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TRIMERIS INC

A PATIENT'S STORY

2003 ANNUAL REPORT

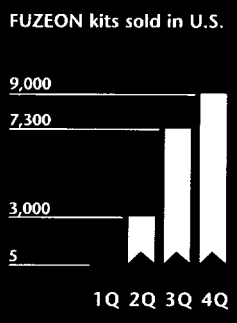
DISCOVERY AND DEVELOPMENT OF NEW DRUGS FOR THE TREATMENT OF VIRAL DISEASES

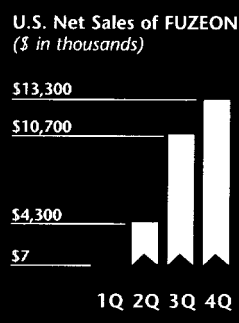
About the Company

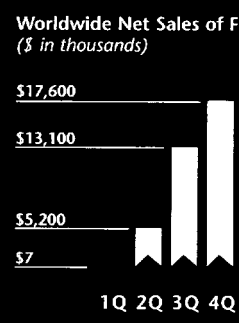
Trimeris, Inc. (Nasdaq: TRMS) is a biopharmaceutical company based in Durham, North Carolina. We are engaged in the discovery, development and commercialization of a new class of antiviral drug treatments called fusion inhibitors. Fusion inhibitors impair viral fusion, a complex process by which viruses attach to, penetrate and infect host cells. By inhibiting the fusion process of particular types of viruses, like the Human Immunodeficiency Virus (HIV), our drug candidates offer a novel mechanism of action with the potential to treat a variety of medically important viral diseases.

Highlights

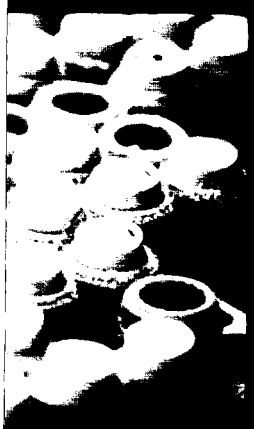
- U.S. Food & Drug Administration (FDA) granted accelerated approval for FUZEON® following a six-month priority review
- European Commission approved FUZEON for use in the European Union
- *The New England Journal of Medicine* published results of international pivotal trial program for FUZEON
- Unprecedented, commercial-scale production of FUZEON demonstrated — one of the most complex peptides ever chemically manufactured
- 48-week data submitted to FDA to support full approval of FUZEON
- FUZEON named one of *Business Week's* Best Products of 2003
- Research agreement with Roche extended to discover and develop next generation of HIV fusion inhibitors







Roche and Trimeris split profits/losses on the sale of FUZEON in the U.S. and Canada. Trimeris receives a royalty on sales in the rest of the world.



On the cover:

Only four years ago, Richard Apodaca was unable to walk as a result of HIV-related nerve problems, and his prospects for survival were growing slimmer each day as the medicines available to him were no longer working. A remarkable turnaround in his health as a result of newer AIDS treatments like FUZEON has allowed Richard to participate in marathons throughout the world.

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

To Our Fellow Shareholders

2003 marks the ten-year anniversary of Trimeris, Inc. and the achievement of the Company's most important milestone to date — the commercial introduction of FUZEON®, our first product for the treatment of HIV. The commercialization of our first drug validates our novel scientific approach and establishes Trimeris as a pioneer and leader in the field of fusion inhibition. FUZEON was developed in collaboration with our partner, F. Hoffmann-La Roche Ltd, and represents the first new class of HIV drugs in seven years. FUZEON is the first drug that inhibits HIV entry into the immune cell and is fully active against viruses that have developed resistance to existing drugs.

While I am extremely proud of our achievements in 2003, we didn't accomplish all that I had expected. Due to product supply concerns at the time of regulatory approval in March 2003, Roche and Trimeris made a strategic decision to launch FUZEON on a progressive basis. This progressive launch contributed to slower adoption of the drug by the market. Now that supply limitations are firmly behind us, we are maximizing our efforts to accelerate FUZEON's uptake. Roche and Trimeris recently expanded FUZEON distribution from a single vendor to retail and specialty pharmacies throughout the U.S. as a result of supply improvements. This significant expansion will simplify the prescribing process for clinicians and improve access and convenience for patients.

We recognize the importance of patient support prior to and during FUZEON therapy, as well as clinician, nurse and patient education. Building on the foundation and momentum of existing initiatives, we are expanding numerous support and educational programs at national, regional and local levels.

In an effort to encourage initiation of therapy, we are intensifying awareness of FUZEON through compelling advertising and promotional campaigns. These print and Internet campaigns, directed to patients, clinicians, pharmacists and treatment educators, began in April in the U.S. and will continue throughout 2004.

We are embarking on a program of post-marketing clinical trials with FUZEON in 2004. These trials are designed to provide additional data on the role of FUZEON in a broader range of potential patients. We are also working to improve the delivery, convenience and formulation of FUZEON.

Based on the strength of our clinical trial data, as well as the clinical performance of FUZEON in the field, we are confident that we have established fusion inhibitors as important medicines in the treatment of HIV. However, due to challenges in achieving the desired properties of the formulation for T-1249, our second drug candidate, the clinical development of T-1249 is currently on hold. Our research will continue to focus on the pursuit of new formulations of T-1249 and next-generation peptide fusion inhibitors that are more convenient for chronic administration and have improved efficacy and resistance profiles.

Much work remains to realize the full potential of FUZEON in revolutionizing the HIV treatment landscape. We have learned a great deal about the issues facing this unique drug and look forward to seeing the results of our focused marketing and support initiatives on the uptake of FUZEON in 2004. We will continue to work diligently with our partners at Roche to leverage the solid foundation we have built to date. I am deeply committed to the success of FUZEON and confident that we have a sound strategy and the ability to carry out our plans.

We have gained a wealth of experience since our inception in 1993 and could not have accomplished so much without the vision and continued support of our partners, employees and shareholders. We are dedicated to creating value for our shareholders through the development of our fusion inhibitor franchise. I look forward to reporting our progress to you in 2004.

NEW TREATMENT OPTION FOR PATIENTS

FUZEON OFFERS AN IMPORTANT

Richard Apodaca

Richard, 61, has been living with HIV for 21 years. Prior to entering clinical trials for FUZEON more than three years ago, Richard's viral load was soaring and his CD4+ immune cell count had plummeted. At one point, Richard was down to nine CD4+ cells. Today, his viral load is undetectable and CD4+ immune cells have rebounded into the triple digits as a result of newer AIDS treatments including FUZEON.

A remarkable turnaround in his health has allowed Richard to participate in marathons around the world. Richard also stays active with numerous AIDS causes and health and fitness programs for overweight children.

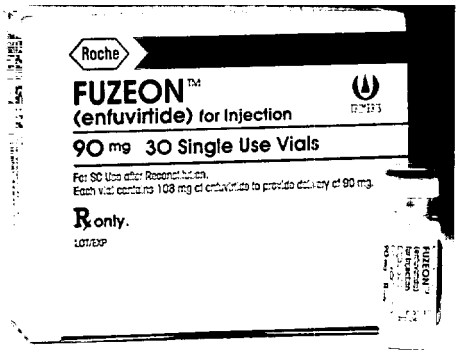
"FUZEON really brought me back. I can't express what a wonderful gift this has been to me — I no longer think of myself as having a death sentence, but a manageable disease."

Richard Apodaca, patient

Reverend Frederick F. Batiste, Jr.

Frederick, 51, was diagnosed with HIV in 1993. Since March 2003, Frederick has been on a treatment regimen containing FUZEON. According to Frederick, FUZEON has worked well for him, and the drug has given him a reason to hope and continue living.

Because of his HIV status, Frederick feels empowered to educate others about the disease and serves as a spokesperson within the African-American community. He feels a sense of achievement knowing his experiences and knowledge about the disease can be beneficial to others and has organized a Healthcare Ministry to educate others about HIV/AIDS.



FUZEON™
enfuvirtide

"Among the African-American community, HIV awareness and education are very limited because of the stigma that comes with the disease. But, I hope that we can get people more educated so that they find it easier to seek treatment. I was very glad to find out that FUZEON was on the market. It's made a remarkable difference in my life. I feel like I can live through this now."

Reverend Frederick F. Batiste, Jr., patient

Beatriz Diaz

Beatriz, 45, a Hispanic mother of four, was diagnosed with HIV in 1993. She was shocked to learn that she would have the additional challenge of living with HIV while raising her children. Since starting FUZEON therapy in March 2002, her viral load has dramatically declined and CD4+ immune cell count has risen.

Beatriz feels energetic enough to walk everyday and also enjoys knitting, crocheting and making ornamental centerpieces. She has a bright outlook on life and renewed hope due to FUZEON.

"I was taking a couple of medications, and they weren't working. I just kept getting sicker. I have been taking FUZEON for two years and my CD4+ count has risen to 414. It's a big jump from what it was. FUZEON has become part of my daily routine. How grateful I am that my doctor suggested trying this treatment. I feel great, and I feel that I can continue with my life."

Beatriz Diaz, patient

Laura Seeley

Laura, 33, was diagnosed with HIV in 1995. After failing as many as 10 combination regimens, Laura entered a FUZEON clinical trial in 2001 hoping for a treatment that would allow her to live a healthier life and enable her to return to work. Within her first six months on FUZEON, Laura's immune system rebounded and her viral load became undetectable.

Today, Laura is the Program Director for Women at Risk, an AIDS service organization for HIV positive women. She has been married since 2000.

"Since enrolling in the FUZEON clinical trial, my life has changed dramatically. I was able to go back to work and really look forward to a future that's filled with possibilities."

Laura Seeley, patient

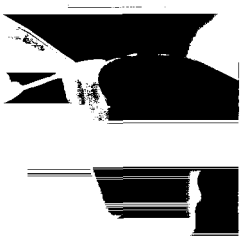
Claire

Claire, 7, is the youngest of six children. Her mother, grandmother and two great uncles are also HIV-infected. She entered a pediatric study for FUZEON in 2002 when her HIV disease reached a critical level. Less than three weeks following treatment initiation with FUZEON, her viral load become undetectable and has remained so ever since. Her CD4+ immune cells have also risen significantly. Her parents believe that access to FUZEON saved their daughter's life, and today Claire is a very happy, active child.

"I'm really glad that I can run and jump. Last summer I got to swim again for the first time in a couple of years"

Claire, patient

EXPANDING OUR FUSION INHIBITOR FRANCHISE



Looking forward, Trimeris' goal is to strengthen and expand our fusion inhibitor franchise. As part of our business strategy, we conduct research and development activities both internally and with collaborative partners.

In January 2004, we announced an extension of our research agreement with Roche to discover, develop and commercialize the next generation of HIV fusion inhibitors. Our peptide research will focus on the investigation of improved formulation and delivery technologies to enable less frequent dosing and the discovery of new peptides with enhanced efficacy and resistance profiles. Our objective is to develop an HIV fusion inhibitor that can be administered on a once-weekly or once-monthly basis.

We are also working with Roche to enhance the product profile of FUZEON. We are investigating the development of a formulation for once-daily dosing, as well as the use of alternative delivery systems for FUZEON administration. Because injection site reactions are the most common adverse events associated with FUZEON, we are conducting studies in an effort to reduce the frequency and severity of these reactions. We believe that any product enhancements made to FUZEON could potentially be applied to other fusion inhibitors.

Outside the scope of our Roche collaboration, we have research programs that are focused on the development of small molecule HIV fusion inhibitors that could be orally administered. We presently have research agreements with Array BioPharma, Inc. and Tranzyme, Inc. (formerly Neokimia, Inc.). We have an active business development program that evaluates additional opportunities on an ongoing basis.

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, 2003

☐ **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	56-1808663
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3518 WESTGATE DRIVE
DURHAM, NORTH CAROLINA 27707
(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, 2003 was approximately $711,199,000 (based on the last sale price of such stock as reported by the Nasdaq National Market System on June 30, 2003).

The number of shares of the registrant's common stock outstanding as of March 11, 2004 was 21,589,443.

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, 2003

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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 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 drug candidates under development offer a novel mechanism of action with the potential to treat a variety of medically important viral diseases.

Fuzeon® is our first-generation HIV fusion inhibitor, developed in collaboration with F. Hoffmann-La Roche Ltd, or Roche. 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 antiretroviral therapy. Anti-HIV drugs are referred to as antiretroviral agents. Fuzeon is delivered via twice daily subcutaneous injections. On March 13, 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. We refer to these clinical trials as TORO-1, which was conducted in North America and Brazil, and TORO-2, which was conducted in Western Europe and Australia. In these clinical trials, 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. In the Fuzeon treatment group, patients received the optimized background regimen in combination with twice daily subcutaneous injections, each delivering 90 mg of Fuzeon. In both TORO-1 and TORO-2, the primary endpoint for the clinical trials, which is the incremental reduction of viral load achieved in the Fuzeon group versus the control group, was met with statistical significance at 24 weeks and 48 weeks. Viral load refers to the amount of HIV virus particles, as measured by the presence of HIV ribonucleic acid, or RNA, found in the blood of an HIV-infected person at a given time. We measure viral load in terms of copies of HIV-1 RNA per milliliter of blood. It is widely viewed that a reduction in HIV RNA levels can be used as a suitable endpoint to determine efficacy of anti-HIV drugs in clinical studies. Additionally, the interim analysis of TORO-1 and TORO-2 showed that important secondary endpoints were also met with statistical significance. Roche submitted a full analysis of 48-week clinical data from TORO-1 and TORO-2 to the FDA in December 2003 seeking full approval for Fuzeon. There are no results from controlled trials evaluating the effect of Fuzeon on the clinical progression of HIV.

