive officers and providing recommendations for the salaries and incentive compensation of all other employees and consultants. The Compensation Committee also administers our benefit plans, including the Amended and Restated Stock Incentive Plan. Dr. Cook serves as the Chairman of the Compensation Committee and the other members of the committee are Mr. Lipton, Dr. Sanders, Mr. Tang and Felix J. Baker. None of Dr. Cook, Dr. Baker, Mr. Lipton, Dr. Sanders or Mr. Tang has served as an officer or employee of Trimeris or has any relationship with Trimeris requiring disclosure under SEC regulations.

Director Compensation

We reimburse our directors for all reasonable and necessary travel and other incidental expenses incurred in connection with their attendance at meetings of the Board. Directors do not receive additional compensation in connection with their attendance at meetings. In addition, all eligible non-employee directors, except the Chairman, automatically receive a grant of an option on the date of our annual meeting to purchase 10,000 shares of common stock. The Chairman automatically receives a grant of an option on the date of our annual meeting to purchase 15,000 shares of common stock. In addition, all eligible non-employee directors serving as members of the Compensation Committee or Audit and Finance Committee, except the directors serving as chairmen of these committees, receive an option on the date of our annual meeting to purchase 1,250 shares of common stock. The directors serving as chairmen of these committees each receives a grant of an option at the date of our annual meeting to purchase 2,500 shares of common stock. These options have an exercise price equal to 100% of the fair market value of our common stock on the grant date and become exercisable after the completion of one year of service following the grant. Newly-elected directors are granted an option to purchase 20,000 shares of common stock, with the options vesting ratably over the three years. These options have an exercise price equal to 100% of the fair market value of our common stock on the grant date. Members of the Nomination and Governance Committee do not receive any compensation for serving on this committee.

Compensation Committee Report on Executive Compensation

The Compensation Committee of the Board of Directors offers this report regarding compensation for our executive officers, including our Chief Executive Officer. The Compensation Committee is composed entirely of independent

directors (as defined in the Nasdaq listing standards) and is responsible for developing and making recommendations to the Board with respect to our executive compensation policies and practices, including the establishment of the annual total compensation for all executive officers, including our Chief Executive Officer.

General Compensation Policy. Our primary objective is to maximize the value of our shares over time. The Compensation Committee, with this objective in mind, authorizes compensation packages for our executive officers designed to retain and attract top quality management and to encourage them to contribute to the achievement of our business objectives. In addition, the Committee attempts to establish compensation packages that are comparable to the packages received by executives of similar companies, in our industry.

We compensate our executive officers with a combination of salary and incentives designed to encourage efforts to achieve both our short-term and long-term goals. The compensation structure attempts to reward both individual contributions and our overall corporate performance. The Committee evaluates corporate performance and makes executive compensation decisions from various performance measures such as sales growth, earnings per share, achieving milestones in the development of drug candidates and raising capital needed for operations.

Section 162(m) of the Code limits the federal income tax deductibility of compensation paid to Trimeris' five most highly compensated executive officers. Under this section of the Code, the Company generally may deduct compensation paid to any such officer to the extent that it does not exceed \$1 million during any calendar year or is "performance-based" as defined in Section 162(m). The Compensation Committee expects that the deductibility limit of Section 162(m) will not currently have a significant effect on the Company. Current cash compensation paid to each of the Company's executives is less than \$1 million per year and is thus generally fully deductible to Trimeris.

The basic components of our compensation packages for our executive officers include the following:

- Base Salary
- Performance Incentive Awards
- Long-term Incentives
- Benefits

Each executive officer's compensation package contains a mix of these components and is designed to provide a level of compensation competitive with the compensation paid to comparable officers of similar biopharmaceutical companies. The Committee favors a compensation structure that aligns the long-term interests of its executive officers with the interests of its stockholders, and as a result places significant weight upon long-term incentives in the form of equity compensation.

Base Salary. Base salary and increases in base salary are determined by both individual and Company performance, as well as the salary levels in effect for similar biopharmaceutical companies. During 2004, the Committee attempted to keep the base salaries of our officers at a level consistent with the median range of the salaries of equivalent officers in similar biopharmaceutical companies. In addition, the Committee considered the following factors in setting the base salaries for executive officers during 2005: our sales of FUZEON, achievement of cost and earnings objectives, our progress in the development of next generation fusion inhibitors, and contributions in any area of special expertise by a particular executive.

