

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

NORTHFIELD LABORATORIES INC /DE/

Form S-3

June 27, 2003

As filed with the Securities and Exchange Commission on June 27, 2003

Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

-----  
FORM S-3  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933  
-----

NORTHFIELD LABORATORIES INC.  
(Exact Name of Registrant as Specified in Its Charter)

DELAWARE  
(State or Other Jurisdiction of  
Incorporation or Organization)

36-3378733  
(I.R.S. Employer  
Identification Number)

1560 SHERMAN AVENUE  
SUITE 1000  
EVANSTON, ILLINOIS 60201-4800  
(847) 864-3500  
(Address, Including Zip Code, and Telephone Number, Including Area Code,  
of Registrant's Principal Executive Offices)

Jack J. Kogut  
Chief Financial Officer  
Northfield Laboratories Inc.  
1560 Sherman Avenue  
Suite 1000  
Evanston, Illinois 60201-4800  
(847) 864-3500  
(Name, Address, Including Zip Code, and Telephone Number,  
Including Area Code, of Agent For Service)

Copies to:

Craig A. Roeder, Esq.  
Baker & McKenzie  
One Prudential Plaza  
130 East Randolph Drive  
Chicago, Illinois 60601  
(312) 861-8000

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement as determined by market conditions and other factors.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. [ ]

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. [X]

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this form is a post-effective amendment filed pursuant to Rule (462) (c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. [ ]

CALCULATION OF REGISTRATION FEE

Title Of Shares To Be Registered	Proposed Maximum Aggregate Offering Price (1) (2)	Proposed Maximum Offering Price Per
Common Stock, par value \$.01 per share(3)	--	--
Preferred Stock, par value \$.01 per share (3)	--	--
Depository Shares(3)	--	--
Stock Purchase Contracts	--	--
Warrants(4)	--	--
Debt Securities	--	--
Total(5)	\$50,000,000 (6)	100%(3)

(1) Or (i) if any debt securities are issued at an original issue discount, such greater principal amount as will result in an aggregate initial offering price equal to the amount to be registered or (ii) if any debt securities are issued with a principal amount denominated in a foreign currency or composite currency, such principal amount as will result in an aggregate initial offering price equivalent thereto in United States dollars at the time of initial offering.

(2) These figures are estimates made solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, exclusive of accrued interest, if any, on the debt securities.

(3) In addition to any securities that may be registered hereunder, we are also registering an indeterminate number of shares of common stock, preferred stock, depository shares and debt securities as may be

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

issued upon conversion, exercise or exchange of the securities issued directly hereunder. No separate consideration will be received for any shares of common stock, preferred stock, depositary shares or debt securities so issued upon conversion, exercise or exchange.

- (4) Includes warrants to purchase common stock, preferred stock, depositary shares and debt securities.
- (5) We will determine the proposed maximum offering price per unit in connection with the issuance of the securities.
- (6) The securities registered hereunder may be sold separately or as units with other securities registered hereby. The aggregate amount of common stock registered hereunder is limited to that which is permissible under Rule 415(a) (4) under the Securities Act, to the extent applicable.

-----

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

[The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.]

Subject to Completion. Dated June 27, 2003.

Prospectus

\$50,000,000

NORTHFIELD LABORATORIES INC.

Common Stock

Preferred Stock

Depositary Shares

Stock Purchase Contracts

Warrants

Debt Securities

THE SECURITIES OFFERED BY THE PROSPECTUS INVOLVE A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 5.

We will provide you with the specific terms of the particular securities being offered in supplements to this prospectus. You should read this

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

prospectus and each related supplement carefully before you invest. This prospectus may not be used to sell securities unless accompanied by a prospectus supplement.

Our common stock is quoted on the Nasdaq Stock Market's National Market System under the symbol "NFLD." The last reported sale price of our common stock on June 24, 2003 was \$8.39 per share.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is June 27, 2003.

