
TRIMERIS
trimeris | annual | report
2015

LETTER TO SHAREHOLDERS

Since our founding in 1993, Trimeris has remained focused on one goal: bringing novel antiviral therapies to patients in need. Over the past year, our team made significant advancements towards delivering on the promise of our world-class science. We are now on the brink of making our vision a reality.

We continue to aggressively pave the way towards commercialization of our innovative fusion inhibitor drugs, which work in a novel manner and offer the potential to help a growing population of HIV patients who have developed resistance to currently available therapies. In 2001, together with our partner F. Hoffmann-La Roche Ltd., we made substantial progress in the clinical development of T-20, our lead product candidate. We presented data at several high-profile scientific meetings throughout the year, demonstrating that T-20 continues to show consistent, impressive trends in safety, tolerability, and antiviral activity. T-20, which has received fast track designation from the United States Food and Drug Administration, is now in Phase III clinical trials, the final stage of testing before submitting the drug for regulatory approval in the second half of 2002. We are closer than ever to bringing this important new drug to market.

We are encouraged by the enthusiasm displayed for T-20 by physicians and patients. The percentage of patients who have grown resistant to their current therapies is growing rapidly; thirty to fifty percent of patients are infected with a strain of the virus that has developed resistance to one or more antiretrovirals, reducing the treatment options available to them. These patients are in desperate need of new treatment options and the medical community is hopeful that T-20 can offer just that.

T-1249, our second generation fusion inhibitor for the treatment of HIV, continues to show promise. A Phase I/II dose escalation study has generated encouraging results, and we plan to initiate Phase II clinical trials later this year. We are excited to take the lead in expanding this class of fusion inhibitors.

The production of T-20 requires an innovative, complex process to manufacture peptides on an unprecedented scale. The Trimeris/Roche collaboration has used its extensive expertise to develop a novel process that will allow us to meet the significant market demand for T-20 we currently anticipate. In July 2001, Trimeris' contributions in this arena were recognized with the awarding of the 2001 American Chemical Society's Southeastern Regional Industrial Innovation Award to Brian Bray, Ph.D., Senior Director of Process Research and Development. Dr. Bray received the award for his pioneering work in the synthesis of complex peptides. The work of Dr. Bray and his colleagues exemplifies the innovative spirit of Trimeris and has furthered our goal of bringing novel antiviral therapies to market.

I am also pleased to report that throughout 2001 we continued to make strides in expanding the applications of our proprietary fusion inhibition technology platform. We are committed to expanding our pipeline with products for additional viral applications both within and beyond HIV. To that end, in August 2001 we announced the signing of an agreement with Array BioPharma, Inc. to discover small molecule fusion inhibitors of HIV and respiratory syncytial virus (RSV). Additionally, we expanded our agreement with Roche to discover, develop and commercialize future generations of HIV peptide fusion inhibitors. By continuing to build a robust product pipeline, we are both driving shareholder value and offering hope to patients in need.

We significantly strengthened our financial position over the past year with successful fundraising efforts adding $84 million to our balance sheet. Despite challenging economic conditions, Trimeris was able to raise money that we anticipate will carry us through the completion of the regulatory filings for T-20 and support our ongoing Research & Development initiatives.

2002 will be a groundbreaking year for Trimeris as we continue to mature and begin to transition into a truly commercial biopharmaceutical company. Our talented team remains more committed and focused than ever on achieving our goal of launching an entirely new class of antiviral therapies desperately needed by patients. We plan to aggressively build on our past successes to make the future brighter for each Trimeris stakeholder - our patients, physicians, investors, employees and corporate partners. I thank you for your continued support of Trimeris and look forward to continuing our journey from vision to reality together.

DANI P. BOLOGNESI, PH.D.
CHIEF EXECUTIVE OFFICER AND CHIEF SCIENTIFIC OFFICER

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THE NEED FOR NEW HIV THERAPIES CONTINUES TO GROW

Although substantial progress has been made during the past fifteen years in the fight against HIV, a cure still eludes medical science. The ultimate goal of anti-HIV drug therapy is to prevent the virus from reproducing and damaging the immune system. All currently approved anti-HIV drugs work by entering HIV infected cells and blocking the function of a viral enzyme — either reverse transcriptase or protease. HIV needs both of these enzymes in order to reproduce. Today, physicians have more than a dozen antiretroviral agents in three different drug classes to manage the disease. Typically, drugs from two or three classes are prescribed in a variety of triple combinations. However, complex dosing regimens sometimes make patient compliance difficult.

The introduction of protease inhibitors and triple-class therapy revolutionized the treatment of HIV, dramatically improving the lives of HIV patients. But, many patients have developed viral resistance to at least one HIV drug — some exhausting all their options — creating an urgent need for new treatments. Unfortunately, when HIV becomes resistant to one drug in a class, other drugs in that class may become less effective. This phenomenon, known as cross-resistance, can further reduce the number of viable treatment options for patients.