Performance Incentive Awards. Performance incentive awards are granted by the Committee based upon its evaluation of the performance of each executive officer and the achievement of our goals during the year. Payment of bonuses occurs as soon as practical in the following calendar year. In February 2005, bonuses totaling \$382,000 were awarded to the Named Executive Officers for achievements in 2004, which included increases in FUZEON sales and progress in the development of a third generation clinical candidate.

Long-term Incentive Compensation. Long-term incentive compensation in the form of stock-based awards is expected to be the largest element of total compensation over time in order to conserve our cash resources, to align the long-term interests of each officer with the interests of our stockholders and to provide long-term incentives for the individual officer to remain with us. Grants are generally made to most employees on their date of hire based on salary level and position. Under our stock option plan, stock option grants made in connection with commencement of employment are priced at the fair market value on the date of grant, generally become exercisable over a period of four years and have a term of up to ten years. All employees, including executive officers, are eligible for subsequent discretionary grants, which are generally based on corporate and/or individual performance. During the period covering

2000-2004, the number of options to be granted was determined each June. The options were granted in June, October, January and April at the fair market value of our common stock on the date of each grant. In order to receive the quarterly grant, the individual employee was required to be employed on the date of grant. Prior to 2000, discretionary grants were awarded on an annual basis at the fair market value on the date of grant and became exercisable over a period of four years. The size of the stock option grant to each officer is based on the officer's current position and expected future contributions to our business. Awards of stock options are designed to have an expected aggregate exercise value over time equal to a multiple of salary, which are expected to create a significant value opportunity based upon stock ownership. Restricted stock grants include a restriction that lapses after three years of service with the Company and are subject to the provisions of the Amended and Restated Stock Incentive Plan.

Benefits. Benefits offered to our executive officers are substantially the same as those offered to all our regular employees and generally include medical insurance, dental insurance, 401(k) plan, employee stock purchase plan, disability insurance, life insurance and flexible spending account.

CEO COMPENSATION

Mr. Skolsky's compensation in 2004, including base salary, bonus award and stock-based incentive grants was determined within the same general framework established for all executive officers of the Company. However, in light of the fact that 2004 was the first year of Mr. Skolsky's employment, the Committee also considered the requirements of attracting a top-level executive to the Company.

Mr. Skolsky's 2004 base salary of \$450,000 was arrived at using various surveys regarding executive compensation at similar biopharmaceutical companies. Prior to the Committee establishing Mr. Skolsky's base salary for 2004, the Committee conducted an extensive study of compensation for officers with similar responsibilities in similar biopharmaceutical companies.

Mr. Skolsky's target bonus is set by contract to range from 25% -75% of his base salary based on financial and other criteria set by the board in consultation with Mr. Skolsky. Mr. Skolsky's bonus award was \$70,000 for 2004, which was pro rated for his partial year of service. The Committee based the bonus on objectives relating to FUZEON sales and other personal objectives.

In September 2004, we entered into an employment agreement with Mr. Skolsky, to serve as our Chief Executive Officer and a member of our Board of Directors. The employment agreement has an initial term of two years and thereafter will automatically be extended for two year periods unless notice of non-renewal is given by either party no later than 90 days prior to the end of the expiration of each term. Under the agreement, Mr. Skolsky will receive an annual salary of \$450,000, as well as other compensation, including bonus opportunities based upon the achievement of financial and other performance criteria. In addition, under the agreement, Mr. Skolsky received a grant of an option to purchase 350,000 shares of the Company's common stock and a grant of 50,000 shares of restricted stock. Both the option grant and the restricted stock grant are subject to the terms of the Company's Amended and Restated Stock Incentive Plan. For a detailed discussion of Mr. Skolsky's employment agreement, please refer to the section entitled "Employment Agreements" on page 11 of this Amendment No. 1.