### TABLE OF CONTENTS

ABOUT THIS PROSPECTUS.....	
WHERE YOU CAN FIND MORE INFORMATION.....	
FORWARD-LOOKING INFORMATION.....	
OUR BUSINESS.....	
RISK FACTORS.....	
USE OF PROCEEDS.....	
RATIO OF EARNINGS TO FIXED CHARGES AND PREFERENCE DIVIDENDS.....	
DILUTION.....	
DESCRIPTION OF THE SECURITIES WE MAY OFFER.....	
PLAN OF DISTRIBUTION.....	
LEGAL MATTERS.....	
EXPERTS.....	
PART II. INFORMATION NOT REQUIRED IN PROSPECTUS.....	

### ----- ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, using a "shelf" registration process. Using this process, we may offer the securities described in this prospectus in one or more offerings with a total initial offering price of up to \$50,000,000 or an equivalent amount in one or more foreign currencies. We may sell these securities separately or in units. This prospectus provides you with a general description of the securities we may offer. Each time we offer securities, we will provide you a prospectus supplement that will contain information about the specific terms of that particular offering. The prospectus supplement may also add, update or change information contained in this prospectus. To obtain additional information that may be important to you, you

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

should read the exhibits filed by us with the registration statement of which this prospectus is a part or our other filings with the SEC. You also should read this prospectus and any prospectus supplement together with the additional information described below under "Where You Can Find More Information."

### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You can read and copy any materials we file with the SEC at its Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. You can obtain information about the operations of the SEC Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site that contains information we file electronically with the SEC, which you can access over the Internet at [www.sec.gov](http://www.sec.gov). You may also access the information we file electronically with the SEC through our website at [www.northfieldlabs.com](http://www.northfieldlabs.com).

2

The SEC allows us to "incorporate by reference" the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus, and later information that we file with the SEC will automatically update and supersede some of this information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 until we sell all of the securities covered by this prospectus. The documents we incorporate by reference are:

- our Annual Report on Form 10-K for the year ended May 31, 2002;
- our Quarterly Reports on Form 10-Q for the quarters ended August 31, 2002, November 30, 2002 and February 28, 2003; and
- the description of our common stock contained in our Registration Statement on Form 8-A, Registration No. 33-76856, filed with the SEC on March 24, 1994, including any amendments or reports filed for the purpose of updating this description.

You may request a copy of these filings (other than an exhibit to the filings unless we have specifically incorporated that exhibit by reference into the filing), at no cost, by writing or telephoning us at the following address:

Northfield Laboratories Inc.  
1560 Sherman Avenue  
Suite 1000  
Evanston, Illinois 60201-4800  
(847) 864-3500

You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. We have not authorized anyone else to provide you with different information. We may only use this prospectus to sell securities if it is accompanied by a prospectus supplement. We are only offering the securities in states where the offer is permitted. You should not assume that the information in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front of those documents.

### FORWARD-LOOKING INFORMATION

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

This prospectus and the documents we incorporate by reference contain forward-looking statements concerning, among other things, our prospects, clinical and regulatory developments affecting our potential product and our business strategies. These forward-looking statements are identified by the use of such terms as "intends," "expects," "plans," "estimates," "anticipates," "should" and "believes" and are in certain cases followed by a cross reference to "Risk Factors."

These forward-looking statements involve risks and uncertainties. Actual results may differ materially from those predicted by the forward-looking statements because of various factors and possible events, including those discussed under "Risk Factors." Because these forward-looking statements involve risks and uncertainties, actual results may differ significantly from those predicted in these forward-looking statements. You should not place undue weight on these statements. These statements speak only as of the date of this prospectus or, in the case of any document incorporated by reference, the date of that document.

All subsequent written and oral forward-looking statements attributable to Northfield or any person acting on our behalf are qualified by the cautionary statements in this section. We will have no obligation to revise these forward-looking statements.

3

### OUR BUSINESS

Northfield Laboratories Inc. is a leader in the development of a safe and effective alternative to transfused blood for use in the treatment of acute blood loss. Our PolyHeme(R) blood substitute product is a solution of chemically modified hemoglobin derived from human blood. PolyHeme simultaneously restores lost blood volume and hemoglobin levels and is designed for rapid, massive infusion. PolyHeme requires no cross-matching, and is therefore immediately available and compatible with all blood types. PolyHeme has an extended shelf life compared to blood. We believe PolyHeme is the only blood substitute in development that has been safely infused in clinical trials in sufficient quantities to be useful in the treatment of urgent, large volume blood loss in trauma and surgical settings, with a particular focus on situations where donated blood is not immediately available.

