NORTHFIELD LABORATORIES INC /DE/
Form ARS
August 18, 2004

2004 Annual Report
FOR THE YEAR ENDED MAY 31, 2004

**We are the leader
in developing an oxygen-carrying blood substitute
for the treatment of urgent, large volume blood
loss in trauma and resultant surgical settings.**

PolyHeme® is a solution of chemically modified human hemoglobin that requires no cross-matching and is compatible with all blood types. It has a shelf-life of over 12 months.

A Message from the Chairman

It is with great pleasure that I report to you on the progress Northfield has made during fiscal 2004. By any measure, this was a year of significant clinical, regulatory and financial accomplishments for our Company.

The highlight of our year was the start of patient enrollment in our pivotal Phase III Ambulance Trial with PolyHeme® . We proudly announced the initiation of the first clinical trial site in late December meeting our stated goal of beginning the trial in 2003. Four sites were enrolling patients by the end of January, and six by April. New sites have continued to join the trial at a steady pace. As this letter is being written, there are 12 Level I trauma centers throughout the country enrolling patients, and an additional four that have received final IRB approval to begin what may well be one of the most logistically complex studies in the history of clinical trials. There were many skeptics who did not believe that this trial could ever be conducted. Northfield has proved them wrong.

Another significant achievement was reaching agreement with FDA on Special Protocol Assessment (SPA) for the PolyHeme® Ambulance Trial. SPA represents acknowledgment and confirmation of a mutual agreement between Northfield and FDA that the data from a successful trial will form the primary basis for an efficacy claim as part of a Biologics License Application. SPA provides us with the regulatory clarity we sought in our efforts to bring PolyHeme® to market.

We recently announced the result of the first of a planned series of interim analyses of the data from the trial. We were pleased to receive the recommendation of an independent data monitoring committee (IDMC) that the trial continue without modification after its initial review of blinded data on mortality and serious adverse events. This is a major achievement. It is a validation of the diligence and concern for patient safety that have characterized the conduct of this trial since its inception.

I am especially pleased to report that our financial position has improved dramatically during the past year. We raised just under $53 million from qualified and institutional investors in three registered direct stock offerings, and each transaction closed at a higher price per share. These financings accomplished a number of important goals: expansion of our institutional ownership, substantial improvement in the liquidity of our stock, and necessary funding for the trial and our ongoing operations.

Investors have become more confident in our future as well. The value of Northfield s stock more than doubled during fiscal 2004. For the past two consecutive quarters, Northfield has been among the biotech industry s top price performers according to *BioCentury.* As an additional measure of our improved status in the capital markets, we were added to the NASDAQ Biotech Index and to the Russell 3000 Index.

We had the opportunity to present Northfield s story to the investment community at a number of important investor conferences this year, including Rodman & Renshaw s Techvest Conferences in Boston and London, S.G. Cowen & Company s Healthcare Conference in Boston, and BioCentury s *Future Leaders in Biotech* and R.W. Baird s Small Cap Conference, both in New York. Increased visibility on Wall Street continues to be one of management s top priorities. To that end, we are in the process of updating our corporate image, including our investor materials such as this annual report and our Web site. This will make it easier for our shareholders and the public to find information about Northfield and PolyHeme® . The new Web site is scheduled to go live just prior to our annual meeting, which will take place on September 21, 2004.

In closing, 2004 was a highly productive and rewarding year for Northfield. Our accomplishments this year have indeed brought us closer to our ultimate goal of transforming the treatment of trauma. I want to personally recognize and express my sincere appreciation to Northfield s employees, whose incredible energy, initiative, and commitment have enabled us to make sustained progress this year. To be sure, the challenges that lie ahead are many before PolyHeme® becomes the standard of care in the early treatment of trauma. But our path is clear, and we remain

focused on successfully completing the ambulance trial and preparing for the commercialization of PolyHeme® .

Steven A. Gould, M.D.
Chairman of the Board and
Chief Executive Officer

Lastly, I want to thank our loyal shareholders for their continued support. I look forward to reporting continued good news to all of you in fiscal 2005.

Steven A. Gould, M.D.
Chairman of the Board and
Chief Executive Officer

Trauma
is the

leading cause of **death** in
Americans under the age of 45.

Many trauma victims bleed to death
before they have access to blood.

PolyHeme®
may address this critical, unmet
clinical need: the unavailability
of blood in

urgent,
life-threatening
blood loss.

The PolyHeme®
Ambulance
Study is a

landmark clinical trial.

The study is underway at Level I trauma centers across the United States.

The many potential clinical settings for the use of PolyHeme® represent a

substantial market opportunity.

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PolyHeme is a registered trademark
of Northfield Laboratories Inc.

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