Roche also filed an application for European marketing approval on September 19, 2002. In March 2003, the Committee for Proprietary Medicinal Products, or CPMP, recommended granting a marketing authorization

for Fuzeon. In May 2003, the European Agency for the Evaluation of Medicinal Products, or EMEA, granted marketing authorization for Fuzeon in Europe. Outside the United States, Roche is in the process of negotiating reimbursement from the countries in which they plan to market Fuzeon.

An analysis of the combined TORO-1 and TORO-2 48-week data show that 30% of patients in the Fuzeon group had a reduction of HIV viral load to below 400 copies per milliliter of blood, compared to 12% of the control group. Reduction of viral load below this level is believed to correlate with long-term durability of response to anti-HIV therapy. On average, patients in the Fuzeon group experienced an increase of twice as many CD4 cells from the initiation of the trial, or baseline, as patients in the control group at 48 weeks, 91 cells/cubic millimeter for the Fuzeon group compared to 45 cells/cubic millimeter for the control group. CD4 cells are a critical component of the human immune system and are often killed by HIV. An increase in CD4 cell count is indicative of immune system restoration and is important in reducing the likelihood of opportunistic infection. We measure CD4 cell counts in units of CD4 cells per cubic millimeter of blood. All of these results were statistically significant.

Roche is manufacturing Fuzeon drug substance in its Boulder, Colorado facility. One of Roche's manufacturing facilities and another third party facility are producing the finished drug product from such bulk drug substance. Roche is working continually to maximize the manufacturing capabilities of its facilities. We believe Roche had drug supply to accommodate up to 18,000 patients receiving drug at December 31, 2003, after taking into account the establishment of a six-month "safety stock" for all patients receiving Fuzeon. 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 2003, we shipped approximately 19,000 kits of Fuzeon to paying patients in the United States and Canada for total net sales of $28.3 million. A kit represents a one-month supply of Fuzeon for a patient. Net sales outside the United States and Canada began in June 2003 and were $7.6 million during 2003.

T-1249 is our second-generation HIV fusion inhibitor being co-developed with Roche. In September 2002, we presented data from a Phase I/II trial of T-1249, which suggest that over 14 days of dosing, T-1249 was well-tolerated and produced dose-related decreases in HIV viral load. In September 2003, we presented final data from a ten-day Phase I/II trial of T-1249, which suggest that T-1249 reduced viral load in most patients who had failed an individualized anti-HIV drug regimen that had previously included Fuzeon. This data suggests that T-1249 is active in patients who have virus that has developed resistance to Fuzeon.

In January 2004, Roche and Trimeris announced that the clinical development of T-1249 was put on hold due to challenges in achieving the desired technical profile of the current formulation. The compound's safety, efficacy and tolerability were not factors affecting the decision. As for any compound in development, the technical development is an evolving process where many challenges are identified. The properties of T-1249 differ from Fuzeon during its manufacturing and formulation. T-1249 remains one of our next-generation drug candidates; however, our focus will be to continue the pursuit of new formulations of T-1249 or future peptide fusion inhibitors that are more patient-friendly for chronic administration.

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 fusion inhibitors. The research agreement will focus on the investigation of improved formulation and delivery technologies to enable less frequent administration of peptide fusion inhibitors and the discovery of new peptides with enhanced efficacy and resistance profiles. Our objective is to develop an HIV fusion inhibitor that can be administered on a once-weekly or once-monthly basis. Our goal is to name our next clinical candidate with this profile during 2004.

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 fusion inhibitors. 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.

Background

It is estimated that approximately 940,000 people in North America and nearly 560,000 people in Western Europe are currently infected with HIV. It is also estimated that an additional 40,000 people are newly infected with HIV each year in the U.S. alone. HIV attacks a class of white blood cells, known as CD4 cells that are responsible for mounting the body's immune response against infection. By attacking these cells, HIV progressively disables the immune system, resulting in opportunistic infections, neurological dysfunctions, malignancies and/or death. The amount of HIV present in a patient's bloodstream has been shown to be related directly to the patient's prognosis: the higher the viral load, the more compromised the patient's immune system becomes and the more likely the patient is to succumb to progressive diseases. In its most advanced stage, this progression into other infections or diseases is known as Acquired Immunodeficiency Syndrome, or AIDS.

The standard approach to treating HIV infection has been to lower viral loads by using drugs other than fusion inhibitors that inhibit 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 eight FDA-approved PIs.

Therapies based on certain combinations of RTIs and PIs have reduced HIV viral loads in many patients for sustained periods to levels that are not detectable by current diagnostic methods. In 2000, the number of deaths in the United States attributable to HIV infection was reduced to approximately 15,000 from 38,000 in 1996, largely due to improvements in treatment regimens. Because of the results achieved by the combined use of RTIs and PIs, total sales in the United States of approved RTIs and PIs exceeded $5 billion in 2002.

While significant progress has been made in combating HIV, current treatments continue to have significant limitations, such as resistance and toxicity that can lead to non-adherence to the complicated treatment regimens. HIV is prone to genetic mutations that produce strains of HIV that are resistant to currently-approved RTIs and PIs. Generally, HIV that is resistant to one drug within a class is likely to become resistant to the entire class, a phenomenon known as cross-resistance. As a result of cross-resistance, attempts to re-establish suppression of HIV viral load by substituting different RTI and PI combinations often fail. It is estimated that, in the U.S., over 70% of patients currently taking medications have failed at least one regimen. Studies suggest that 10% to 15% of newly-infected HIV patients are infected with a strain of HIV that is resistant to at least one anti-HIV drug. According to independent market research, we believe that there are approximately 110,000 HIV patients in the U.S. who are either on or beyond their third treatment regimen. We believe that this patient population represents the target market for Fuzeon.

Over time, in addition to generating resistance to drugs, many patients develop intolerance to different medications. Data suggest that some HIV-infected patients refuse to commence or continue taking RTIs and PIs, either alone or in combination, because of side effects and difficult dosing regimens. Severe side effects commonly associated with currently approved anti-HIV drugs include neurological disorders, gastrointestinal disorders, diabetes-like symptoms, elevated cholesterol levels, other signs of abnormal lipid metabolism and bone disorders. Dosing regimens can include taking as many as 30 pills per day. The emergence of drug-resistant strains of HIV, as well as toxic side effects associated with existing therapies, has heightened demand for new HIV therapies that work by novel mechanisms of action, have unique resistance profiles and have fewer side effects.

HIV Fusion Inhibitors: Fuzeon and T-1249

We are engaged in the discovery, development and commercialization of a class of anti-HIV compounds that works by a novel mechanism of action. Unlike existing classes of antiviral drugs, which work inside the cell after it has been infected, fusion inhibitors work outside of the cell to inhibit the virus' ability to infect cells and replicate. We believe that fusion inhibitors will have fewer long-term side effects than other approved therapies and will be active against strains of HIV that are resistant to other classes of HIV drugs. Fuzeon, our lead product, has been approved for marketing in the United States, Canada, Switzerland and the European Union.

Fuzeon

Fuzeon is our first drug product for HIV fusion inhibition. Fuzeon has been shown to inhibit HIV viral fusion with host cells by blocking the conformational rearrangement of an HIV protein called gp41. On March 13, 2003, the FDA granted accelerated approval for the commercial sale of Fuzeon, and commercial sales of Fuzeon began in March 2003. We have various postmarketing commitments that Roche and we are in the process of fulfilling. These commitments include various clinical, pharmacological, and virological studies, and manufacturing activities. Roche received accelerated approval of Fuzeon based on the 24-week data and has submitted 48-week clinical data from TORO-1 and TORO-2 to the FDA seeking full approval. Roche also filed an application for European marketing approval in September 2002. In March 2003, the CPMP adopted a positive opinion, recommending to the EMEA that marketing authorization for Fuzeon be granted. The EMEA granted marketing authorization for Fuzeon in Europe in May 2003.

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

Commercial sales of Fuzeon began in the United States in March 2003, and in Canada in the fourth quarter of 2003. Under our collaboration agreement with Roche, we share profits equally from the sale of Fuzeon in the United States and Canada. We shipped approximately 3,000 kits, 7,000 kits, and 9,000 kits for the quarters ended June 30, September 30 and December 31, 2003, respectively, to paying patients in the United States and Canada. Net sales of Fuzeon in the United States and Canada totaled $4.3 million, $10.7 million and $13.3 million for the quarters ended June 30, September 30 and December 31, 2003, respectively. The number of kits shipped and the resulting sales levels may not remain constant and may increase or decrease in the future.

We believe the number of prescriptions received for new patients in the United States was relatively constant at around 400-500 per month during the three months ended December 31, 2003, adjusted for fluctuations during holiday periods. New patient prescriptions include prescriptions for patients who eventually receive Fuzeon through reimbursement by traditional HIV drug reimbursement channels, patients who eventually receive Fuzeon through reimbursement by the Fuzeon Patient Assistance Program, and patients who never receive Fuzeon. The number of prescriptions received for new patients may not remain constant and may increase or decrease in the future.

Commercial sales of Fuzeon outside the United States and Canada began in June 2003. Net sales outside the United States and Canada were $870,000, $2.3 million and $4.4 million for the quarters ended June 30, September 30 and December 31, 2003, respectively. Fuzeon was commercially launched in Switzerland, France, the United Kingdom, Ireland, Germany, Austria, The Netherlands, Denmark, Sweden, Norway, Finland, Mexico and Argentina during 2003.

Planned Initiatives for 2004

We have reviewed our experience to date with the launch of Fuzeon in the United States with the intent of improving patient acceptance of Fuzeon, which is administered via twice daily subcutaneous injection. Based on information at December 31, 2003, we estimate that approximately 25% of patients who received at least one Fuzeon kit during 2003 are currently not on therapy. This percentage is subject to variability based on the intervals that patients either do or do not reorder additional kits. In addition, we believe that the majority of these discontinuations occurred within the first three months of therapy, with the bulk occurring in the first month. We have developed and are developing specific programs that we anticipate will improve patient retention upon initiation of therapy.

First, we and Roche are launching two nursing support programs that are designed to augment the existing Fuzeon treatment hotline, local nursing programs, and in-office training efforts by HIV healthcare providers. The first of these programs 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. 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. We believe that these adherence and persistency initiatives will improve patient retention from the very 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. We and Roche will heighten awareness of Fuzeon through ongoing advertising and promotional campaigns. These print and internet campaigns, directed to patients, clinicians, pharmacists, nurses, and treatment educators, will be implemented across the U.S. throughout 2004 and are expected to continue in various forms beyond that time.

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 approximately 2,500 physicians in the United States have prescribed Fuzeon through December 31, 2003. We now have the physician and patient experience that most HIV drugs enjoy when they launch.

Phase III Clinical Trials of Fuzeon

Trial Design

TORO-1. In June 2001, we completed enrollment of TORO-1, a 48-week Phase III clinical trial in North America and Brazil. The trial is evaluating 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. In the Fuzeon treatment group, patients received the optimized background regimen in combination with twice daily subcutaneous injections, each

delivering 90 mg of Fuzeon. The background regimen was optimized 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. In August 2001, we completed enrollment of TORO-2, a 48-week Phase III clinical trial in Western Europe and Australia. The protocol for TORO-2 is substantially similar to TORO-1 and involves 504 HIV-infected patients.

The following table gives background information and describes the patient populations enrolled in the TORO-1 and TORO-2 clinical trials and the pooled analysis of both trials:

	TORO-1		TORO-2		POOLED	
	Fuzeon	Control	Fuzeon	Control	Fuzeon	Control
Total number of sites	49		64		113	
Site locations	North America, Brazil		Western Europe, Australia			
Total number of patients	491		504		995	
Approximate randomization	2:1		2:1		2:1	
Number of patients per group	326	165	335	169	661	334
Median viral load at trial start (log_{10} copies/milliliters)	5.2		5.1		5.2	5.1
Median CD4 cell count at trial start (cells/cubic millimeter)	76	87	98	102	88	97
Average number of anti-HIV drugs exposed to prior to trial	12		12		12	12
Phenotypic sensitivity score	1.7		1.4		1.6	1.6
Genotypic sensitivity score	1.9		1.6		1.7	1.8

Phenotypic sensitivity scores and genotypic sensitivity scores are measures of viral resistance. Specifically, the sensitivity scores depicted in the table above represent the average number of drugs, out of all the currently approved anti-HIV drugs, that could be expected to be active against the tested virus.