We have conducted Phase II and Phase III clinical trials of PolyHeme at multiple locations in the United States in trauma and emergency surgical applications, in elective surgical procedures, and as life-saving therapy in situations of compassionate use. The observations in these trials have demonstrated the potential clinical utility of PolyHeme in the treatment of urgent blood loss and life-threatening hemoglobin levels. In these trials in hospitalized trauma patients, PolyHeme significantly improved survival compared to historical control patients who did not receive blood. Our trials have involved high dosage and rapid infusion of PolyHeme in situations that are life-threatening and where massive blood loss routinely occurs. We believe that this application addresses the largest world-wide clinical need and has the greatest market opportunity. We believe we are the only company in our field with an oxygen-carrying blood substitute that has been rapidly infused at such high doses -- as much as 20 units (1,000 grams) or twice the blood volume of the average adult.

On March 5, 2003, we received clearance from the U.S. Food and Drug Administration, or FDA, to proceed with a pivotal Phase III trial in which PolyHeme will be used for the first time in civilian, urban trauma settings to treat severely injured patients in hemorrhagic shock before they reach the hospital. Under this protocol, treatment with PolyHeme will begin at the scene

of the injury or in the ambulance and continue during transport and the initial 12 hour post-injury period in the hospital. Since blood is not presently carried in ambulances, the use of PolyHeme in this setting has the potential to improve survival and thereby address a critical, unmet medical need.

On June 11, 2003, we received a response from FDA on our request for Special Protocol Assessment, or SPA, for our urban ambulance trial, confirming that agreement had been reached on the primary endpoints for the protocol and the concepts for clinical indications those endpoints would support. An SPA represents acknowledgement and confirmation of a mutual agreement between a clinical trial sponsor and FDA that successful completion of the proposed trial will form the primary basis for an efficacy claim in a marketing application for product approval. Such agreements become part of the administrative record and may only be changed by mutual agreement of the parties, or if FDA identifies a substantial scientific issue relevant to safety or efficacy after the trial has begun.

We are currently in contact with over 30 potential clinical sites in an effort to complete the trial at the earliest possible date. We anticipate that approximately 20 Level I trauma centers throughout the United States will eventually participate in the PolyHeme trial, which has an expected enrollment of 720 patients. The process of public disclosure and community consultation required under the regulations is underway at a number of potential trial sites across the country.

Our principal executive offices are located at 1560 Sherman Avenue, Suite 1000, Evanston, Illinois 60201-4800, and our telephone number is (847) 864-3500. We maintain an Internet web site at [www.northfieldlabs.com](http://www.northfieldlabs.com). The information contained on our web site, or on other web sites linked to our web site, is not a part of this prospectus.

4

#### RISK FACTORS

The securities offered by this prospectus involve a high degree of risk. You should consider the following risk factors when reviewing the information contained in this prospectus. You also should consider the other information incorporated by reference in this prospectus. These risk factors may be supplemented and amended by any risk factors set forth in a prospectus supplement.

#### RISKS RELATED TO OUR BUSINESS

##### WE ARE REQUIRED TO CONDUCT ADDITIONAL CLINICAL TRIALS IN THE FUTURE.

The results of our clinical trials conducted to date are not sufficient to demonstrate adequately the safety and effectiveness of PolyHeme in order to obtain approval from FDA for the commercial sale of PolyHeme. We are preparing to commence enrollment a pivotal Phase III trial in which PolyHeme will be used for the first time in civilian trauma applications to treat severely injured patients before they reach the hospital. Under this protocol, treatment with PolyHeme will begin at the scene of the injury and continue during transport to the hospital by ambulance. This trial is likely to be expensive and time-consuming and the timing of FDA review process is uncertain. We cannot ensure that we will be able to complete our clinical trials successfully or obtain FDA approval of PolyHeme, or that FDA approval, if obtained, will not include limitations on the indicated uses for which PolyHeme may be marketed. Our business, financial condition and results of operations are critically dependent on receiving FDA approval of PolyHeme. A significant delay in our planned clinical trials or a failure to achieve FDA approval of commercial sales

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

of PolyHeme would have a material adverse effect on us and could result in the cessation of our business. We or FDA may in the future suspend clinical trials at any time if it is believed that the subjects participating in such trials are being exposed to unacceptable health risks.