Additionally, although combination therapy can be effective in reducing viral loads, many patients cannot tolerate the toxic side effects over the long-term. Some side effects are serious and include abnormal fat metabolism, kidney stones, and heart disease. Other side effects, such as nausea, vomiting, and insomnia, are less serious but still problematic for HIV patients on a lifetime of chronic drug therapy.

PROBLEMS WITH CURRENT HIV DRUG REGIMENS

- Complex Dosing Regimens
- Viral Resistance
- Cross-Resistance with other drugs
- Toxic Side Effects

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BLOCKING HIV FUSION STOPS HIV REPRODUCTION

HIV, like other viruses, is an infectious agent that lacks the ability to reproduce on its own. In order for HIV to reproduce, it must first invade a host CD4+ T cell — a critical component of the body's immune system. It then uses the cell's own machinery to make copies of itself. Viral replication typically results in the formation of billions of new viral particles and the death of the once healthy CD4+ T cell.

Scientists have determined that some viruses — including HIV — must undergo a complex process called fusion in order to enter the host cell and reproduce. During fusion, the outer membrane of the virus merges with the membrane of the CD4+ T cell. If HIV cannot undergo fusion, it cannot reproduce itself and subsequently kill the vital CD4+ T cell.

FUSION INHIBITORS | CLOSING THE DOOR ON HIV

Trimeris researchers are leading the discovery and development of peptide fusion inhibitors — drugs that block the viral fusion process and consequently, HIV reproduction. Fusion inhibitors function in a way that is completely different from all currently approved anti-HIV drugs. This unique "mechanism of action" offers the potential for the class to be effective against drug-resistant HIV strains. Unlike reverse transcriptase and protease inhibitors — which work inside a cell — fusion inhibitors function on the outside of a cell. By remaining outside and blocking HIV before it gains entry to the cell, fusion inhibitors are less likely to negatively interact with other drugs. This is a major advantage because it may decrease the likelihood of side effects, minimize drug-drug interactions, and simplify dosing.

POTENTIAL BENEFITS OF FUSION INHIBITORS

Novel Mechanism of Action

Potent against Drug-Resistant HIV Strains

Minimal Side Effects

Simplified Dosing

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FIRST IN CLASS | LATE STAGE DEVELOPMENT

T-20 is the first member of the new class of viral fusion inhibitors to be developed by Trimeris. This molecule, a 36 amino acid peptide, has shown significant promise in Phase I and II clinical testing. These studies suggest that T-20 is well-tolerated and may have potent antiviral activity. T-20 is currently in Phase III clinical trials, the final stage of testing before regulatory approval. To date, more than 1,000 patients have experience with T-20 as part of their drug regimens, and some have been on treatment with T-20 for more than three years.

T-20 HIGHLIGHTS

Phase III, pivotal trial program — the final stage of pre-approval clinical testing

Fast Track Designation by FDA — six-month review granted for products that may provide significant improvement for the treatment of serious or life threatening disease

Complementary with reverse transcriptase and protease inhibitors and lack of cross-resistance

Based on patient surveys, twice daily injections of T-20 did not substantially interfere with activities of daily living

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THE PROMISE OF EXPANDING HIV TREATMENT OPTIONS

T-1249 is the second fusion inhibitor in the Trimeris product development portfolio. This molecule, a 39 amino acid peptide, holds the promise of further expanding the treatment options for HIV patients. We are currently conducting Phase I/II clinical trials with T-1249 and plan to initiate a Phase II program in 2002.

T-1249 HIGHLIGHTS

Fast Track Designation by the FDA

Rationally designed in the laboratory to potentially improve dosing — binds to a slightly different region of HIV gp41 protein than T-20

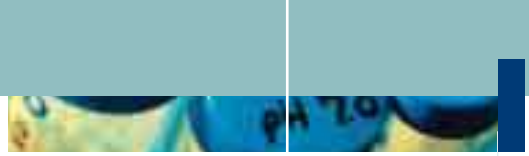
Potent HIV suppression in laboratory tests

May possess resistance profile distinct from currently approved anti-HIV drugs and T-20 (i.e. no cross-resistance)

RESEARCH PROGRAMS

Beyond our clinical drug candidates, T-20 and T-1249, Trimeris' research is focused on expanding the applications of our proprietary fusion inhibition technology platform. Trimeris hopes to discover longer-acting and more potent anti-HIV peptide fusion inhibitors and small molecules.

Through our study and knowledge of the HIV fusion process, Trimeris is investigating potential fusion targets in other viruses that rely on fusion to penetrate host cells. One such virus is the Respiratory Syncytial Virus (RSV). RSV affects children, the elderly and immuno-compromised people.



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THERAPEUTIC PEPTIDES

Proteins are among the most important molecules found in nature. Peptides, which are small versions of proteins, are composed of molecular building blocks called amino acids — linked together in long chains. Trimeris is a leader in the research and development of therapeutic peptides to treat human disease.