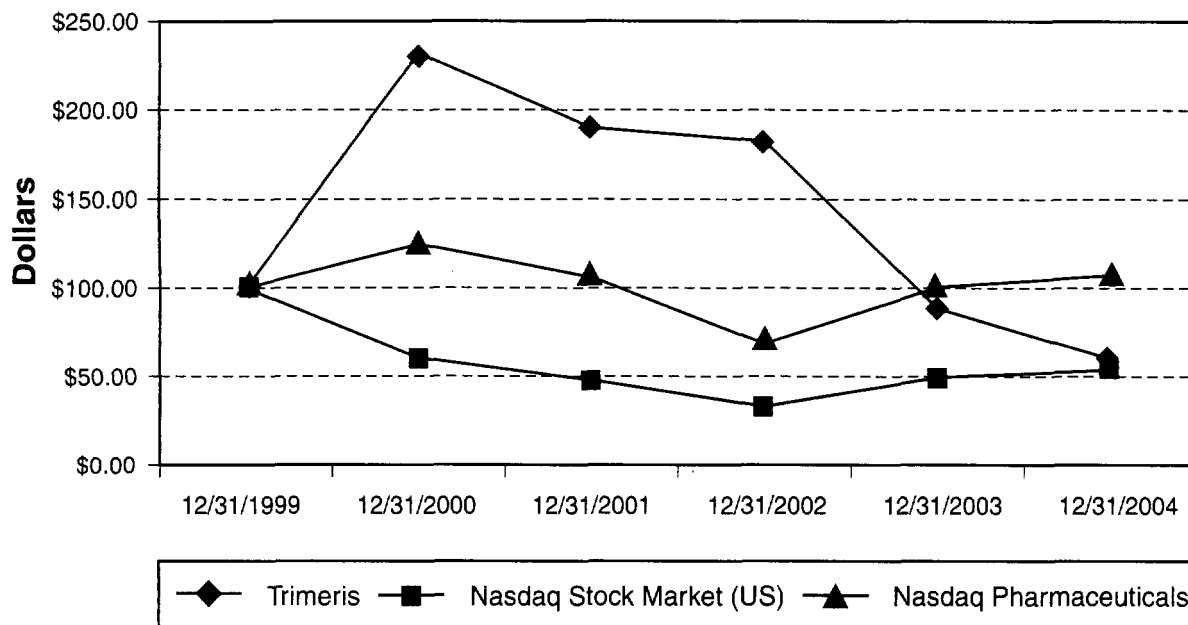
The Committee expects that stock options will represent the largest element of Mr. Skolsky's compensation and will provide a direct link between Mr. Skolsky's compensation and the Company's performance overall. The Committee believes that Mr. Skolsky's inducement package was appropriate to attract an executive of Mr. Skolsky's background and experience and are comparable to the compensation offered to chief executive officers in similar biopharmaceutical companies. In addition, it is the Committee's judgment that Mr. Skolsky's commercial experience and management leadership skills are extremely important to the Company, and it is therefore essential to provide Mr. Skolsky with a significant unvested stock ownership position.

Compensation Committee of the Board of Directors

E. Gary Cook, Ph.D., Chairman
Felix J. Baker, Ph.D.
Jeffrey M. Lipton
Charles A. Sanders, M.D.
Kevin C. Tang

Stock Performance Graph

**Comparative Total Returns
December 31, 1999
through December 31, 2004**



The following table compares the yearly percentage change in the cumulative total stockholder return on Trimeris common stock during the five fiscal years ended December 31, 2004 with cumulative total return on the Nasdaq stock market and the Nasdaq Pharmaceuticals index. The comparison assumes \$100 was invested on December 31, 1999 in Trimeris common stock and in each of such indices and assumes reinvestment of any dividends.