OUR ACTIVITIES ARE AND WILL CONTINUE TO BE SUBJECT TO EXTENSIVE GOVERNMENT REGULATION.

Our research, development, testing, manufacturing, marketing and distribution of PolyHeme are, and will continue to be, subject to extensive regulation, monitoring and approval by FDA. The regulatory approval process to establish the safety and effectiveness of PolyHeme and the safety and reliability of our manufacturing process has already consumed several years and considerable expenditures. The data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent FDA regulatory approval. The lack of established criteria for evaluating the effectiveness of blood substitute products could also delay or prevent FDA regulatory approval. In addition, delay or rejection could be caused by changes in FDA policies and regulations. We cannot ensure that, even after extensive clinical trials, regulatory approval will ever be obtained for PolyHeme. We will be required to file a Biologics License Application, or BLA, with FDA in order to obtain regulatory approval for the commercial sale of PolyHeme in the United States. Under FDA guidelines, FDA may comment upon the acceptability of a BLA following its submission. After a BLA is submitted there is an initial review by FDA to be sure that all of the required elements are included in the submission. There can be no assurance that the submission will be accepted for filing or that FDA may not issue a refusal to file, or RTF. If an RTF is issued, there is opportunity for dialogue between the sponsor and FDA in an effort to resolve all concerns. There can be no assurance that such a dialogue will be successful in leading to the filing of the BLA. If the submission is filed, there can be no assurance that the full review will result in product approval. Moreover, if regulatory approval of PolyHeme is granted, the approval may include limitations on the indicated uses for which PolyHeme may be marketed. Further, even if such regulatory approval is obtained, we do not presently have manufacturing facilities sufficient to produce commercial quantities of PolyHeme. In order to seek FDA approval of the sale of PolyHeme produced at its first commercial manufacturing facility, we may be required to conduct a portion of our clinical trials with product manufactured at that facility. Discovery of previously unknown problems with PolyHeme or unanticipated problems with our manufacturing facilities, even after FDA approval of PolyHeme for commercial sale, may result in the imposition of significant restrictions, including withdrawal of PolyHeme from the market. Additional laws and

5

regulations may also be enacted which could prevent or delay regulatory approval of PolyHeme, including laws or regulations relating to the price or cost-effectiveness of medical products. Any delay or failure to achieve regulatory approval of commercial sales of PolyHeme is likely to have a material adverse effect on our financial condition. FDA continues to review products even after they receive agency approval. If and when FDA approves PolyHeme, its manufacture and marketing will be subject to ongoing regulation, including compliance with current good manufacturing practices, adverse event reporting requirements and FDA's general prohibitions against promoting products for unapproved or "off-label" uses. We are also subject to inspection and market surveillance by FDA for compliance with these and other requirements. Any enforcement action resulting from failure, even by inadvertence, to comply with these requirements could affect the manufacture and marketing of PolyHeme. In addition, FDA could withdraw a previously approved product from the market upon receipt of newly discovered information. FDA could also require us to conduct additional, and potentially expensive, studies in areas outside our approved indicated uses.



## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

WE ARE A DEVELOPMENT STAGE COMPANY WITHOUT REVENUES OR PROFITS.

Northfield was founded in 1985 and is a development stage company. Since 1985, we have been engaged primarily in the development and clinical testing of PolyHeme. No revenues have been generated to date from commercial sales of PolyHeme. Our revenues to date have consisted solely of license fees. We cannot ensure that our clinical testing will be successful, that regulatory approval of PolyHeme will be obtained, that we will be able to manufacture PolyHeme at an acceptable cost and in appropriate quantities or that we will be able to successfully market and sell PolyHeme. We also cannot ensure that we will not encounter unexpected difficulties which will have a material adverse effect on us, our operations or our properties.