Clinical Trial Results

In September 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 analysis of TORO-1 and TORO-2 showed that important secondary endpoints, including the increase of CD4 count from baseline and suppression of viral load below the level of detection were also met with statistical significance. CD4 cells are a critical component of the human immune system and are often killed by HIV. An increase in CD4 cell count is indicative of immune system restoration and is important in reducing the likelihood of opportunistic infection. We measure CD4 cell counts in units of CD4 cells per cubic millimeter of blood. 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 control 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

Primary endpoint. The primary endpoint in both TORO-1 and TORO-2 was a 0.5 log_{10} incremental reduction of viral load achieved in the patient groups treated with Fuzeon versus the reduction in viral load achieved in the control groups. It is widely viewed that a reduction in HIV RNA levels can be used as a suitable endpoint to determine efficacy of anti-HIV drugs in clinical studies.

Secondary endpoints. In both TORO-1 and TORO-2, multiple secondary endpoints were also met with statistical significance and characterize the clinical benefit of Fuzeon, as well as the durability of response to the drug through 48 weeks. An important secondary endpoint in these clinical trials is the increase in CD4 cell count achieved in the Fuzeon groups versus the increase achieved in the control groups.

Additional secondary endpoints in TORO-1 and TORO-2 are the percentages of patients who achieved a reduction of HIV viral load below two pre-defined levels, 400 copies per milliliter of blood and 50 copies per milliliter of blood. Reduction of viral load below these levels is believed to correlate with long-term durability of response to the anti-HIV therapy. Another important endpoint is the percentage of patients treated with Fuzeon who achieved a reduction of viral load greater than 1.0 log_{10} versus the percentage of the control group patients who achieved viral load reduction of that magnitude. Finally, the comparison between the number of Fuzeon treated patients and the patients in the control groups who experienced virological failure is also an important secondary endpoint. Virologic failure refers to the inability of an anti-HIV drug regimen to reduce or suppress HIV in accordance with measures defined in the trial protocols.

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 $\log_{10}$, 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 $\log_{10}$ 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 duration of virological benefit in the Fuzeon group of 32 weeks was approximately three times longer than the duration of 11 weeks in the control group. All of these results were highly statistically significant.

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. These clinical trials also evaluated patient acceptance of the subcutaneous administration of Fuzeon.

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 sharps (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%).

Future Fuzeon Clinical Trials

We expect to initiate various clinical trials with Fuzeon during 2004. These trials plan to focus on the following primary needs in potential Fuzeon patients: the contribution of Fuzeon to combination therapy; the effect of a more convenient regimen; 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.

Pediatric Clinical Trials of Fuzeon

In December 2001, we presented 24-week data from T20-204, a 12 patient pediatric Phase I/II clinical trial for Fuzeon. In T20-204, patients were randomly assigned to two treatment groups to receive Fuzeon at different dosage levels in combination with a background regimen of other anti-HIV drugs. At 24 weeks, this trial showed that Fuzeon was well-tolerated by children and that children receiving the highest dose experienced a 90% reduction in viral load. In September 2003, we presented 24-week safety and efficacy data from T20-310, a Phase I/II clinical trial designed to evaluate long-term usage of Fuzeon in adolescents. Twenty-eight heavily pre-treated patients of 12-16 years of age were studied through 24 weeks. Patients achieved an average reduction of HIV viral load of 0.98 $\log_{10}$, and a average increase in CD4 cell count of 148 cells, when compared to baseline levels. The safety profile was favorable and consistent with the safety observed in TORO-1 and TORO-2.

Safety Results

The following safety results reflect the data included in the 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 were the most frequent adverse events associated with the use of Fuzeon. In TORO-1 and TORO-2, 98% of subjects had at least 1 local injection site reaction, or 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: 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.

48-week Safety Data

A detailed 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 reaction at the site of injection, such as pain/discomfort, redness, hardness, bumps, itching or bruising. Less than five percent of patients discontinued treatment due to injection site reactions. 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 injection site reactions, 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 (15.8 per 100

patient-years in the Fuzeon group versus 24.1 in the control group), insomnia (16.6 vs. 19.7), and vomiting (15.8 vs. 26.5). Among events reported more commonly in the Fuzeon group compared to the control group were pain or numbness in the peripheral nervous system (15.4 per 100 patient years in the Fuzeon group vs. 13.6 in the control group), weight decrease (11.1 vs. 10.5), sinusitis (9.5 vs. 6.2), decreased appetite (8.6 vs. 4.9), swelling of lymph nodes (5.9 vs. 1.2) and pneumonia (6.7 vs. 0.6). 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.

Other Observations

Neutralizing Antibodies. We have examined patient samples taken throughout the clinical trials to assess potential antibody responses to Fuzeon. Data through 48 weeks show that Fuzeon does not appear to produce an immune response in the body that could compromise Fuzeon's efficacy.

A combined pooled analysis of TORO-1 and TORO-2 at 48 weeks found that the existence of anti-gp41 antibodies, which the immune system develops in response to HIV infection, does not influence the efficacy or safety of Fuzeon. Most patients in these trials had detectable levels of anti-gp41 antibodies that also interact with Fuzeon prior to exposure to Fuzeon, as would be expected since Fuzeon is essentially similar to a portion of gp41.

Resistance. Decreased sensitivity to Fuzeon in TORO-1 and TORO-2 patients who experienced virologic failure within 24 weeks of treatment was highly correlated with changes in the amino acid sequence 36 through 45 in the HIV protein gp41. This resistance profile does not overlap with the resistance profiles of any of the currently-approved anti-HIV drugs. In addition, Fuzeon has demonstrated additive or synergistic antiviral activity in laboratory studies when combined with representative members of the currently approved classes of anti-HIV drugs.

Drug-drug Interactions. A series of pharmacokinetic, or PK, studies found no clinically relevant drug interactions for Fuzeon with the following other drugs frequently used by patients infected with HIV: ritonavir; boosted saquinavir, which is 1000 milligrams of saquinavir combined with 100 milligrams of ritonavir twice-daily; or rifampicin. These findings are consistent with the expected low potential for drug-drug interactions with a peptide drug such as Fuzeon.

Baseline Sensitivity to Fuzeon. A pooled analysis of TORO-1 and TORO-2 data combined showed that a patient's virus sensitivity to Fuzeon varied across a range. Virologic response to Fuzeon therapy was not correlated with the baseline sensitivity of the patient's virus. In addition, virologic response was not correlated with the co-receptor type contained in the patient's virus.

Manufacturing

The synthetic manufacture of peptides historically has been complex and expensive. This constraint has not limited the commercialization of most existing peptide therapeutics, which are administered in relatively small doses. Dosing levels of Fuzeon are relatively high compared to therapeutic peptides currently prescribed for other indications. We have developed a novel peptide manufacturing process, which has allowed us to produce Fuzeon on a large-scale basis. 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 scale-up of production of Fuzeon bulk drug substance at Boulder was achieved during the second half of 2002. Not surprisingly, production yields were lower and cycle times were longer than projected in the initial batches. Simple process modifications were made during the scale-up process that brought the yields in subsequent batches to the projected target levels derived from pilot plant production. Once the target yields were

achieved, we and Roche identified the final purification stage as the rate limiting step that resulted in longer than projected cycle times. Based on analysis of this stage, Roche installed a duplicate piece of equipment that reduced the cycle time of the purification stage and allowed us to exceed our initial targeted cycle times for the bulk drug substance production process.

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.

T-1249

T-1249 is our second-generation fusion inhibitor for HIV. In January 2004, Roche and Trimeris announced that the clinical development of T-1249 was put on hold due to challenges in achieving the desired technical profile of the current formulation. The compound's safety, efficacy and tolerability were in no way related to the decision. As for any compound in development, the technical development is an evolving and dynamic process where many challenges are identified. The properties of T-1249 differ from Fuzeon during its manufacturing and formulation. T-1249 remains one of our next-generation drug candidates; however, our focus will be to continue the pursuit of new formulations of T-1249 or future peptide fusion inhibitors that are more patient-friendly and appropriate for chronic administration.

The history of HIV treatment has demonstrated that the existence of multiple drugs within the RTI and PI classes have allowed for a variety of drug combinations and improved patient treatment. We believe that multiple HIV fusion inhibitors may further enhance HIV therapy by providing an even broader range of treatment options. To date, T-1249 has demonstrated potent HIV suppression in vitro, and is highly active against a wide range of HIV strains in vitro, including strains resistant to Fuzeon.

Phase I/II—T1249-101

In July 1999, we initiated T1249-101, a Phase I/II clinical trial designed to assess the safety, antiviral activity, and pharmacokinetics of escalating doses of T-1249 given without any other anti-HIV drugs for 14 days. For at least two weeks prior to entering the clinical trial, these patients had not received any other anti-HIV drugs. Patients in the trial had a clinical history of exposure to a median of ten anti-HIV drugs.

Results of this clinical trial have been reported on two occasions. In February 2001, we reported interim results for patients who received doses of T-1249 ranging from 6.25 milligrams given once daily via subcutaneous injection to 25 milligrams given twice daily via subcutaneous injection, which showed a dose-dependent response in reduction in HIV viral load. In September 2002, we announced final results including additional patients who received doses of 50 milligrams, 100 milligrams, 150 milligrams, and 200 milligrams given once daily via subcutaneous injections. Of 115 patients entering the clinical trial, 113, or 98%, completed the 14-day dosing period. Dose-dependent decreases in HIV viral load were observed, including a median maximum reduction of 2.0 $\log_{10}$ copies per milliliter, or 99%, in patients receiving T-1249 at a dose of 200 milligrams per day.

No treatment-related, clinically important laboratory abnormalities occurred and no dose-limiting toxicities were identified. The most common adverse event reported in T1249-101 was mild to moderate local skin irritations at the site of injection. Three serious adverse events assessed by the investigators as possibly related to T-1249 occurred. One patient experienced an allergic reaction, a second patient exhibited a low white blood cell count, or neutropenia, and a third patient experienced fever associated with injection site reaction.

T1249-102

In September 2003, we announced final data from study T1249-102. This study evaluated the antiviral activity and safety of T-1249 over a 10-day period in patients who had failed an individualized anti-HIV drug

regimen that had previously included Fuzeon. Eligible patients were participating in Phase II or Phase III studies of Fuzeon and were experiencing evidence of viral replication while on this drug regimen. Patients in this study discontinued Fuzeon and added T-1249 to the unchanged background regimen of anti-HIV drugs. A total of 53 patients received T-1249 in this trial. The median viral load decline from baseline viral load after ten days of treatment was 1.26 log10 copies per milliliter. There were no serious adverse events judged possibly to be related to T-1249 in the trial. These data demonstrate that T-1249 retains short term antiviral activity in most patients who are failing an anti-HIV drug regimen containing Fuzeon.

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, Roche has agreed to pay us up to $68 million in upfront and milestone payments, of which we have received $27.5 million as of December 31, 2003.

We have also entered into a research agreement with Roche to discover, develop and commercialize additional anti-HIV fusion inhibitor peptides. We will share equally the worldwide research, development and commercialization expenses and profits from the worldwide sales of anti-HIV fusion inhibitor peptides discovered after July 1, 1999. 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. The joint research obligations under the agreement were renewed through December 31, 2005 during 2003.

Array Biopharma

In July 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.

Tranzyme, Inc. (formerly Neokimia, Inc.)

In April 2002, we entered into an agreement with Neokimia Inc., or Neokimia, to discover and develop small molecule HIV fusion inhibitors. In December 2003, Neokimia merged with Tranzyme, Inc., or Tranzyme, and Tranzyme acquired Neokimia's rights and obligations under the April 2002 agreement. We will initially screen a library of small molecule compounds provided by Tranzyme. Tranzyme will use its proprietary drug discovery platform to optimize lead compounds. We will collaborate with Tranzyme to identify preclinical drug candidates. Tranzyme 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 Tranzyme on a non-exclusive basis on these targets. We, with Tranzyme, 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. Tranzyme will be entitled to receive payments and royalties on net product sales based on achievement of certain developmental and commercial milestones. Tranzyme 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. Subsequent to the date of our agreement with Neokimia, but not in connection with such agreement, Robert R. Bonczek, our Chief Financial Officer and General Counsel, was appointed to the Board of Directors of Neokimia. Subsequent to the merger of Neokimia with Tranzyme, Mr. Bonczek is not a member of the Board of Directors of Neokimia or Tranzyme.

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.

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.

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 or manufacture. Fuzeon is currently delivered via a twice daily subcutaneous injection. We believe that incremental improvements in delivery convenience could enhance its market acceptance. We are currently working with Roche to explore more convenient delivery devices, including auto-injection devices, needle-free delivery devices, multi-dose vials, improved formulations and other enhancements. Fuzeon is currently manufactured using a complex process developed by Trimeris.

Novel Peptide HIV 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 through pegylation, which is the attachment of polyethylene glycol to a peptide which has been shown to extend the half-life of other drugs. Another approach to half-life extension is the attachment of other substances such as albumin 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 have become resistant to other HIV fusion inhibitors, similar to the profile of T-1249 that we have seen both in the laboratory and in clinical trials. 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.

Small Molecule HIV Fusion Inhibitors. We also have discovery programs that are focused on discovering an orally available small molecule HIV fusion inhibitor. 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 Tranzyme, Inc., which acquired these rights through its merger with Neokimia, to discover small molecule fusion inhibitors of HIV.

Sales, Marketing and Distribution

We have limited experience in sales, marketing or distribution of pharmaceuticals. We do 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, our 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 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.