CUMULATIVE TOTAL RETURN

	<u>12/31/99</u>	<u>12/31/00</u>	<u>12/31/01</u>	<u>12/31/02</u>	<u>12/31/03</u>	<u>12/31/04</u>
TRIMERIS, INC.	\$100	\$232	\$190	\$183	\$ 89	\$ 60
NASDAQ STOCK MARKET-US	\$100	\$ 60	\$ 48	\$ 33	\$ 49	\$ 54
NASDAQ PHARMACEUTICALS	\$100	\$125	\$106	\$ 69	\$101	\$107

Notwithstanding anything to the contrary set forth in any of our previous or future filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, that might incorporate this report or future filings made by the Company under those statutes, the Compensation Committee Report and Stock Performance Graph are not deemed filed with the Securities and Exchange Commission and shall not be deemed incorporated by reference into any of those prior filings or into any future filings made by us under those statutes.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of April 26, 2005, for each person or group of affiliated persons, whom we know to beneficially own more than 5% of our common stock. The table also sets forth such information for our directors and executive officers, individually and as a group.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission, or SEC. Except as indicated by footnote, to our knowledge, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them. Options to purchase shares of common stock that are exercisable within 60 days of April 26, 2005 are deemed to be beneficially owned by the person holding such options for the purpose of computing ownership of such person, but are not treated as outstanding for the purpose of computing the ownership of any other person. Applicable percentage of beneficial ownership is based on 21,949,847 shares of common stock outstanding as of April 26, 2005.

Unless otherwise indicated in the footnotes, the address for each listed stockholder is: c/o Trimeris, Inc., 3500 Paramount Parkway, Morrisville, North Carolina 27560.

<u>Beneficial Owner</u>	<u>Number of Options Beneficially Owned(#)</u>	<u>Number of Shares Beneficially Owned(#)</u>	<u>Total Number of Options and Shares Beneficially Owned(#)</u>	<u>Percentage of Total Number of Shares and Options Owned</u>
Felix J. Baker and Julian C. Baker (1)	34,582	3,642,369	3,676,951	16.8%
Mazama Capital Management, Inc. (2)		2,988,135	2,988,135	13.6%
T. Rowe Price Associates, Inc. (3)		2,837,420	2,837,420	12.9%
Franklin Advisors, Inc. (4)		2,530,616	2,530,616	11.5%
Andrew H. Tisch, Daniel R. Tisch, James S. Tisch and Thomas J. Tisch (5)		2,158,848	2,158,848	9.8%
Barclays Global Investors (6)		1,298,157	1,298,157	5.9%
Steven D. Skolsky (7)	65,625	50,635	116,260	*%
Dani P. Bolognesi (8)	575,825	90,331	666,156	3.0%
Robert R. Bonczek (9)	325,893	43,234	369,127	1.7%
Barney Koszalka (10)	22,698	12,930	35,628	*%
Andrew L. Graham (11)	937	381	937	*%
Jeffrey M. Lipton (12)	110,000	175,822	285,822	1.3%
E. Gary Cook (13)	70,000	3,500	73,500	*%
J. Richard Crout (14)	56,667	6,870	63,537	*%
Charles A. Sanders	88,383	7,804	96,187	*%
Kevin C. Tang (15)	53,750	185,500	239,250	1.1%
All executive officers and directors as a group (twelve persons) (16)	1,404,360	4,219,376	5,623,736	25.6%

* Less than 1%.

- (1) Based on a information provided by Felix J. Baker and Julian C. Baker each reported shared voting power and shared dispositive power over the shares listed. Julian C. Baker is the beneficial owner of 16,666 options and Felix J. Baker is the beneficial owner of 17,916 options. The address of Felix J. Baker and Julian C. Baker is: 667 Madison Avenue, New York, New York 10021.
- (2) Based on Schedule 13G/A filed with the SEC on February 14, 2005, Mazama Capital Management, Inc. held sole voting power as to 1,585,750 shares and sole dispositive power as to 2,988,135 shares. The address for Mazama Capital Management, Inc. is: One S.W. Columbia, Suite 1500, Portland, Oregon 97258.
- (3) Based on Schedule 13G/A filed with the SEC on February 14, 2005, T. Rowe Price Associates, Inc. held sole voting power as to 820,020 shares and sole dispositive power as to 2,837,420 shares. T. Rowe Price Associates, Inc.'s address is 100 East Pratt Street, Baltimore, Maryland 21202.