WE WILL NEED TO RAISE ADDITIONAL CAPITAL TO CONTINUE OUR BUSINESS.

We intend to use the proceeds of this offering to fund our planned clinical trials and ongoing business operations and for other general corporate purposes. We will be required to raise capital, in addition to the proceeds of this offering, to achieve commercial production of PolyHeme. Our future capital requirements will depend on many factors, including the scope and results of our clinical trials, the timing and outcome of regulatory reviews, administrative and legal expenses, the status of competitive products, the establishment of manufacturing capacity and the establishment of collaborative relationships. We cannot ensure that this additional funding will be available or, if it is available, that it can be obtained on terms and conditions we will deem acceptable. If we are unable to raise additional capital, our independent accountants may qualify their audit opinions based on uncertainty regarding our ability to continue as a going concern. A qualification of this type may interfere with our ability to issue our securities to the public or in private transactions. Any additional funding derived from the sale of equity securities may result in significant dilution to our existing stockholders.

WE ARE DEVELOPING A SINGLE PRODUCT THAT IS SUBJECT TO A HIGH LEVEL OF TECHNOLOGICAL RISK.

Our operations have to date consisted primarily of the development and clinical testing of PolyHeme. We do not expect to realize product revenues unless we successfully develop and achieve commercial introduction of PolyHeme. We expect that such revenues, if any, will be derived solely from sales of PolyHeme. We also expect the use of PolyHeme to be limited primarily to the acute blood loss segment of the transfusion market. The biomedical field has undergone rapid and significant technological changes. Technological developments may result in PolyHeme becoming obsolete or non-competitive before we are able to recover any portion of the research and development and other expenses we have incurred to develop and clinically test PolyHeme. Any such occurrence would have a material adverse effect on us and our operations.

WE ARE NOT CERTAIN THAT WE WILL BE ABLE TO MANUFACTURE POLYHEME COMMERCIALY.

Commercial-scale manufacturing of PolyHeme will require the construction of a manufacturing facility significantly larger than that currently being used to produce PolyHeme for our clinical trials. We have no experience in commercial-

scale manufacturing, and there can be no assurance that we can achieve commercial-scale manufacturing capacity. It is also possible that we may incur substantial cost overruns and delays compared to existing estimates in building and equipping a commercial-scale manufacturing facility. Moreover, in order to

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

seek FDA approval of the sale of PolyHeme produced at our first commercial manufacturing facility, we may be required to conduct a portion of our clinical trials with product manufactured at that facility. Accordingly, a delay in achieving scale-up of commercial manufacturing capabilities will have a material adverse effect on sales of PolyHeme. Additionally, the manufacture of PolyHeme will be subject to extensive government regulation. Among the conditions for marketing approval is that our quality control and manufacturing procedures conform to FDA's good manufacturing practice regulations. We cannot ensure that we will be able to obtain the necessary regulatory clearances or approvals to manufacture PolyHeme on a timely basis or at all.

THERE MAY BE LIMITATIONS IN THE SUPPLY OF THE STARTING MATERIAL FOR POLYHEME.

We currently purchase donated blood from The American Red Cross and Blood Centers of America for use as the starting material for PolyHeme. We have also entered into an agreement with hemerica, Inc., a subsidiary of Blood Centers of America, under which hemerica would supply us with up to 160,000 units per year of packed red cells, the source material for PolyHeme. We have not purchased any blood supplies under this agreement to date. We have plans to enter long-term supply arrangements with other blood collectors. We cannot ensure that we will be able to enter into satisfactory long-term arrangements with blood bank operators, that the price we may be required to pay for starting material will permit us to price PolyHeme competitively or that we will be able to obtain an adequate supply of starting material. Additional demand for blood may arise from competing blood substitute products, some of which are derived from human blood, thereby limiting our available supply of starting material.

THERE ARE SIGNIFICANT COMPETITORS DEVELOPING SIMILAR PRODUCTS.