Roche has entered into an exclusive distribution arrangement with Chronimed, Inc. to distribute Fuzeon in the United States during the initial commercial launch in 2003. The current exclusivity contract with Chronimed expires on March 27, 2004. In the event Chronimed is unable or unwilling to fulfill its obligations to Roche in accordance with this agreement, it would have a material adverse effect on our business, financial condition, results of operations and the market price of our stock. Additional specialty distributors are currently being evaluated to expand the distribution and commercial availability of Fuzeon in the United States during 2004.

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 more than 25 issued United States patents, numerous pending United States patent applications, and certain corresponding foreign patents and patent applications. Most of our issued 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 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. There is no royalty payable with respect to T-1249.

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 just under $20,000 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 an 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 drug candidates under development 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. Although Fuzeon received accelerated FDA approval on March 13, 2003, accelerated FDA approval and/or fast track designation do not guarantee that Fuzeon will receive full FDA approval, or that Fuzeon will receive regulatory approvals in other countries.

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.

In March 2003, Roche announced that the WAC of a one year's supply of Fuzeon in the United States will be just under $20,000. 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, 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 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 2004.

Outside the United States, Roche in the process of negotiating reimbursement from the countries in which they plan to market Fuzeon. Fuzeon was commercially launched in Switzerland, France, the United Kingdom, Ireland, Germany, Austria, The Netherlands, Denmark, Sweden, Norway, Finland, Mexico and Argentina during 2003.

Human Resources

During January of 2004, we put future clinical development of T-1249 on hold. In connection with this programmatic change, the Company reduced its workforce by approximately 25%. As of February 28, 2004, we had 100 full-time employees, including a technical scientific staff of 70. None of our employees are covered by collective bargaining arrangements, and management considers relations with our employees to be good.

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 our lead drug candidate and is our 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 uptake 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 a one year's supply of Fuzeon in the United States is just under $20,000. 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.

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

As of December 31, 2003, our accumulated deficit since beginning our operations in January 1993 was approximately $330.3 million. We had net losses of approximately $66.7 million in 2001, approximately $75.7 million in 2002, and approximately $65.7 million in 2003. 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.

Under our collaboration agreement with Roche, we 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, we are able to defer a substantial portion of the selling and marketing expense related to Fuzeon to be incurred in 2004. As a result, we expect our contribution to the selling and marketing expense for Fuzeon in 2004 to be approximately $10 million, even though Roche expects to spend

significantly more on these expenses. If we achieve certain cumulative levels of sales for Fuzeon in the United States and Canada, our share of any additional expenses incurred by Roche during 2004 will be payable to Roche at a future date over several years. At current sales levels, based on this limitation on marketing expenses, we believe we could realize positive cash flow from the sale of Fuzeon in the United States and Canada in 2004. In addition, we expect to receive royalties from Roche on the sale of Fuzeon outside the United States and Canada.

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, Roche has agreed to pay us up to $68 million in upfront and milestone payments, of which we have received $27.5 million as of December 31, 2003. 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 our other 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 other 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 drug candidates.

Even if we are successful in developing a commercially viable drug, in order to become profitable we will need to maintain arrangements with third parties for the sale, marketing and distribution of our 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 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 other 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 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 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.

Roche has entered into an exclusive distribution arrangement with Chronimed, Inc. to distribute Fuzeon in the United States. The exclusivity of this agreement ends in March 2004. In the event Chronimed is unable or unwilling to fulfill its obligations to Roche in accordance with this agreement, it would have a material adverse effect on our business, financial condition, results of operations and the market price of our stock. Roche plans to enter into non-exclusive agreements with additional specialty distributors to expand the distribution and commercial availability of Fuzeon in the United States during 2004.

If sufficient amounts of Fuzeon and our other drug candidates 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.

Roche's current manufacturing infrastructure does not allow the flexibility in the short-term to increase production beyond current capacity, and Roche and other third-party manufacturers may not succeed in increasing capacity to manufacture sufficient amounts of Fuzeon to meet demand in the future. Failure of our third-party manufacturers to increase their manufacturing capabilities will mean that even if we develop promising new drugs, we may not be able to produce them. In addition, we may be required to reimburse Roche for our share of costs to expand its current manufacturing infrastructure or to build new manufacturing facilities. Further, we may incur expenses under contracts with other third-party manufacturers for the production of our drugs.

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. None of these currently-approved drugs are viral fusion inhibitors.
- 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 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, T-1249 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 Fuzeon or our other drug candidates or approvals may be delayed.

Our research and development activities and the testing, development, manufacturing and commercialization of Fuzeon and our other drug candidates are 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 Fuzeon or our other 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.

We cannot assure you that the results of the clinical trials we have conducted and intend to conduct for Fuzeon will support the applications for full regulatory approval. The timing of NDA submissions, the outcome of reviews by the FDA and the initiation and completion of other clinical trials are subject to uncertainty, change and unforeseen delays. Moreover, favorable results in later stage clinical trials do not ensure full FDA approval to commercialize a product. Some companies that have believed their products performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval of their products. Roche completed filing of the Fuzeon NDA in September 2002 based on the 24-week data collected from TORO-1 and TORO-2. The FDA notified Roche on October 11, 2002, that the Fuzeon NDA had been granted priority review status. On March 13, 2003, the FDA granted accelerated approval for the commercial sale of Fuzeon. Roche submitted a full analysis of 48-week clinical data from TORO-1 and TORO-2 to the FDA in December 2003 seeking full approval. The FDA may not grant full approval based on this data, and may rescind accelerated approval. Roche also filed an application for European marketing approval on September 19, 2002. In March 2003, the Committee for Proprietary Medicinal Products, or CPMP, recommended granting marketing authorization for Fuzeon. In May 2003, the European Agency for the Evaluation of Medicinal Products, or EMEA, granted marketing authorization for Fuzeon in Europe.

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.

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. The conventional approach to treating HIV, as represented by all currently-marketed anti-HIV drugs, is to inhibit 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 very 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.

HIV is likely to develop resistance to Fuzeon and our other 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 strains of HIV resistant to particular drug treatments. HIV has developed resistance, in varying degrees, to each of the currently approved anti-HIV drug treatments. 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 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.

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

On March 13, 2003, the FDA granted accelerated approval for the commercial sale of Fuzeon, and commercial sales of Fuzeon began in March 2003 in the United States. None of our other drug candidates 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.

To date:

- we have completed preclinical testing and Phase I/II and Phase II clinical trials of Fuzeon;
- we and Roche have collected and analyzed 24-week and 48-week data regarding Fuzeon from TORO-1 and TORO-2, and the FDA has granted accelerated approval of the Fuzeon NDA based largely on the 24-week data;
- we and Roche have submitted the 48-week data for full approval and the FDA is currently reviewing this submission; and
- we have completed preclinical testing, a Phase I/II clinical trial, and analysis of two Phase I/II clinical trials of T-1249, from which we have collected clinically relevant data.

We cannot assure you that the results of prior clinical trials will warrant further clinical trials or the submission of NDAs for a particular drug candidate. 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. 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;
- 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
- reevaluation 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 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 anticipate that our expenditures will increase further with the additional collection and analysis of data from TORO-1 and TORO-2 and the costs of marketing activities that will need to be undertaken in connection with the commercialization of Fuzeon and, to a lesser extent, as a result of the ongoing costs of our clinical trials. Barring unforeseen developments, 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 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, T-1249, 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 25 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 that we believe will limit our ability to use, manufacture, market or sell Fuzeon or our other 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 other 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 just under $20,000. 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 2004.

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 $5 million per occurrence and $5 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, including the full FDA approval of Fuzeon;
- 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, including Dani P. Bolognesi, Ph.D., our Chief Executive Officer and Chief Scientific Officer. We have entered into employment agreements with Dr. Bolognesi, M. Nixon Ellis, Ph.D., our President, 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.

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, 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.

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 2004. Our premiums for these policies continue to increase over previous years. For future renewals, we anticipate that in light of the current business environment, if we are able to retain coverage, we will 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 18,000 square feet of office space at 3518 Westgate Drive, Durham, North Carolina. We lease this space under a sublease agreement that expires on December 31, 2004. 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 2003.

PART II.

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

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 future. As of March 9, 2004 we had approximately 132 shareholders of record, and believe we had approximately 6,500 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,			
	2002		2003	
	High	Low	High	Low
1st Quarter	$46.21	$33.98	$47.36	$39.03
2nd Quarter	$53.16	$37.80	$55.59	$38.05
3rd Quarter	$49.99	$35.78	$55.29	$23.58
4th Quarter	$56.80	$37.85	$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,				
	1999	2000	2001	2002	2003
Statements of Operations Data:					
Revenue:					
Milestone revenue	$ 4,681	$ 956	$ 1,304	$ 1,133	$ 2,964
Royalty revenue	—	—	—	—	755
Total revenue	4,681	956	1,304	1,133	3,719
Operating expense:					
Collaboration loss	—	—	—	—	25,515
Marketing expense	—	973	3,825	16,722	—
Research and development:					
Non-cash compensation	2,174	5,386	(969)	250	(1)
Other research and development expense	17,582	32,970	59,409	50,976	36,824
Total research and development expense	19,756	38,356	58,440	51,226	36,823
General and administrative:					
Non-cash compensation	2,524	7,018	1,905	1,645	767
Other general and administrative expense	6,156	7,142	8,048	9,340	7,810
Total general and administrative expense	8,680	14,160	9,953	10,985	8;577
Total operating expenses	28,436	53,489	72,218	78,933	70,915
Operating loss	(23,755)	(52,533)	(70,914)	(77,800)	(67,196)
Interest income	1,729	6,114	4,362	2,230	1,534
Interest expense	(161)	(257)	(189)	(108)	(41)
Total other income (expense)	1,568	5,857	4,173	2,122	1,493
Loss before cumulative effect of change in accounting principle	(22,187)	(46,676)	(66,741)	(75,678)	(65,703)
Cumulative effect of change in accounting principle	—	(4,180)	—	—	—
Net loss	$(22,187)	$(50,856)	$(66,741)	$(75,678)	$(65,703)
Basic and diluted net loss per share (1):					
Before cumulative effect of accounting change	$ (1.79)	$ (3.00)	$ (3.96)	$ (3.93)	$ (3.06)
Accounting change	—	(0.27)	—	—	—
Basic and diluted net loss per share	$ (1.79)	$ (3.27)	$ (3.96)	$ (3.93)	$ (3.06)
Weighted average shares used in computing basic net loss per share (1)	12,411	15,548	16,870	19,272	21,460

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

	As of December 31,				
	1999	2000	2001	2002	2003
			(in thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 37,023	$ 31,349	$ 22,288	$ 119,729	$ 85,714
Working capital	36,856	73,998	51,636	128,389	75,741
Total assets	51,650	98,933	80,644	154,539	98,600
Long-term notes payable and capital lease obligations, less current installments	1,206	1,861	1,014	321	—
Accumulated deficit	(71,298)	(122,154)	(188,895)	(264,573)	(330,276)
Total stockholders' equity	39,066	73,379	53,494	130,127	68,668

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

	Q1 2002	Q2 2002	Q3 2002	Q4 2002
Statements of Operations Data:				
Milestone revenue	$ 326	$ 326	$ 326	$ 155
Operating expense:				
Marketing expense	1,525	2,985	3,640	8,572
Research and development:				
Non-cash compensation	(21)	149	98	24
Other research and development expense	14,759	11,925	12,232	12,060
Total research and development expenses	14,738	12,074	12,330	12,084
General and administrative:				
Non-cash compensation	403	415	414	413
Other general and administrative expense	1,865	2,031	2,502	2,942
Total general and administrative expenses	2,268	2,446	2,916	3,355
Total operating expenses	18,531	17,505	18,886	24,011
Operating loss	(18,205)	(17,179)	(18,560)	(23,856)
Interest income	537	516	446	731
Interest expense	(33)	(31)	(24)	(20)
Total other income, net	504	485	422	711
Net loss	$(17,701)	$(16,694)	$(18,138)	$(23,145)
Basic and diluted net loss per share (1)	$ (0.97)	$ (.89)	$ (0.97)	$ (1.09)
Weighted average shares used in computing basic net loss per share (1)	18,286	18,736	18,776	21,281

	Q1 2003	Q2 2003	Q3 2003	Q4 2003
Statements of Operations Data:				
Revenue				
Milestone revenue	$ 236	$ 750	$ 989	$ 989
Royalty revenue	—	87	234	434
Total revenue	236	837	1,223	1,423
Operating expense:				
Collaboration loss	4,452	5,763	5,231	10,069
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	9,623	10,897	10,725	5,578
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	2,580	2,632	2,210	1,155
Total operating expenses	16,655	19,292	18,166	16,802
Operating loss	(16,419)	(18,455)	(16,943)	(15,379)
Interest income	506	414	323	291
Interest expense	(15)	(11)	(9)	(6)
Total other income, net	491	403	314	285
Net loss	$(15,928)	$(18,052)	$(16,629)	$(15,094)
Basic and diluted net loss per share (1)	$ (0.75)	$ (0.84)	$ (0.77)	$ (0.70)
Weighted average shares used in computing basic net loss per share (1)	21,375	21,418	21,513	21,525

(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

We began our operations in January 1993 and prior to 2003 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, 2003, had an accumulated deficit of approximately $330.3 million. We have received revenue only from federal small business innovative research grants, otherwise known as SBIR grants, an investigative contract, and an initial collaboration payment and milestone payments from Roche. We may never generate significant revenue from product sales or royalties.