- (4) Based on Schedule 13G filed with the SEC on February 13, 2005, Franklin Advisors, Inc. held sole voting power as to 2,530,616 shares and sole dispositive power as to 2,530,616 shares. Franklin Advisors, Inc.'s address is One Franklin Parkway, San Mateo, CA 94403.
- (5) Based on a Schedule 13G filed with the SEC on April 28, 2004. Each person reported shared voting power and shared dispositive power over certain of the shares listed. Because of certain family relationships among the reporting persons, they filed the Schedule 13G jointly, but each reporting person disclaimed beneficial ownership of shares owned by any other reporting person. The address of Andrew H. Tisch, James S. Tisch and Thomas J. Tisch is 667 Madison Avenue, New York, New York 10021. The address of Daniel R. Tisch is: 500 Park Avenue, New York, New York 10022.
- (6) Based on Schedule 13G filed with the SEC on February 14, 2005, Barclays Global Investors, N.A., Inc. held sole voting power as to 1,180,416 shares and sole dispositive power as to 1,298,157 shares. The address for Barclays Global Investors, N.A. is: 45 Fremont Street, San Francisco, CA 94105.
- (7) Includes 50,000 restricted stock shares that were granted pursuant to the Amended and Restated Stock Incentive Plan, in connection with his initial employment agreement. These shares vest 100% in September 2008. Also includes 635 shares held in Mr. Skolsky's 401(k) plan account. Mr. Skolsky is not currently vested in any of these 401(k) plan shares. Mr. Skolsky holds voting power as to his restricted stock and his 401(k) shares.
- (8) Includes 31,300 restricted stock shares that were granted pursuant to the Amended and Restated Stock Incentive Plan. These restricted stock shares vest 100% in June 2007. Also includes 2,559 shares held in Dr. Bolognesi's 401(k) plan account. Dr. Bolognesi is currently vested in 100% of these 401(k) plan shares. Dr. Bolognesi holds voting power as to his restricted stock and his 401(k) shares. Includes further, the following shares as to which Dr. Bolognesi disclaims beneficial ownership: 9,000 shares of common stock owned by Sarah Bolognesi, Dr. Bolognesi's wife, and 7,153 shares that Mrs. Bolognesi may acquire pursuant to certain stock options exercisable within 60 days after April 26, 2003.
- (9) Includes 15,700 restricted stock shares granted pursuant to the Amended and Restated Stock Incentive Plan. These restricted stock shares vest 100% in June 2007. Also includes 2,180 shares held in Mr. Bonczek's 401(k) plan account. Mr. Bonczek is currently vested in 100% of these 401(k) plan shares. Mr. Bonczek holds voting power as to his restricted stock and his 401(k) shares.
- (10) Includes 11,000 restricted stock shares granted pursuant to the Amended and Restated Stock Incentive Plan. These restricted stock shares vest 100% in June 2007. Includes further, 1,930 shares held in Dr. Koszalka's 401(k) plan account. Dr. Koszalka is currently vested in 75% of these 401(k) plan shares. Dr. Koszalka holds voting power as to his restricted stock and his 401(k) shares.
- (11) Includes 381 shares held in Mr. Graham's 401(k) plan account. Mr. Graham is not currently vested in any of these 401(k) plan shares.
- (12) Includes the following shares as to which Mr. Lipton disclaims beneficial ownership: 8,540 shares beneficially owned by Shelley Lipton, Mr. Lipton's wife and 3,300 shares held by his sons and grandchildren.
- (13) Includes the following shares as to which Dr. Cook disclaims beneficial ownership: 1,500 shares beneficially owned by Brenda B. Cook, Dr. Cook's wife.
- (14) Includes the following shares as to which Dr. Crout disclaims beneficial ownership: 1,500 shares beneficially owned by the Keith R. Crout Irrevocable Trust, for which Keith R. Crout, Dr. Crout's son who shares Dr. Crout's house, is the sole beneficiary and Linda C. Spevacek, Dr. Crout's daughter, is the sole trustee; 470 shares beneficially owned by Keith R. Crout, Dr. Crout's son who shares Dr. Crout's house; and 900 shares beneficially owned by Carol K. Crout, Dr. Crout's wife.
- (15) Includes 22,500 shares that Mr. Tang contributed to the Tang Family Trust u/t/d August 27, 2002, of which Mr. Tang is co-trustee. Includes 163,000 shares owned by Tang Capital Partners, LP of which Tang Capital Management, LLC is the general partner. Mr. Tang disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein. Mr. Tang is the sole managing member of Tang Capital Management, LLC.
- (16) See notes (1) and (7)—(15).