If approved for commercial sale, PolyHeme will compete directly with established therapies for acute blood loss and may compete with other technologies currently under development. We cannot ensure that PolyHeme will have advantages which will be significant enough to cause medical professionals to adopt it rather than continue to use established therapies or to adopt other new technologies or products. We also cannot ensure that the cost of PolyHeme will be competitive with the cost of established therapies or other new technologies or products. The development of blood substitute products is a rapidly evolving field. Competition is intense and expected to increase. Several companies have developed or are in the process of developing technologies which are, or in the future may be, the basis for products which will compete with PolyHeme. Certain of these companies are pursuing different approaches or means of accomplishing the therapeutic effects sought to be achieved through the use of PolyHeme. Some of these companies have substantially greater financial resources, larger research and development staffs, more extensive facilities and more experience than Northfield in testing, manufacturing, marketing and distributing medical products. We cannot ensure that one or more other companies will not succeed in developing technologies or products which will become available for commercial use prior to PolyHeme, which will be more effective or less costly than PolyHeme or which would otherwise render PolyHeme obsolete or non-competitive. A bovine-source hemoglobin-based oxygen-carrier has been approved for human use in South Africa and a BLA is under review by FDA for its use in the United States.

WE DO NOT HAVE EXPERIENCE IN THE SALE AND MARKETING OF MEDICAL PRODUCTS.

If approved for commercial sale, we intend to market PolyHeme in the United States using our own sales force. We have no experience in the sale or marketing of medical products. Our ability to implement our sales and marketing strategy for the United States will depend on our ability to recruit, train and retain a marketing staff and sales force with sufficient technical expertise. We

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

cannot ensure that we will be able to establish an effective marketing staff and sales force, that the cost of establishing such a marketing staff and sales force will not exceed revenues from the sale of PolyHeme or that our marketing and sales efforts will be successful.

7

WE HAVE A HISTORY OF LOSSES AND OUR FUTURE PROFITABILITY IS UNCERTAIN.

From Northfield's inception through February 28, 2003, we have incurred net operating losses totaling \$107,142,000. We will require substantial additional expenditures to complete clinical trials, to pursue regulatory approval for PolyHeme, to establish commercial scale manufacturing processes and facilities, and to establish marketing, sales and administrative capabilities. These expenditures are expected to result in substantial losses for at least the next several years. The expense and the time required to realize any product revenues or profitability are highly uncertain. We cannot ensure that we will be able to achieve product revenues or profitability on a sustained basis or at all.

THE MARKET MAY NOT ACCEPT OUR PRODUCT.

We anticipate that the market price for PolyHeme, if FDA approval is received, will exceed the cost of transfused blood. Competitors may also develop new technologies or products which are more effective or less costly than PolyHeme. We cannot ensure that the price of PolyHeme, considered in relation to PolyHeme's expected benefits, will be perceived by health care providers and third party payors as cost-effective, or that the price of PolyHeme will be competitive with transfused blood or with other new technologies or products. Our results of operations may be adversely affected if the price of PolyHeme is not considered cost-effective or if PolyHeme does not otherwise receive market acceptance.

OUR PATENTS AND OTHER PROPRIETARY RIGHTS MAY NOT PROTECT OUR TECHNOLOGY.

Our ability to compete effectively with other companies will depend, in part, on our ability to protect and maintain the proprietary nature of our technology. We cannot be certain as to the degree of protection offered by our patents or as to the likelihood that additional patents in the United States and certain other countries will be issued based upon pending patent applications. Patent applications in the United States are maintained in secrecy until patents are issued. We cannot be certain that we were the first creator of the inventions covered by our patents or pending patent applications or that we were the first to file patent applications for our inventions. The high costs of enforcing patent and other proprietary rights may also limit the degree of protection afforded to us. We also rely on unpatented proprietary technology, and we cannot ensure that others may not independently develop the same or similar technology or otherwise obtain access to our proprietary technology. We cannot ensure that our patents or other proprietary rights will be determined to be valid or enforceable if challenged in court or administrative proceedings or that we will not become involved in disputes with respect to the patents or proprietary rights of third parties. An adverse outcome from these proceedings could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to stop using this technology, any of which would result in a material adverse effect on our results of operations.