Currently, our only significant source of revenue is from the sale of Fuzeon. Under our collaboration agreement with Roche, we 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. Marketing expenses in the United States and Canada exceeded the gross margin from the sale of Fuzeon in these countries during 2003, resulting in negative cash flow from the sale of Fuzeon in these countries in 2003. During 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 sale of Fuzeon worldwide during 2003.

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 as 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 status of our research and development activities,
- product candidate discovery and development efforts, including preclinical testing and clinical trials,
- the timing of regulatory actions, including the potential full approval of Fuzeon by the FDA,

- 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 we achieve increased Fuzeon sales levels.

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 collectibility 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

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 is 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 is expected to be longer, the amount of revenue recognized would be less per quarter than currently being recognized. If either term is expected to be shorter, the amount of revenue recognized would be more per quarter than currently being recognized.

During the fourth quarter of 2002, we increased our estimate of the length of this development term based on the expected development schedule of T-1249 or a replacement compound, the final compound covered by

our collaboration agreement with Roche. Our expectations at that time for development of T-1249 would result in the end of the development period ranging from late 2005 to mid 2007. This estimate is subject to significant variability since T-1249 has only completed two Phase I/II trials. Any future change in our judgment of the length of this research and development term will result in a prospective change in the milestone revenue to be recognized under our collaboration with Roche. Any future research and development milestone payments received from Roche under our collaboration agreement will be amortized from the date the milestone is achieved to the end of the remaining research and development term. We recorded an $8 million milestone in March 2003 and a $5 million milestone in May 2003. Through December 31, 2003, these milestones were amortized on a straight line basis from the date recorded to mid 2007. We also recorded a $2.5 million milestone related to Fuzeon manufacturing in June 2003 that will be amortized on a straight line basis from the date recorded through the end of the current patent life of Fuzeon, which is our current estimate of the commercial life of Fuzeon.

During the first quarter of 2004, we put future clinical development of T-1249 on hold. As a result, we increased our estimate of the length of the research and development period for our Roche collaboration to 2010 based on an estimate of the development period for T-1249 or a replacement compound that may be substituted under our collaboration agreement. As a result, revenue recognized related to these payments in 2004 is expected to be approximately $900,000 less than the amount recognized in 2003.

Royalty Revenue

Under our collaboration agreement with Roche, we receive a royalty based on net sales of Fuzeon outside the United States and Canada, which began in June 2003. These royalties are recognized as revenue when the sales are earned. Royalties of $755,000 were recognized as revenue during 2003.

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 income (loss) in the Statements of Operations. Collaboration 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 is reduced by costs of goods sold resulting in gross margin. Gross margin is reduced by selling and marketing 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. Roche has entered into an exclusive distribution arrangement with Chronimed, Inc. ("Chronimed") to distribute Fuzeon in the United States. This exclusive arrangement terminates on March 27, 2004, unless renewed. Revenue from product sales is recognized when title and risk of loss has passed to Chronimed, which is when Chronimed allocates drug for shipment to a patient. Roche prepares its estimates for sales returns and allowances, discounts and rebates based primarily on their historical experience with 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.

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, 2003, 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 2004. 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, 2003, there were options to purchase approximately 22,000 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.

Call Transaction Accounting

In September 2001 and April 2002, we entered into derivative transactions with a financial institution that could have been settled by selling 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. We received proceeds from the sale of these call options that were accounted for as an increase to additional paid-in capital in accordance with EITF Issue No. 00-19. An extensive list of requirements, including the ability to settle the transaction by issuing stock, is required by EITF Issue No. 00-19 in order to allow accounting for proceeds received as an increase to additional paid-in capital. The contracts for our derivative transactions met the detailed requirements in EITF Issue No. 00-19. Proceeds of $344,000 and $388,000 were received and credited to additional paid-in-capital in the years ended December 31, 2001 and 2002, respectively. In the event these contracts did not meet the requirements in EITF Issue No. 00-19, these transactions would be accounted for in accordance with SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS No. 133 requires derivatives to be recorded on the balance sheet at fair value and would require the carrying value of these call options to be adjusted at the end of each reporting period until their expiration or exercise. All outstanding derivative transactions have expired unexercised.

RESULTS OF OPERATIONS

Comparison Of Years Ended December 31, 2001, 2002 and 2003

Milestone Revenue. Total milestone revenue of $1.3 million, $1.1 million and $3.0 million for 2001, 2002 and 2003, respectively, represents the amortization of milestone payments from Roche for milestones achieved under our collaboration agreement, recorded at the time the specific milestone was achieved. We recorded and are amortizing a $10 million initial collaboration payment from Roche, net of the $5.4 million assigned to the warrant granted to Roche concurrent with the initiation of our collaboration, a $2.0 million milestone recorded in 2000, and milestones of $8.0 million, and $5.0 million recorded in 2003, over the expected research and development period of our collaboration with Roche in accordance with SAB No. 101. We recorded a $2.5 million milestone related to manufacturing in 2003 that we are amortizing over the expected commercial life of Fuzeon. During the fourth quarter of 2002, we increased our estimate of the length of this development period

based on the expected development schedule of T-1249 or a replacement compound, the final compound covered by our collaboration agreement with Roche. This estimate is subject to significant variability since T-1249 has only completed two Phase I/II trials. This change in estimated term resulted in a prospective adjustment to milestone revenue recognized beginning in the fourth quarter of 2002 in accordance with APB 20. The change in our estimate of the development term resulted in less revenue recognized in 2002 than in 2001.

During the first quarter of 2004, we put future clinical development of T-1249 on hold. As a result, we increased our estimate of the length of the research and development period for our Roche collaboration to 2010 based on an estimate of the development period for T-1249 or another development compound under our collaboration agreement. As a result, revenue recognized related to these payments in 2004 is expected to be approximately $900,000 less than the amount recognized in 2003.

Royalty Revenue Total royalty revenue was $755,000 for 2003. 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. Total net sales outside the United States and Canada for 2003 were $7.6 million, including $4.4 million during the three months ended December 31, 2003.

Collaboration Loss. Under our collaboration agreement with Roche, we share profits equally from the sale of Fuzeon in the United States and Canada. Collaboration loss is calculated as follows. Total gross sales of Fuzeon in the United States and Canada are reduced by any sales returns, allowances, discounts 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 and marketing expenses related to the sale of Fuzeon, resulting in operating income or loss. Our 50% share of the operating income or loss is reported as collaboration income or loss. Product sales of Fuzeon began in the United States on March 27, 2003. Total net sales of Fuzeon were $28.3 million during 2003. During 2003, sales and marketing expenses exceeded the gross margin from the sale of Fuzeon resulting in our 50% share of operating loss from the sale of Fuzeon in the United States of $25.5 million. Roche has entered into an exclusive distribution arrangement with Chronimed to distribute Fuzeon in the United States during the initial commercial launch in 2003. Revenue from product sales is recognized when title and risk of loss has passed to Chronimed, which is when Chronimed allocates drug for shipment to a patient.

During 2003, we shipped approximately 19,000 kits of Fuzeon to paying patients in the United States and Canada. A kit represents a one-month supply of Fuzeon for a patient. We shipped approximately 3,000 kits during the quarter ended June 30, 2003, 7,000 kits during the quarter ended September 30, 2003, and 9,000 kits during the quarter ended December 31, 2003. The number of kits shipped may not remain constant and may increase or decrease in the future.

We believe the number of prescriptions received for new patients was relatively constant at around 400-500 per month during the three months ended December 31, 2003, adjusted for fluctuations during holiday periods. The number of prescriptions received for new patients may not remain constant and may increase or decrease in the future. These new patient prescriptions include prescriptions for patients who eventually receive Fuzeon through reimbursement by traditional HIV drug reimbursement channels, patients who eventually receive Fuzeon through reimbursement by the Fuzeon Patient Assistance Program, and patients who never receive Fuzeon.

Marketing Expense. Marketing expense during 2002 included expenses incurred for pre-launch activities related to Fuzeon and consisted primarily of expenses for market research and presentation of data on our Fuzeon Phase III trials at various scientific meetings. During 2003, sales and marketing expenses related to Fuzeon are included in collaboration loss because we launched Fuzeon on March 27, 2003.

Research And Development Expenses. Total research and development expenses were $58.4 million, $51.2 million and $36.8 million for 2001, 2002 and 2003, respectively. 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 until December 30, 2003 for Fuzeon and T-1249.

Non-cash compensation expense changed from $969,000 in expense reversal in 2001 to $250,000 in expense in 2002. The change in expense resulted because the cumulative 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" for stock options previously granted to non-employees was less at December 31, 2001 compared to December 31, 2000, because of the decrease in the market price of our stock from December 31, 2000 to December 31, 2001. The cumulative expense calculated under EITF 96-18 was slightly higher at December 31, 2002 compared to December 31, 2001 due to additional vesting of the options. The closing market price per share of our stock was $54.88, $44.97, and $43.17 on December 31, 2000, 2001 and 2002, respectively. EITF 96-18 requires that compensation costs related to stock options granted to non-employees be measured at the end of each reporting period to account for changes in the fair value of our common stock until the options are vested. During the three months ended June 30, 2002, a significant number of the options previously granted to non-employees became vested.

Non-cash compensation expense changed from $250,000 in expense in 2002 to $1,000 in expense reversal in 2003. 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 are vested.

Total other research and development expenses which are total research and development expenses net of non-cash compensation charges decreased from $59.4 million in 2001 to $51.0 million in 2002 because during 2002 we incurred less expense than in 2001 for:

- the purchase of drug material for future clinical trials,
- our two Phase III clinical trials for Fuzeon which were initiated in late 2000, and
- our Phase II clinical trials for Fuzeon which were substantially completed in 2002.

This decrease in expenses was partially offset by increases in expenses during 2002 because we:

- continued preparation of materials for the submission of an NDA for Fuzeon to the FDA which was completed on September 16, 2002,
- increased the number of our personnel to support our clinical trial, manufacturing process development and research activities, and
- settled litigation with a former consultant regarding the amount of payment of a fee for services rendered.

Total other research and development expenses decreased from $51.0 million in 2002 to $36.8 million in 2003 because during 2003 we incurred less expense than in 2002 for:

- 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 received reimbursement from Roche for their 50% share of certain research and development expenses incurred during 2003.

These decreases in expenses were partially offset by an increase in expenses compared to 2002 for production of drug material for T-1249 clinical trials.

Total research personnel were 70, 88 and 91 at December 31, 2001, 2002 and 2003, respectively. We expect research and development expenses, net of the reimbursements for Fuzeon and T-1249 development costs from Roche, to decrease during 2004, barring any unforeseen changes, due to:

- reduced development expenses for T-1249 due to the decision to put that development program on hold,
- reduced development 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
- reduced expenses as a result of a headcount reduction that we implemented in January 2004.

General and Administrative Expenses. Total general and administrative expenses were $10.0 million, $11.0 million and $8.6 million for 2001, 2002 and 2003, respectively.

Non-cash compensation expense decreased from $1.9 million in 2001 to $1.6 million in 2002 primarily due to the effect that the lower market value of our stock at December 31, 2002 compared to the market value of our stock at December 31, 2001, had on the calculation of this expense under EITF 96-18 for stock options granted to non-employees, and the fact that some of the options previously granted to a former consultant who became an employee during 2001 became vested during 2002.

Non-cash compensation expense decreased from $1.6 million in 2002 to $800,000 in 2003 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 increased from $8.0 million in 2001 to $9.3 million in 2002 because during 2002, we:

- increased administrative personnel from 30 in 2001 to 40 in 2002 to support our growth,
- incurred increased professional fees related to a legal dispute with a former consultant, and
- incurred increased professional fees to support our growth.

Other general and administrative expense decreased from $9.3 million in 2002 to $7.8 million in 2003 because during 2003 we:

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

These decreases were partially offset by increased expenses in 2003 because we:

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

Total general and administrative employees were 30, 40 and 41 at December 31, 2001, 2002 and 2003, 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, and
- increased costs for directors and officers' insurance and other insurance coverage.

These expected increases will be partially offset by reduced expenses due to a headcount reduction that we implemented in January 2004.

Other Income (Expense). Other income (expense) consists of interest income and expense. Total other income was $4.2 million, $2.1 million and $1.5 million for 2001, 2002 and 2003, respectively. The decrease in 2002 was primarily due to lower interest income because of lower interest rates on our portfolio during 2002 compared to 2001, net of a slight increase in average investment balances during 2002 compared to 2001. The decrease in 2003 was primarily due to lower interest income because of lower interest rates on our portfolio during 2003 compared to 2002, net of a slight increase in average investment balances during 2003 compared to 2002. We expect yields on our investment portfolio to remain at current levels for the foreseeable future based on the current short-term interest rate environment.

LIQUIDITY AND CAPITAL RESOURCES

Operating Activities. Since inception, we have financed our operations primarily through private placements and public offerings of common stock, equipment lease financing and payments under our collaboration agreement with Roche. Net cash used by operating activities was $60.6 million, $73.0 million, and $56.7 million for 2001, 2002 and 2003, respectively. The cash used by operating activities was used primarily to fund research and development relating to Fuzeon, T-1249 and other product candidates. The amount used was higher in 2002 primarily due to the increase in other research and development expense to fund development of Fuzeon and due to an increase in marketing expenses. The amount used was lower in 2003 due to milestone payments received from Roche and reduced research and development expenses for the development of Fuzeon.