CREATING COMPETITIVE ADVANTAGE THROUGH RAPID PROCESS DEVELOPMENT

INVENTING THE FUTURE OF COMMERCIAL PEPTIDE MANUFACTURING

Several years ago it was considered impossible to commercially develop a therapeutic peptide — especially one as complex as T-20 — because the process of manufacturing the drug was simply uneconomical. Traditional methods of peptide synthesis — designed to make small quantities in the laboratory — were too wasteful, slow, and costly for commercial production. In addition, the highly specialized amino acids that serve as raw materials were never produced in the quantities required for T-20. Trimeris and Roche scientists are successfully tackling all of the T-20 manufacturing challenges with rapid innovation in chemical process development.

The complexity of T-20's molecular structure dwarfs other anti-HIV drugs. While large peptide molecules are used in very low doses to treat other diseases, the quantities of T-20 needed for commercial use are unprecedented in pharmaceutical history. As the most complex synthetic peptide ever manufactured on such a massive scale, T-20 presents an enormous challenge that requires the creation of an entirely new chemical process, utilizing manufacturing equipment and techniques never previously used.

THE BOTTOM LINE - WHAT IT TAKES TO MAKE T-20

Over 100 separate, precisely controlled chemical steps, whereas a typical protease inhibitor requires less than ten

44 different raw materials — about three times more than a typical drug — and many have never been produced on such a large scale

45,000 kilograms of raw materials are required to manufacture only 1,000 kilograms of T-20

Almost six months from the start of the manufacturing process to delivery of the final drug product

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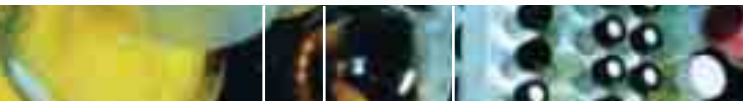
BREAKING NEW GROUND IN PHARMACEUTICAL MANUFACTURING

LARGE-SCALE CHEMICAL SYNTHESIS OF THERAPEUTIC PEPTIDES

With the impending commercial launch of T-20, the Trimeris/Roche alliance is clearly transforming the practice of clinical virology. However, the alliance is also creating a revolution in pharmaceutical manufacturing. Because of the large and growing number of HIV patients who are failing available medications, the worldwide demand for T-20 is expected to be significant. Meeting this demand will require the production of several metric tons of the peptide. This scale of chemical production of peptide is unparalleled in the history of pharmaceutical manufacturing.

To satisfy this worldwide need, Trimeris worked in collaboration with Roche scientists and engineers to design and build a state-of-the-art manufacturing plant at the Roche Colorado facility in Boulder, Colorado. Completed in 2001, this facility will be capable of producing several metric tons of therapeutic peptides on an annual basis.



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THE TRIMERIS / ROCHE STRATEGIC ALLIANCE

A POTENT COMBINATION

The process of taking a new drug from the laboratory to the market on a global scale is a challenge for every company in the pharmaceutical industry. To expedite the global development, approval and commercialization of T-20 and T-1249, Trimeris formed a strategic alliance with F. Hoffmann-La Roche, Ltd. — a global leader in HIV diagnostics and therapeutics. Roche brings its worldwide development expertise, marketing resources, manufacturing capability and financial strength to the collaboration. In June 2001, Trimeris and Roche expanded the scope of their HIV partnership beyond T-20 and T-1249. Together, we hope to discover longer-acting and more potent anti-HIV peptide fusion inhibitors.

THE ROCHE ADVANTAGE

Roche

Global clinical development capabilities needed to obtain marketing approvals in all major pharmaceutical markets

Highly trained and experienced team of HIV sales representatives and clinical support specialists

Outside of the collaboration, Roche markets an existing portfolio of anti-HIV products — Fortovase®, Invirase®, Hivid®, Viracept® (Europe)

Large-scale commercial manufacturing expertise and capacity

THE TRIMERIS / ARRAY BIOPHARMA COLLABORATION

In August 2001, Trimeris and Array BioPharma announced the signing of an agreement to discover small molecule fusion inhibitors of HIV and RSV. We will collaborate with Array to identify preclinical candidates that may supplement our own small molecule research program.

THE ARRAY BIOPHARMA ADVANTAGE

ARRAY BIOPHARMA

World-class scientific team with a track record of success in creating small molecule drugs

Drug discovery technologies integrating chemistry, biology and informatics

ANNUAL SHAREHOLDERS MEETING

The Trimeris Annual Shareholders Meeting will be held on June 26, 2002 at 2 p.m. at the North Carolina Biotechnology Center, 15 Alexander Drive, Research Triangle Park, North Carolina. All shareholders are cordially invited to attend.

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FINANCIAL AND OTHER INFORMATION

A copy of the Company's Annual Report filed with the Securities and Exchange Commission on Form 10-K is available to stockholders without charge. To obtain a copy contact:

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Electronic copies of the Annual Report and Form 10-K are also available at www.trimeris.com

Except for any historical information presented herein, matters presented in this annual report are forward-looking statements that involve risks and uncertainties. The results of the Company's previous clinical trials are not necessarilyindicative of future clinical trials, and future operating and clinical results could differ materially from the results presented herein. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors"section included in the Company's Form 10-K for the year ended December 31, 2001 filed with the Securities and Exchange Commission on March 25, 2002.

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