OUR PROFITABILITY WILL BE AFFECTED IF WE INCUR PRODUCT LIABILITY CLAIMS IN EXCESS OF OUR INSURANCE COVERAGE.

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

The testing and marketing of medical products, even after FDA approval, have an inherent risk of product liability. We maintain limited product liability insurance coverage for our clinical trials in the total amount of \$10 million. However, our profitability will be adversely affected by a successful product liability claim in excess of our insurance coverage. We cannot guarantee that product liability insurance will be available in the future or be available on reasonable terms.

WE DEPEND ON THE SERVICES OF A LIMITED NUMBER OF KEY PERSONNEL.

Our success is highly dependent on the continued services of a limited number of skilled managers and scientists. The loss of any of these individuals could have a material adverse effect on us. In addition, our success will depend, among other factors, on the recruitment and retention of additional highly skilled and

8

experienced management and technical personnel. We cannot ensure that we will be able to retain existing employees or to attract and retain additional skilled personnel on acceptable terms given the competition for such personnel among numerous large and well-funded pharmaceutical and health care companies, universities and non-profit research institutions.

HEALTH CARE REFORM AND CONTROLS ON HEALTH CARE SPENDING MAY LIMIT THE PRICE WE CAN CHARGE FOR POLYHEME AND THE AMOUNT WE CAN SELL.

The federal government and private insurers have considered ways to change, and have changed, the manner in which health care services are provided in the United States. Potential approaches and changes in recent years include controls on health care spending and the creation of large purchasing groups. In the future, it is possible that the government may institute price controls and limits on Medicare and Medicaid spending. These controls and limits might affect the payments we collect from sales of our product. Assuming we succeed in bringing PolyHeme to market, uncertainties regarding future health care reform and private market practices could affect our ability to sell PolyHeme in large quantities at profitable pricing.

UNCERTAINTY OF THIRD-PARTY REIMBURSEMENT COULD AFFECT OUR PROFITABILITY.

Sales of medical products largely depend on the reimbursement of patients' medical expenses by governmental health care programs and private health insurers. There is no guarantee that governmental health care programs or private health insurers will reimburse our sales of PolyHeme, or permit us to sell our product at high enough prices to generate a profit.

RISKS RELATED TO THE OFFERING

OUR STOCK PRICE COULD BE VOLATILE AND YOUR INVESTMENT COULD SUFFER A DECLINE IN VALUE.

The market price of our common stock has fluctuated significantly in response to a number of factors, many of which are beyond our control, including:

- regulatory developments relating to our PolyHeme blood substitute product;
- announcements by us relating to the results of our clinical trials of PolyHeme;

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

- developments relating to our efforts to obtain additional financing to fund our operations;
- announcements by us regarding transactions with potential strategic partners;
- announcements relating to blood substitute products being developed by our competitors;
- changes in industry trends or conditions;
- our issuance of additional debt or equity securities; and
- sales of significant amounts of our common stock or other securities in the market.

In addition, the stock market in general, and the Nasdaq National Market and the biotechnology industry market in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, securities class action litigation has often been instituted following periods of volatility in the market price of a

9

company's securities. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of our management's attention and resources.

ANTI-TAKEOVER PROVISIONS CONTAINED IN OUR CHARTER AND BYLAWS COULD DISCOURAGE POTENTIAL TAKEOVER ATTEMPTS.

Our certificate of incorporation contains a "fair price" provision which requires approval of the holders of at least 80% of our voting stock, excluding shares held by certain interested stockholders and their affiliates, as a condition to mergers or certain other business combinations with, or proposed by, any holder of 15% or more of our voting stock, except in cases where approval of our disinterested directors is obtained or certain minimum price criteria and other procedural requirements are satisfied. In addition, our board of directors has the authority, without further action by our stockholders, to fix the rights and preferences and issue shares of preferred stock. These provisions, and other provisions of the our certificate of incorporation and bylaws and Delaware law, may have the effect of deterring hostile takeovers or delaying or preventing changes in our control or management, including transactions in which stockholders might otherwise receive a premium for their shares over the then prevailing market prices.