Investing Activities. Cash provided by investing activities was $7.3 million, $21.4 million and $20.7 million for 2001, 2002 and 2003, respectively. The amount provided for 2001, 2002 and 2003 resulted from the sale of short-term investments to fund our operating activities. Cash provided by financing activities was $44.2 million, $149.0 million, and $2.0 million in 2001, 2002 and 2003, respectively. During 2001 and 2002, the cash provided was primarily the result of the sale of our common stock during those years. During 2003, the cash provided was primarily due to the exercise of employee stock options.

Cash Flow. As of December 31, 2003, we had $92.2 million in cash and cash equivalents and short-term-investments, compared to $149.2 million as of December 31, 2002. The decrease is primarily a result of the cash used by operating activities during 2003.

In September 2001 and April 2002, we entered into derivative transactions with a financial institution, which are described below under "Off-Balance Sheet Arrangements." Proceeds of $344,000 and $388,000 were received and credited to additional paid-in-capital in December 31, 2001 and 2002, respectively, in accordance with EITF 00-19. We may enter into similar transactions in the future, subject to market conditions.

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 our other potential drug candidates 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 product candidates, and
- the development of our proprietary technology platform.

Under our collaboration agreement with Roche, we 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, we expect our contribution to the selling and marketing expenses for Fuzeon in 2004 to be approximately $10 million, even though Roche expects to spend significantly more on these expenses. If we achieve certain cumulative levels of sales for Fuzeon in the United States and Canada, our share of any additional expenses incurred by Roche during 2004 will be payable to Roche at a future date over several years. At current sales levels, based on this limitation on marketing expenses, we believe we could realize positive cash flow from the sale of Fuzeon in the United States and Canada in 2004. In addition, we expect to receive royalties from Roche on the sale of Fuzeon outside the United States and Canada.

Based on our new cost structure subsequent to our headcount reduction and our decision with Roche to put development of T-1249 on hold in January 2004, gross cash expenditures for 2004 are expected to range from $44 million to $52 million. These gross expenditures include $22 to $27 million for research and development expenses, $12 to $15 million for general and administrative expenses, and $10 million for our share of Fuzeon selling and marketing expense. At current Fuzeon sales levels, our share of the gross margin from the sale of

Fuzeon in the United States and Canada, combined with royalties from the sale of Fuzeon in the rest of the world, would range from $14 million to $17 million. At these sales levels, we believe our net cash outflow would range from $27 million to $38 million for 2004. If sales levels are higher or expenses are lower, our net cash outflow would be lower, if sales levels are lower or expenses are higher, our net cash outflow would be higher.

As of December 31, 2003, we had commitments of approximately $1.2 million to purchase product candidate materials and fund various clinical studies over the next 15 months contingent on delivery of the materials or performance of the services. Substantially all of these expenditures will be shared equally by Roche under our collaboration agreement. Under this collaboration agreement, we are obligated to share equally the future development expenses for Fuzeon and T-1249 in the United States and Canada. We also expect to have capital expenditures of approximately $1.2 million during 2004 that will not be shared with Roche. Our share of these expenditures may be financed with capital or operating leases, debt or working capital.

Barring unforeseen developments, 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 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 and T-1249, our capital requirements would increase substantially beyond our current expectations.

Financing Activities. 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 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 financings and/or arrangements with new or existing collaborative partners. Any debt financings may contain restrictive terms that limit our operating flexibility. Arrangements with 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.

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; the availability of funds from Roche under our collaboration agreement; the condition of public 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; and other factors, many of which are outside of our control.

Contractual Obligations. The following table summarizes our material contractual commitments at December 31, 2003 (in thousands):

Contractual Obligation	2004	2005	2006	2007	Total
Capital leases	$ 279	$ —	$—	$—	$ 279
Operating leases*	1,483	739	—	—	2,222
Other contractual obligations**	1,132	80	—	—	1,212
Total	$2,894	$819	$—	$—	$3,713

* We believe that we will either extend our current real estate leases or enter into leases with similar terms and conditions in the future.

** Includes contracts to purchase product candidate materials 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.

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 as described below. These transactions represent 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 have no subsidiaries or other unconsolidated limited purpose entities, and we have not guaranteed or otherwise supported the obligations of any other entity.

In September 2001 and April 2002, we entered into derivative transactions with a financial institution that could have been settled by selling up to 307,000 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 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. These contracts were expected to be settled by issuing shares of our stock in the event the options were exercised. These agreements expired unexercised. We received approximately $344,000 and $388,000 in 2001 and 2002, respectively, in proceeds for the sale of these call options that were 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.

Trimeris 401(k) Plan

We have a 401(k) Profit Sharing Plan (the "Plan") covering all qualified employees. Employees may elect a salary reduction from 1% to 75% as a contribution to the Plan, up to the annual Internal Revenue Service allowable contribution limit. Employee contributions may not be invested in Trimeris stock. The Plan permits us to match employees' contributions. Beginning in 1998, we matched up to 100% of an employee's annual contributions with Trimeris stock, provided the employee was employed on the last day of the year. The number of shares issued is based on the employee's contributions to be matched divided by the closing price of Trimeris stock on the last trading day of the year. At December 31, 2003, there were approximately 47,000 shares of our stock held by the Plan. These shares vest ratably based on a participant's years of service and are fully vested after four years of service. Employees may sell their vested shares at any time, subject to applicable laws and the requirements of our insider trading policy, and reinvest the proceeds in the other investment options available within the Plan.

On October 17, 2003, Plan participants were notified of a change to the provider for our Plan that was effective on December 1, 2003. As a result of this change, there was a temporary suspension of trading, or blackout period, in plan assets, including Trimeris stock held in the Plan. This blackout period began on November 21, 2003 and ended on January 16, 2004. As required by The Sarbanes-Oxley Act of 2002, directors and officers of Trimeris were prohibited during this blackout period from executing transactions involving or relating to any shares of Trimeris stock acquired in connection with their service or employment as a director or officer of Trimeris.

Net Operating Loss Carryforwards

As of December 31, 2003, we had a net operating loss carryforward of approximately $310.5 million. We have recognized a valuation allowance equal to the deferred asset represented by this net operating loss carryforward and other deferred tax assets, and therefore recognized no tax benefit. Our ability to utilize these net operating loss carryforwards may be subject to an annual limitation in future periods pursuant to the "change in ownership rules" under Section 382 of the Internal Revenue Code of 1986, as amended.

Accounting and Other Matters

SFAS No. 143, "Accounting for Asset Retirement Obligations", addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement cost. This standard requires us to record the fair value of an asset retirement obligation as a liability in the period in which we incur a legal obligation associated with the retirement of tangible long-lived assets that results from the acquisition, construction, development and/or normal use of the assets. We also are required to record a corresponding increase to the carrying amount of the related long-lived asset and to depreciate that cost over the life of the asset. The liability is changed at the end of each period to reflect the passage of time and changes in the estimated future cash flows underlying the initial fair value measurement. This statement is effective for the fiscal years beginning after June 15, 2002. The adoption of SFAS No. 143 had no impact on our financial statements.

SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities", was issued in July 2002, and addresses financial accounting and reporting for costs associated with exit or disposal activities. It nullifies EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." SFAS No. 146 requires that a liability be recognized for costs associated with an exit or disposal activity only when the liability is incurred. SFAS No. 146 also establishes fair value as the objective for initial measurement of liabilities related to exit or disposal activities. The statement is effective for exit or disposal activities that are initiated after December 31, 2002. We believe that this standard will have no impact on our financial statements.

SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure, an amendment of FASB Statement No. 123" was issued in December 2002. This Statement amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements. Certain of the disclosure modifications are required for fiscal years ending after December 15, 2002 and are included in the notes to our financial statements.

SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities", amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, collectively referred to as derivatives, and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003, except certain hedging relationships designated after June 30, 2003, as defined in SFAS No. 149. In addition, except as defined in SFAS No. 149, all provisions of SFAS No. 149 should be applied prospectively. The adoption of SFAS No. 149 had no impact on our financial statements.

SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity", was issued in May 2003. SFAS No. 150 establishes standards for how we classify and measure certain financial instruments with characteristics of both liabilities and equity. It requires us to classify a financial instrument that is within its scope as a liability or an asset in some circumstances. Many of those instruments were previously classified as equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003, except for mandatorily redeemable financial instruments of nonpublic entities. It is to be implemented by reporting the cumulative effect of a change in an accounting principle for financial instruments created before the issuance date of SFAS No. 150 and still existing at the beginning of the interim period of adoption. Restatement is not permitted. The adoption of SFAS No. 150 had no impact on our financial statements.

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. We do not believe that adoption of EITF 00-21 will have a material 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).

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, 2003. 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.

	Carrying Amount	Average Interest Rate
	(thousands)	
Cash equivalents—fixed rate	$85,117	1.23%
Short-term investments—fixed rate	6,484	1.35%
Overnight cash investments—fixed rate	597	0.25%
Total investment securities	$92,198	1.23%

In September 2001 and April 2002, we entered into a series of call transactions with respect to our common stock. These transactions are described in detail under Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations—Off Balance Sheet Transactions." Derivative transactions relating to 107,000 of these shares expired unexercised in September 2002. Derivative transactions relating to the remaining 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

Our Chief Executive Officer and Chief Financial Officer reviewed and evaluated the effectiveness of the design and operation of our disclosure controls and procedures, with the participation of the Company's management as of December 31, 2003. Disclosure controls and procedures are controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. In designing and evaluating the disclosure controls and procedures, the Company and its management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Based on their required evaluation, our Chief Executive Officer and Chief Financial Officer have each concluded that our disclosure controls and procedures are effective as of December 31, 2003.

There were no changes in our internal control over financial reporting identified in connection with the evaluation that have materially affected, or are reasonably likely to materially affect our internal control. Internal controls are designed with the objective of providing reasonable assurance that (1) our transactions are properly authorized; (2) our assets are safeguarded against unauthorized or improper use; and (3) our transactions are properly recorded and reported, all to permit the preparation of our financial statements in conformity with generally accepted accounting principles.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by Item 10 as to directors and executive officers 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 ACCOUNTING 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, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

The following documents are filed as part of this report:

(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 14(c) of Form 10-K.

(b) Reports on Form 8-K

We furnished a report on Form 8-K on October 16, 2003 under Item 12 attaching a press release announcing our financial results for the third quarter of 2003.

We furnished a report on Form 8-K on October 17, 2003 under Item 12 attaching the transcript of our conference call held on October 15, 2003.

We filed a report on Form 8-K on October 21, 2003 under Item 11 attaching a press release describing a blackout period for the Trimeris, Inc. Employee 401 (k) Plan.

We filed a report on Form 8-K on October 27, 2003 under Item 5 attaching a press release providing information on additional analysis of 48-week data from clinical trials of Fuzeon.

We filed a report on Form 8-K on December 16, 2003 under Item 5 attaching a press release announcing the submission of 48-week data to the FDA seeking full approval of Fuzeon.

We filed a report on Form 8-K on December 19, 2003 under Item 11 announcing the temporary suspension of trading under the Trimeris, Inc. Employee 401(k) Plan.

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INDEPENDENT AUDITORS' REPORT

The Board of Directors and Stockholders of Trimeris, Inc.:

We have audited the accompanying balance sheets of Trimeris, Inc. (the "Company") as of December 31, 2002 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, 2003. 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 auditing standards generally accepted in the United States of America. 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, 2002 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, 2003, in conformity with accounting principles generally accepted in the United States of America.

/s/ KPMG LLP

Raleigh, North Carolina
February 3, 2004

TRIMERIS, INC.

BALANCE SHEETS
(in thousands, except par value)

	As of December 31, 2002	As of December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 119,729	$ 85,714
Short-term investments	29,453	6,484
Accounts receivable	1	1
Prepaid expenses	1,130	2,105
Total current assets	150,313	94,304
Property, furniture and equipment, net of accumulated depreciation and amortization of $8,695 and $10,306 at December 31, 2002 and 2003, respectively	2,816	2,578
Other assets:		
Patent costs, net of accumulated amortization of $125 and $196 at December 31, 2002 and 2003, respectively	1,245	1,650
Equipment deposits	165	68
Total other assets	1,410	1,718
Total assets	$ 154,539	$ 98,600
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,492	$ 893
Accounts payable—Roche	15,249	11,029
Current installments of obligations under capital leases	694	274
Accrued compensation	2,967	1,739
Deferred revenue—Roche	620	3,954
Accrued expenses	902	674
Total current liabilities	21,924	18,563
Obligations under capital leases, excluding current installments	321	—
Deferred revenue—Roche	2,167	11,369
Total liabilities	24,412	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, 2002 and 2003	—	—
Common Stock at $0.001 par value per share, authorized 60,000 shares; issued and outstanding 21,366 and 21,573 shares at December 31, 2002 and 2003, respectively	21	22
Additional paid-in capital	395,536	398,925
Accumulated deficit	(264,573)	(330,276)
Deferred compensation	(824)	—
Accumulated other comprehensive income (loss)	(33)	(3)
Total stockholders' equity	130,127	68,668
Commitments and contingencies		
Total liabilities and stockholders' equity	$ 154,539	$ 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,		
	2001	2002	2003
Revenue:			
Milestone revenue	$ 1,304	$ 1,133	$ 2,964
Royalty revenue	—	—	755
Total revenue	1,304	1,133	3,719
Operating expenses:			
Collaboration loss	—	—	25,515
Marketing expense	3,825	16,722	—
Research and development:			
Non-cash compensation	(969)	250	(1)
Other research and development expense	59,409	50,976	36,824
Total research and development expense	58,440	51,226	36,823
General and administrative:			
Non-cash compensation	1,905	1,645	767
Other general and administrative expense	8,048	9,340	7,810
Total general and administrative expense	9,953	10,985	8,577
Total operating expenses	72,218	78,933	70,915
Operating loss	(70,914)	(77,800)	(67,196)
Other income (expense):			
Interest income	4,362	2,230	1,534
Interest expense	(189)	(108)	(41)
	4,173	2,122	1,493
Net loss	$(66,741)	$(75,678)	$(65,703)
Basic and diluted net loss per share	$ (3.96)	$ (3.93)	$ (3.06)
Weighted average shares used in per share computations	16,870	19,272	21,460

See accompanying notes to financial statements.