Equity Compensation Plans

The following table sets forth certain information as of December 31, 2004, regarding shares authorized for issuance under our equity compensation plans.

The equity compensation plans approved by our stockholders are the Amended and Restated Stock Incentive Plan and our 1997 Trimeris, Inc. Employee Stock Purchase Plan. As of December 31, 2004, we did not have any equity compensation plans that were not approved by our stockholders.

Equity Compensation Plan Information as of December 31, 2004

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights(#)	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans(#) (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	3,473,000(1)	\$27.09	652,000(2)
Equity compensation plans not approved by security holders	<u>—</u>	<u>—</u>	<u>—</u>
Total	<u>3,473,000</u>	<u>\$27.09</u>	<u>652,000</u>

(1) This amount includes the following awards granted pursuant to the Amended and Restated Stock Incentive Plan:

- 3,244,000 shares issuable upon the exercise of outstanding stock options.
- 229,000 restricted stock shares. Since these restricted stock awards are freely transferable upon vesting and have no exercise price, they are not included in the weighted average exercise price calculation in column (b).

(2) Includes 556,000 options remaining available for grant under the Amended and Restated Stock Incentive Plan, and 96,000 shares issuable under the Trimeris, Inc. 1997 Employee Stock Purchase Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

In 2004, the Board of Directors voted to expand the Board and to appoint Felix J. Baker and Julian C. Baker as new directors. In connection with their appointment to the Board, the Company granted the Bakers certain registration rights related to the resale of Trimeris common stock.

During 2004, there were no other transactions between the Company and any officer, director or principal stockholder except those related to employment and executive compensation.

For information regarding compensation and employment agreements with our directors and executive officers, see Item 11, "Executive Compensation."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The aggregate fees billed to Trimeris by KPMG LLP for services rendered related to 2004 are set forth in the following table:

<u>Type of Service</u>	<u>Amount of Fee</u>
Audit Fees	
Audit fees for the 2004 financial statements (including quarterly reviews)	\$177,510
Attestation report of effectiveness of internal control over financial reporting and management's assessment	202,940
Audit related fees (miscellaneous consultation)	12,055
Comfort Letters and registration statements	—
Audit related fees	
Audit of 401(k) plan	22,000
Total audit and audit related fees	<u>\$414,505</u>
Tax fees	
Tax compliance	11,785
Tax consulting (relating to compensation and benefits issues)	—
Total tax service fees	<u>\$ 11,785</u>
All other fees	
Total fees	<u><u>\$426,290</u></u>

The aggregate fees billed to Trimeris by KPMG LLP for services rendered related to 2003 are set forth in the following table:

<u>Type of Service</u>	<u>Amount of Fee</u>
Audit fees	
Audit fees for the 2003 financial statements (including quarterly reviews)	\$139,000
Attestation report of effectiveness of internal control over financial reporting and management's assessment	—
Audit related fees (miscellaneous consultation)	—
Comfort Letters and registration statements	4,960
Audit related fees	
Audit of 401(k) plan	—
Total audit and audit related fees	<u>\$143,960</u>
Tax fees	
Tax compliance	8,375
Tax consulting (relating to compensation and benefits issues)	1,950
Total tax service fees	<u>10,325</u>
All other fees	
Total fees	<u><u>\$154,285</u></u>

Pre-Approval Policy and Procedures

The Audit Committee has adopted a policy that requires advance approval of all audit, audit-related, tax and other services performed by the independent registered public accounting firm. During the year, circumstances may arise when it becomes necessary to engage the independent auditor for additional services that are not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval before engaging the independent auditor. The Audit Committee has delegated to the chair of the Audit Committee the authority to pre-approve audit related and non-audit services not prohibited by law to be performed by the Company's independent registered public accounting firm and associated fees up to a maximum for any one audit-related or non-audit service of \$5,000 per service in a calendar year. The chairman is required to report, for informational purposes only, any pre-approval decisions that have been made to the Audit Committee at its next scheduled meeting. The Audit Committee is prohibited from delegating to management its responsibilities to pre-approve services performed by the independent auditor.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TRIMERIS, INC.