TRIMERIS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2001, 2002, and 2003
(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, 2000	—	—	15,863	$16	$196,844	$(122,154)	$(1,394)	$ 76	$ (9)	$ 73,379
Loss for the year	—	—	—	—	—	(66,741)	—	—	—	(66,741)
Unrealized gain on available for sale securities	—	—	—	—	—	—	—	113	—	113
Comprehensive (loss) income for period									—	(66,628)
Issuance of shares in private placement, net	—	—	1,396	1	43,384	—	—	—	—	43,385
Exercise of stock options	—	—	127	—	1,249	—	—	—	—	1,249
Issuance of stock for 401 (K) match		—	10	—	481	—	—	—	—	481
Issuance of stock under Employee Stock Purchase Plan	—	—	18	—	348	—	—	—	—	348
Proceeds from sale of call options	—	—	—	—	344	—	—	—	—	344
Amortization of deferred compensation (reversal of compensation expense)	—	—	—	—	(1,254)	—	2,190	—	—	936
Deferred compensation recorded for consultant that became an employee	—	—	—	—	3,329	—	(3,329)	—	—	—
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	—	—	—	—	79
Restricted stock grant	—	—	3	—	164	—	(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

See accompanying notes to financial statements.

TRIMERIS, INC.

STATEMENTS OF CASH FLOWS
(in thousands)

	For the years ended December 31,		
	2001	2002	2003
Cash flows from operating activities:			
Net loss	$ (66,741)	$ (75,678)	$ (65,703)
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation and amortization of property, furniture and equipment	1,870	1,912	1,615
Non-cash compensation expense	936	1,895	766
Amortization of deferred revenue—Roche	(1,304)	(1,133)	(2,964)
Other amortization	43	37	71
401 (K) plan stock match	481	662	724
Restricted stock donation	—	79	—
Patent costs expensed	—	677	424
Decrease (increase) in assets:			
Accounts receivable and loans to employees	2	1	—
Prepaid expenses	39	(776)	(975)
Other assets	60	30	97
Increase (decrease) in liabilities:			
Accounts payable	(782)	(1,202)	(599)
Accounts payable—Roche	3,313	2,380	(4,220)
Accrued compensation	689	919	(1,228)
Accrued expenses	773	(2,775)	(228)
Deferred revenue—Roche	—	—	15,500
Net cash used by operating activities	(60,621)	(72,972)	(56,720)
Cash flows from investing activities:			
Purchase of property, furniture and equipment	(1,666)	(949)	(1,377)
Sales of short-term investments	—	1,100	—
Purchases of short-term investments	(102,997)	(67,991)	(12,725)
Maturities of short-term investments	112,623	89,728	35,724
Patent costs	(633)	(445)	(900)
Net cash provided by investing activities	7,327	21,443	20,722
Cash flows from financing activities:			
Principal payments under capital lease obligations	(1,093)	(927)	(741)
Proceeds from issuance of Common Stock, net	43,385	147,491	—
Proceeds from sale of call options	344	388	—
Proceeds from exercise of stock options	1,249	1,508	2,244
Employee stock purchase plan stock issuance	348	501	480
Repayment of notes receivable from stockholders	—	9	—
Net cash provided by financing activities	44,233	148,970	1,983
Net increase (decrease) in cash and cash equivalents	(9,061)	97,441	(34,015)
Cash and cash equivalents at beginning of year	31,349	22,288	119,729
Cash and cash equivalents at end of year	$ 22,288	$119,729	$ 85,714
Supplemental disclosure of cash flow information:			
Cash paid during the period for interest	$ 189	$ 108	$ 41

See accompanying 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 during the year ended December 31, 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.

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 $119.7 million and $85.7 million at December 31, 2002 and 2003, 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. Cash equivalents at December 31, 2002 includes $13.5 million of amounts due from a financial institution for securities matured before December 31, 2002 and settled on January 2, 2003. The carrying amount of cash and cash equivalents approximates fair value.

Short-Term Investments

Short-term investments, which consist of short-term debt securities, commercial paper and federal agency securities, are classified as available-for-sale securities, 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 short-term investments held by the Company include accounts receivable, notes receivable, 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 $1.2 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. There were no impairments identified during 2001. During 2002 and 2003, $677,000 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.

Milestone Revenue and Deferred Revenue—Roche

The $10 million license fee and milestone payments of $15 million received under our collaboration with Roche were recorded as deferred revenue when received and recognized as milestone revenue ratably over the remainder of the research and development period. A $2.5 million milestone related to manufacturing was recorded as deferred revenue when received and is being amortizing over the expected commercial life of Fuzeon. Deferred revenue—Roche represents license and milestone payments received to be recognized as revenue in future periods.

During the fourth quarter of 2002, we increased our estimate of the length of the research and development period based on the expected development schedule of T-1249, the final compound covered by our collaboration agreement with Roche. Our expectations at that time for development of T-1249 would result in the end of the development period ranging from late 2005 to mid 2007. As a result of the change in our estimate of the length of the research and development period during the fourth quarter of 2002, we recognized $171,000 less in revenue in 2002 than we would have, had the period remained unchanged.

During the first quarter of 2004, we put future clinical development of T-1249 on hold. As a result, we increased our estimate of the length of the research and development period for our Roche collaboration to 2010 based on an estimate of the development period for T-1249 or another development compound that may be substituted under our collaboration agreement. As a result, revenue recognized related to these payments in 2004 is expected to be approximately $900,000 less than the amount recognized for the year ended 2003.

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 $755,000 were recognized as revenue during the year ended December 31, 2003.

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. Collaboration 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 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 $28.3 million during the year ended December 31, 2003. During 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 $25.5 million. Roche has entered into an exclusive distribution arrangement with Chronimed, Inc. ("Chronimed") to distribute Fuzeon in the United States. This exclusive arrangement terminates on March 27, 2004, unless renewed at Roche's option. Additional specialty distributors are currently being evaluated to expand the distribution and commercial availability of Fuzeon in the United States during 2004. Revenue from product sales is recognized when title and risk of loss has passed to Chronimed, which is when Chronimed allocates drug for shipment to a patient.

Research and Development

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

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 carryforwards. 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; our estimate of sales returns and allowances, discounts and rebates related to sales of Fuzeon; our estimate of losses incurred related to unusable product and supplies; and our 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, and stock warrants, would have an antidilutive effect. At December 31, 2001, 2002 and 2003, there were 2,161,000, 2,484,000 and 2,701,000 options to purchase common stock outstanding, respectively. At December 31, 2001, 2002 and 2003 there was a warrant outstanding 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.

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.

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):

	2001	2002	2003
Net loss:			
As reported	$(66,741)	$(75,678)	$(65,703)
Compensation cost recorded under APB 25	2,190	1,873	824
Compensation cost resulting from common stock options, restricted stock and employee stock purchase plan	(12,174)	(11,833)	(13,813)
Pro forma	$(76,725)	$(85,638)	$(78,692)
Basic and diluted loss per share:			
As reported	$ (3.96)	$ (3.93)	$ (3.06)
Pro forma	$ (4.55)	$ (4.44)	$ (3.67)

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:

	2001	2002	2003
Estimated dividend yield	0.00%	0.00%	0.00%
Expected stock price volatility	50.0%	45.0%	50.0%
Risk-free interest rate	4.00%	4.00%	3.50%
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.

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 drug candidates 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.

Barring unforeseen developments, 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 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 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 and T-1249, 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 until such time, if ever, as we are able to generate significant funds from operations.

2. SHORT-TERM INVESTMENTS

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, 2002				
Corporate debt securities, maturing in less than 1 year	$13,927	$13	$13	$13,927
Other debt securities, maturing in less than 1 year	3,506	3	—	3,509
Other debt securities, maturing in 3.3 years	2,000	—	27	1,973
Federal agency securities, maturing in less than 1 year	8,051	2	12	8,041
Federal agency securities, maturing in 1 year	2,002	1	—	2,003
	$29,486	$19	$52	$29,453
December 31, 2003				
Corporate debt securities, maturing in less than 1 year	$ 6,487	$ —	$ 3	$ 6,484

There were no sales of these investments or realized gains or losses during 2001 or 2003. There were sales of $1.1 million of investments in 2002, with a gross realized gain of $3,000 and a gross realized loss of $3,000.

3. LEASES

The Company is obligated under various capital leases for furniture and equipment that expire at various dates during the next three years. 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, 2002 and 2003 (in thousands):

	2002	2003
Furniture and equipment	$ 2,999	$ 1,268
Less accumulated amortization	(2,519)	(1,173)
	$ 480	$ 95

The Company also has several non-cancelable operating leases, primarily for office space and office equipment, that extend through September 2005. Rental expense, including maintenance charges, for operating leases during 2001, 2002 and 2003 was $1.0 million, $1.7 million, and $1.7 million respectively.

Future minimum lease payments under non-cancelable operating leases (with initial or remaining lease terms in excess of one year) and future minimum capital lease payments as of December 31, 2003 (in thousands) are:

	CAPITAL LEASES	OPERATING LEASES
Year ending December 31:		
2004	$279	$1,483
2005	—	739
2006	—	—
Total minimum lease payments	279	$2,222
Less amount representing interest	5	
Present value of net minimum capital lease payments	274	
Less current installments of obligations under capital leases	274	
Obligations under capital leases, excluding current installments	$ —	

4. PROPERTY, FURNITURE AND EQUIPMENT

Property, furniture and equipment consists of the following at December 31, 2002 and 2003 (in thousands):

	2002	2003
Furniture and equipment	$ 7,695	$ 10,733
Leasehold improvements	817	883
Furniture and equipment under capital lease	2,999	1,268
	11,511	12,884
Less accumulated depreciation and amortization	(8,695)	(10,306)
	$ 2,816	$ 2,578

5. STOCKHOLDERS' EQUITY

Offerings of Common Stock

In May 2001, the Company closed a private placement of approximately 1.4 million shares of common stock at $33.00 per share. The net proceeds of the offering were approximately $43.4 million after deducting applicable issuance costs and expenses of approximately $2.7 million.

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 September 2001 and April 2002, the Company entered into derivative transactions with a financial institution that could have been settled by selling up to a total of 307,000 shares of its stock to the financial institution at prices significantly higher than the market price per share of the Company's stock at the inception of the transaction. The Company received approximately $344,000 and $388,000, respectively, 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. Derivative transactions relating to 107,000 of these shares expired unexercised in September 2002. Derivative transactions relating to the remaining 200,000 shares expired unexercised in April 2003.

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, 2003, there were approximately 1,384,000 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, 2001, 2002 and 2003 are as follows:

	2001	Weighted Average Exercise Price	2002	Weighted Average Exercise Price	2003	Weighted Average Exercise Price
Options outstanding at January 1	1,817,000	$22.19	2,161,000	$27.12	2,484,000	$31.32
Granted	578,000	40.22	499,000	43.30	472,000	40.74
Exercised	(127,000)	9.82	(155,000)	9.75	(156,000)	14.35
Cancelled	(107,000)	34.73	(21,000)	42.07	(99,000)	47.01
Options outstanding at end of period	2,161,000	$27.12	2,484,000	$31.32	2,701,000	$33.38

The following summarizes information about stock options outstanding as of December 31, 2003:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number Outstanding as of 12/31/03	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.34-1.00	100,000	2.70	$ 0.48	100,000	$ 0.48
$5.88-8.00	192,000	4.30	$ 7.87	192,000	$ 7.87
$9.00-11.625	460,000	5.30	$11.63	460,000	$11.63
$11.626-20.00	162,000	5.65	$16.54	162,000	$16.54
$20.01-40.00	314,000	8.16	$30.37	147,000	$31.74
$40.00-45.11	731,000	8.27	$42.82	461,000	$43.19
$45.11-50.00	465,000	8.10	$47.71	193,000	$48.22
$50.00-78.50	277,000	6.56	$63.40	203,000	$63.50
$0.34-78.50	2,701,000	6.90	$33.38	1,918,000	$29.37

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. In 2001, the Company recorded a deferred charge of $3,329,000 representing the difference between the fair value of the Company's Common Stock on the date a former consultant became an employee, and the exercise price of the Common Stock Options held at that date. In 2002, the Company recorded a deferred charge of $164,000 representing the fair value of restricted common stock granted to an employee.