May 2, 2005

By: _____ /s/ Steven D. Skolsky _____

Steven D. Skolsky
Chief Executive Officer

EXHIBIT INDEX

- 3.1 * Amended and Restated Bylaws of the Registrant.
- 3.2^(d) Fourth Amended and Restated Certificate of Incorporation of the Registrant
- 4.1 * Specimen certificate for shares of Common Stock.
- 4.2 * Description of Capital Stock (contained in the Fourth Amended and Restated Certificate of Incorporation of the Corporation of the Registrant, filed as Exhibit 3.2).
- 10.1 * License Agreement dated February 3, 1993, between the Registrant and Duke University.
- 10.2 Trimeris, Inc. Amended and Restated Stock Incentive Plan. †
- 10.3 * Trimeris, Inc. Employee Stock Purchase Plan.
- 10.4 * Sixth Amended and Restated Registration Rights Agreement dated June 27, 1997, by and among the Registrant and certain stockholders of the Registrant.
- 10.5 * Form of Indemnification Agreements.
- 10.6 * License Agreement dated September 9, 1997 between the Registrant and The New York Blood Center.
- 10.7^(j) Poyner & Spruill, L.L.P. Defined Contribution Prototype Plan and Trust for the Trimeris, Inc. Employee 401(k) Plan. †
- 10.8⁽ⁱ⁾ Adoption Agreement for the Trimeris, Inc. Employee 401(k) Plan.
- 10.9^(a) Chief Executive Employment Agreement between Trimeris and Dani P. Bolognesi dated April 21, 1999.
- 10.10 Executive Employment Agreement between Trimeris, Inc. and George W. Koszalka dated June 21, 2004.
- 10.11^(m) Executive Employment Agreement by and between Trimeris, Inc. and Steven Skolsky dated September 8, 2004. †
- 10.12 Incentive Stock Option Agreement by and between Trimeris, Inc. and Steven Skolsky dated September 9, 2004. †
- 10.13 Restricted Stock Agreement by and between Trimeris, Inc. and Steven Skolsky dated September 9, 2004. †
- 10.14 Development and License Agreement between Trimeris and Hoffmann-La Roche dated July 1, 1999 (Portions of this exhibit have been omitted pursuant to an order of the Commission granting confidential treatment.).
- 10.15 Financing Agreement between Trimeris, Inc. and Roche Finance Ltd. dated as of July 9, 1999.
- 10.16^(b) Registration Rights Agreement between Trimeris, Inc. and Roche Finance Ltd. dated as of July 9, 1999.
- 10.17^(b) Lease between Trimeris, Inc. and University Place Associates dated April 14, 1999.
- 10.18^(m) Sublease Agreement between Trimeris, Inc. and PPD Development, LP dated June 30, 2004.
- 10.19^(m) Lease Agreement and Amendments between PPD Development, LP (formerly PPD Pharmaco, Inc.) and Weeks Realty, LP relating to Sublease Agreement filed as Exhibit 10.17 hereto.
- 10.20 + Executive Agreement between Trimeris and Robert R. Bonczek dated January 7, 2000. †
- 10.21^(c) Employment Agreement between Trimeris, Inc. and M. Nixon Ellis dated March 31, 2000. †
- 10.22^(m) Settlement Agreement and Release between Trimeris, Inc. and M. Nixon Ellis dated July 1, 2004. †
- 10.23^(e) Research Agreement between Trimeris, Inc., F. Hoffmann-La Roche Ltd, and Hoffmann-La Roche, Inc. dated January 1, 2000 (Portions of this exhibit have been omitted pursuant to an order of the Commission granting confidential treatment.).

- 10.24^(f) Form of Purchase Agreement dated as of May 7, 2001 by and between Trimeris, Inc. and the purchasers set forth on the signature page thereto.
- 10.25⁽ⁱ⁾ Sublease Agreement dated as of December 14, 2001 between Trimeris, Inc. and Triangle Pharmaceuticals, Inc.
- 10.26⁽ⁱ⁾ Second Amendment dated as of January 21, 2002 between University Place Properties, LLC and Trimeris, Inc.
- 10.27^(g) Form of Equity Option Confirmation for Call Transaction.
- 10.28^(o) First Amendment to the Research Agreement by and between Trimeris, Inc. and F. Hoffmann-La Roche Ltd. And Hoffmann-La Roche Inc. dated November 13, 2003. (Portions of this exhibit have been omitted pursuant to a request for confidential treatment filed with the Commission.)
- 10.29^(h) Form of Purchase Agreement dated as of January 23, 2002 by and between Trimeris, Inc. and the purchasers set forth on the signature page thereto.
- 10.30^(m) Rescission of the Amendment to the Development and License Agreement dated July 12, 2004.
- 10.31^(p) Amendment to the Development and License Agreement between Trimeris, Inc. and Hoffman-La Roche dated on July 12, 2004. (Portions of this exhibit have been omitted pursuant to a request for confidential treatment filed with the Commission.)
- 10.32^(k) Third Amendment of Lease between University Place Properties, LLC and Trimeris, Inc. dated May 28, 2003.
- 10.33^(l) Agreement of Sublease by and between Gilead Sciences, Inc. and Trimeris, Inc.
- 10.34 + Description of compensation arrangement for Andrew L. Graham. †
- 10.35 + Description of non-management director compensation arrangements. †
- 23 + Consent of KPMG LLP.
- 31.1 + Rule 13a-14(a) Certification by Steven D. Skolsky as Chief Executive Officer
- 31.2 + Rule 13a-14(a) Certification by Robert R. Bonczek as Chief Financial Officer.
- 31.3 ** Rule 13a-14(a) Certification by Steven D. Skolsky as Chief Executive Officer
- 31.4 ** Rule 13a-14(a) Certification by Robert R. Bonczek as Chief Financial Officer.
- 32.1 + Section 1350 Certification by Steven D. Skolsky as Chief Executive Officer.
- 32.2 + Section 1350 Certification by Robert R. Bonczek as Chief Financial Officer.

† Management contract or compensatory plan or arrangement required to be filed as an exhibit to this form pursuant to Item 15(a) of this report.

* *Incorporated by reference to Trimeris' Registration Statement on Form S-1, as amended (File No. 333-31109) initially filed with the Commission on July 11, 1997.*

** Filed herewith.

+ Previously filed.

(a) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended March 31, 1999.

(b) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended June 30, 1999.

(c) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended March 31, 2000.

(d) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.

(e) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

(f) Incorporated by reference to Trimeris' Current Report on Form 8-K filed on May 11, 2001.

(g) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.

(h) Incorporated by reference to Trimeris' Current Report on Form 8-K filed with the Commission on January 30, 2002.

(i) Incorporated by reference to Trimeris' Annual Report on Form 10-K for the year ended December 31, 2001 filed with the Commission on March 25, 2002.

(j) Incorporated by reference to Trimeris' Annual Report on Form 10-K for the year ended December 31, 2002 filed with the Commission on March 27, 2003.

- (k) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended June 30, 2003.
- (l) Incorporated by reference to Trimeris' Annual Report on Form 10-K for the year ended December 31, 2004 filed with the Commission on March 12, 2004.
- (m) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.
- (n) Incorporated by reference to Trimeris' Current Report on Form 8-K filed with the Commission on September 10, 2004.
- (o) Incorporated by reference to Trimeris' Annual Report on Form 10-K/A for the year ended December 31, 2003, filed with the Commission on October 15, 2004.
- (p) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q/A for the quarter ended June 30, 2004, filed with the Commission on October 15, 2004.

All financial statement schedules have been omitted because either they are not required, are not applicable or the information is otherwise set forth in the Financial Statements and Notes thereto.

CERTIFICATION

I, Steven D. Skolsky, certify that:

I have reviewed this Amendment No.1 to Form 10-K of Trimeris, Inc.; and

Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

May 2, 2005

/s/ STEVEN D. SKOLSKY

Steven D. Skolsky
Chief Executive Officer

CERTIFICATION

I, Robert R. Bonczek, certify that:

I have reviewed this Amendment No. 1 to Form 10-K of Trimeris, Inc.; and

Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

May 2, 2005

/s/ ROBERT R. BONCZEK

Robert R. Bonczek
Chief Financial Officer

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