Compensation expense for employee stock options was approximately $2.2 million, $1.9 million and $767,000 for 2001, 2002 and 2003, 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 $1.3 million and $58,000 for the years ended December 31, 2001 and 2003, respectively, was recorded as a decrease to additional paid-in capital.

7. INCOME TAXES

At December 31, 2003, the Company has net operating loss carryforwards (NOLs) for federal and state income tax purposes of approximately $310.5 million which expire in varying amounts between 2008 and 2023. The Company has research and development credits of $8.2 million which expire in varying amounts between 2008 and 2023.

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

The components of deferred tax assets and deferred tax liabilities as of December 31, 2002 and 2003 are as follows (in thousands):

	2002	2003
Deferred tax assets:		
Tax loss carryforwards	$ 98,041	$ 119,906
Tax credits	6,645	8,242
Deferred revenue	1,073	5,918
Reserves and accruals	3,630	3,527
Total gross deferred tax assets	109,389	137,593
Valuation allowance	(109,389)	(137,593)
Net deferred asset	—	—
Deferred tax liabilities:		
Deferred tax liability	—	—
Net deferred tax assets (liability)	$ —	$ —

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 $27.6 million, $32.6 million, and $28.2 million for the years ended December 31, 2001, 2002 and 2003, respectively.

The reasons for the difference between the actual income tax benefit for the years ended December 31, 2001, 2002 and 2003 and the amount computed by applying the statutory federal income tax rate to losses before income tax benefit are as follows (in thousands):

	2001	% of Pre-tax Loss	2002	% of Pre-tax Loss	2003	% of Pre-tax Loss
Income tax benefit at statutory rate	$(22,692)	(34.00)%	$(25,730)	(34.00)%	$(22,339)	(34.00)%
State income taxes, net of federal benefit	—	—	—	—	—	—
Non-deductible meals and entertainment expenses	13	0.02%	14	0.02%	14	0.02%
Non-deductible compensation	745	1.12%	600	0.79%	261	0.40%
Generation of research credit	(2,162)	(3.24)%	(2,280)	(3.01)%	(1,597)	(2.43)%
Change in federal portion of valuation allowance	24,096	36.10%	27,396	36.20%	23,661	36.01%
Income tax benefit	$ —	—	$ —	—	$ —	—

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 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 2001, 10,000 shares were issued, and compensation expense of $481,000 was recognized. During 2002, 15,000 shares were issued, and compensation expense of $662,000 was recognized. During 2003, 35,000 shares were issued, and compensation expense of $724,000, 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 18,000, 14,000, and 16,000 shares were issued under this plan in 2001, 2002, and 2003, respectively. At December 31, 2003 there were 111,000 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, currently 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 2001, 2002 and 2003 consisted of the following (in thousands):

	2001	2002	2003
Service cost	$ 7	$17	$29
Interest cost	1	3	6
Recognized net actuarial loss	—	—	1
Amortization of prior service costs	2	3	3
Total	$10	$23	$39

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

	2002	2003
Accumulated post-retirement benefit obligation	$(74)	$(137)
Unrecognized prior service cost	33	29
Unrecognized net loss	8	36
Accrued post-retirement benefit cost	$(33)	$ (72)

The accumulated post-retirement benefit obligation was determined using a discount rate of 6.75% and 6.25% at December 31, 2002 and 2003, respectively. A change in the assumed medical care cost trend rate or the discount rate does not affect the accumulated post-retirement benefit obligation since the benefit is a fixed contribution amount by the Company.

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 equally 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 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, and a $2.5 million milestone in June 2003. Roche will provide up to an additional $40.5 million in cash upon achievement of developmental, regulatory and commercial milestones. This agreement with Roche grants them an exclusive, world-wide 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.

Under provisions of this agreement, the Company expects its contribution to the selling and marketing expenses for Fuzeon in 2004 to be approximately $10 million, even though Roche expects to spend significantly more on these expenses. If certain cumulative levels of sales for Fuzeon are achieved in the United States and Canada, the Company's share of any additional expenses incurred by Roche during 2004 will be payable to Roche at a future date over several years.

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 at December 31, 2003. 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. 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 10 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 equally fund worldwide research, development and commercialization costs, as well as share equally in 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.

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. In December 2003, Neokimia merged with Tranzyme, Inc. ("Tranzyme") and Tranzyme acquired Neokimia's rights and obligations under the April 2002 agreement. Array and Tranzyme will be entitled to receive payments and royalties based on achievement of certain developmental and commercial milestones.

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 $179,000 were expensed during 2003.

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, 2003, the Company had commitments of approximately $1.2 million to purchase product candidate materials and fund various clinical studies over the next fifteen 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 equally the future development expenses for Fuzeon and T-1249 for the United States and Canada.

12. REDUCTION IN WORKFORCE

During January of 2004, we put future clinical development of T-1249 on hold. In connection with this programmatic change, the Company reduced its workforce by approximately 25%. Severance and other related costs of approximately $600,000 will be charged to expense in the first quarter of 2004.

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 12, 2004

/s/ DANI P. BOLOGNESI

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

Signature	Capacity	Date
/s/ DANI P. BOLOGNESI Dani P. Bolognesi, Ph.D.	Chief Executive Officer (principal executive officer), Chief Scientific Officer and Director	March 12, 2004
/s/ ROBERT R. BONCZEK Robert R. Bonczek	Chief Financial Officer and General Counsel (principal financial officer)	March 12, 2004
/s/ M. NIXON ELLIS M. Nixon Ellis	President	March 12, 2004
/s/ TIMOTHY J. CREECH Timothy J. Creech	Vice President of Finance and Secretary (principal accounting officer)	March 12, 2004
/s/ JEFFREY M. LIPTON Jeffrey M. Lipton	Chairman of the Board of Directors	March 12, 2004
/s/ E. GARY COOK E. Gary Cook, Ph.D.	Director	March 12, 2004
/s/ CHARLES A. SANDERS Charles A. Sanders, M.D.	Director	March 12, 2004
/s/ J. RICHARD CROUT J. Richard Crout, M.D.	Director	March 12, 2004
/s/ KEVIN C. TANG Kevin C. Tang	Director	March 12, 2004

EXHIBIT INDEX

(a) Exhibits

3.1 *	Amended and Restated Bylaws of the Registrant.
3.2[f]	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 *	Cooperation and Strategic Alliance Agreement dated April 21, 1997, between the Registrant and MiniMed Inc.
10.3[j]	Trimeris, Inc. Amended and Restated Stock Incentive Plan.
10.4 *	Trimeris, Inc. Employee Stock Purchase Plan.
10.5 *	Sixth Amended and Restated Registration Rights Agreement dated June 27, 1997, by and among the Registrant and certain stockholders of the Registrant.
10.6 *	Form of Indemnification Agreements.
10.7 *	License Agreement dated September 9, 1997 between the Registrant and The New York Blood Center.
10.8[a]	Master Lease Agreement dated May 28, 1998 between the Company and Finova Technology Finance, Inc.
10.9[m]	Poyner & Spruill, L.L.P. Defined Contribution Prototype Plan and Trust for the Trimeris, Inc. Employee 401(k) Plan.
10.10[m]	Adoption Agreement for the Trimeris, Inc. Employee 401(k) Plan.
10.11[b]	Chief Executive Employment Agreement between Trimeris and Dani P. Bolognesi dated April 21, 1999.
10.12[c]	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.).
10.13[c]	Financing Agreement between Trimeris, Inc. and Roche Finance Ltd. dated as of July 9, 1999.
10.14[c]	Registration Rights Agreement between Trimeris, Inc. and Roche Finance Ltd. dated as of July 9, 1999.
10.15[c]	Lease between Trimeris, Inc. and University Place Associates dated April 14, 1999.
10.16[c]	Sublease Agreement between Trimeris, Inc. and Blue Cross and Blue Shield of North Carolina dated May 15, 1999.
10.17[c]	Lease Agreement between Hamad Jassim Althani and Blue Cross and Blue Shield of North Carolina, relating to Sublease Agreement filed as Exhibit 10.21 hereto.
10.18[d]	Executive Agreement between Trimeris and Robert R. Bonczek dated January 7, 2000.
10.19[e]	Employment Agreement between Trimeris, Inc. and M. Nixon Ellis dated March 31, 2000.
10.20[g]	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.).

10.21[h]	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.
10.22[l]	Lease Assignment and Modification Agreement dated as of September 27, 2001 between Trimeris, Inc., Blue Cross and Blue Shield of North Carolina, and Hamad Jassim Althani.
10.23[l]	Third Amendment to Lease dated as of November 30, 2001 between Hamad Jassim Althani and Trimeris, Inc.
10.24[m]	Fourth Amendment to Lease dated as of February 28, 2003 between Hamad Jassim Althani and Trimeris, Inc.
10.25[l]	Sublease Agreement dated as of December 14, 2001 between Trimeris, Inc. and Triangle Pharmaceuticals, Inc.
10.26[l]	Second Amendment dated as of January 21, 2002 between University Place Properties, LLC and Trimeris, Inc.
10.27[i]	Form of Equity Option Confirmation for Call Transaction.
10.28[k]	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.
10.29[n]	Third Amendment of Lease between University Place Properties, LLC and Trimeris, Inc. dated May 28, 2003
10.30	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.).
10.31	Amendment to the Development and License Agreement by and between Trimeris, Inc. and F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. dated January 4, 2004 (Portions of this exhibit have been omitted pursuant to a request for confidential treatment filed with the Commission.).
10.32	Agreement of Sublease by and between Gilead Sciences, Inc. and Trimeris, Inc.
23	Consent of KPMG LLP.
31.1	Rule 13a-14(a) Certification by Dani P. Bolognesi 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 Dani P. Bolognesi as Chief Executive Officer
32.2	Section 1350 Certification by Robert R. Bonczek as Chief Financial Officer

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* *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 June 30, 1998.

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

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

(d) Incorporated by reference to Trimeris' Annual Report on Form 10-K for the year ended December 31, 1999 filed with the Commission on March 29, 2000.

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

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

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

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

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

(j) Incorporated by reference to Trimeris' Registration Statement on Form S-8 filed with the Commission on November 30, 2001.

(k) Incorporated by reference to Trimeris' Current Report on Form 8-K filed with the Commission on January 30, 2002.
(l) 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.
(m) 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.
(n) Incorporated by reference to Trimeris' Quarterly Report on Form 10-Q for the quarter ended June 30, 2003.

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.

Exhibit 31.1

CERTIFICATION

I, Dani P. Bolognesi, certify that:

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

2. Based on my knowledge, this annual 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 annual report;

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

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

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 12, 2004

/s/ DANI P. BOLOGNESI

Dani P. Bolognesi
Chief Executive Officer

Exhibit 31.2

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 annual 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 annual report;

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

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

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 12, 2004

/S/ ROBERT R. BONCZEK

Robert R. Bonczek
Chief Financial Officer

Exhibit 32.1

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, 2003 as filed with Securities and Exchange Commission on the date hereof (the "Report"), I, Dani P. Bolognesi, 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 results of operations of the Company.

/s/ DANI P. BOLOGNESI
Dani P. Bolognesi

Chief Executive Officer
March 12, 2004

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.

A signed original of this written statement required by § 906 has been provided to Trimeris, Inc. and will be retained by Trimeris, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

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, 2003 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 results of operations of the Company.

/s/ ROBERT R. BONCZEK

Robert R. Bonczek

Chief Financial Officer
March 12, 2004

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.

A signed original of this written statement required by § 906 has been provided to Trimeris, Inc. and will be retained by Trimeris, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Annual Meeting of Shareholders

The Trimeris Annual Meeting of Shareholders will be held on June 22, 2004 at 9 a.m. at the North Carolina Biotechnology Center, 15 Alexander Drive, Research Triangle Park, North Carolina. All shareholders are cordially invited to attend.

Independent Auditors

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

Transfer Agent

EquiServe Trust Company, N.A.
P.O. Box 219045
Kansas City, MO 64121-9045
877.282.1168
www.equiserve.com

Legal Counsel

Wilmer Cutler Pickering 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.
5110 Westgate Drive, 3rd Floor
Durham, North Carolina 27707
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

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

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

J. Richard Crout, M.D.
President, Crout Consulting

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

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

Kevin C. Tang
Managing Director, Tang Capital Management LLC

Corporate Officers & Senior Management

Dani P. Bolognesi, Ph.D.
Chief Executive Officer, Chief Scientific Officer, and Director

Robert R. Bonczek
Chief Financial Officer, General Counsel

M. Nixon Ellis, Ph.D.
President

George W. Koszalka, Ph.D.
Senior Vice President, Corporate Strategy

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

Timothy J. Creech
Corporate Secretary, Vice President of Finance

Trademarks

FUZEON® is a registered trademark of Hoffmann-LaRoche Inc.
Trimeris and the Trimeris logo are registered trademarks of Trimeris, 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," "may," "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 manufacturing; 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 12, 2004 and its periodic reports filed with the SEC.

TRIMERIS
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