THERE IS A LARGE NUMBER OF SHARES THAT MAY BE SOLD IN THE MARKET FOLLOWING THIS OFFERING, WHICH MAY DEPRESS THE MARKET PRICE OF OUR COMMON STOCK.

Sales of a substantial number of shares of our common stock or securities convertible into or exercisable for our common stock in the public market following this offering could cause the market price of our common stock to decline. If there are more shares of common stock offered for sale than buyers are willing to purchase, then the market price of our common stock may decline to a market price at which buyers are willing to purchase the offered shares of common stock and sellers remain willing to sell the shares. All of the shares sold in the offering will be freely tradeable without restriction or

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

further registration under the Securities Act, except for any shares purchased by our "affiliates" as defined in Rule 144 of the Securities Act.

### YOU WILL EXPERIENCE IMMEDIATE AND SUBSTANTIAL DILUTION.

The public offering price of the securities offered hereby is likely to be substantially higher than the book value per share of our common stock. Investors purchasing common stock in this offering may, therefore, incur immediate dilution in net tangible book value per share of common stock. Investors will also incur additional dilution upon the exercise of outstanding stock options and warrants. See "Dilution" for a more detailed discussion of the dilution you will incur in this offering.

### USE OF PROCEEDS

Unless we inform you otherwise in the prospectus supplement, we intend to use the proceeds of this offering to fund our planned clinical trials and ongoing business operations and for other general corporate purposes. Pending any specific application, we may initially invest funds in short-term marketable securities.

### RATIO OF EARNINGS TO FIXED CHARGES AND PREFERENCE DIVIDENDS

We reported no revenues or earnings during our last five fiscal years. During this period, we did not have any debt or related interest expense and were not a party to any capital lease arrangements. No preference securities were outstanding during this period.

### DILUTION

Our net tangible book value at February 28, 2003 was \$10,504,000, or \$.74 per share of common stock. Net tangible book value per share represents total tangible assets less total liabilities divided by

10

the number of outstanding shares of our common stock on February 28, 2003. Assuming that we issue an aggregate of \$50 million of common stock at an assumed public offering price of \$8.39 per share (the last reported sale price of our common stock on the Nasdaq National Market on June 24, 2003), with estimated net proceeds to us (after assumed commissions and expenses) of \$46,375,000, our pro forma net tangible book value at February 28, 2003 would have been \$56,879,000 or \$2.81 per share. This represents an immediate increase in the tangible book value of \$2.07 per share to our existing stockholders and an immediate dilution of \$5.58 per share to new investors purchasing common stock in this offering, as illustrated in the following table:

Assumed public offering price per share(1)		\$8.39
Net tangible book value per share as of February 28, 2003	\$0.74	
Increase per share attributable to new investors	\$2.07	
Pro forma net tangible book value per share after offering		\$2.81
		-----
Dilution per share to new investors		\$5.58
		=====

(1) We assumed an offering price of \$8.39 per share based on the last reported sale price of the common stock on the Nasdaq National Market on June 24, 2003. The assumed offering price of the common stock at the time any common

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

stock is offered hereby may differ significantly from the offering price assumed for purposes of this prospectus.

The computations in the table above assume no exercise of any outstanding stock options after February 28, 2003. At February 28, 2003, there were options outstanding to purchase a total of 958,000 shares of our common stock at a weighted average exercise price of \$9.62 per share. If any of these options are exercised, there will be further dilution to new investors.

If the securities offered hereby are common stock, the prospectus supplement will include a revised dilution table setting forth any increase in net tangible book value to existing stockholders and any dilution to new investors based on the proposed number of shares of common stock to be offered and the public offering price at the time of such offering.

### DESCRIPTION OF THE SECURITIES WE MAY OFFER

We may offer up to \$50,000,000 of common stock, preferred stock, depository shares, stock purchase contracts, warrants and debt securities, in one or more offerings and in any combination. A prospectus supplement, which we will provide each time we offer securities, will describe the specific amounts, prices and terms of these securities.

We may sell the securities to or through underwriters, dealers or agents or directly to purchasers. We, as well as any persons acting on our behalf, reserve the sole right to accept and to reject in whole or in part any proposed purchase of securities. Each prospectus supplement will set forth the names of any underwriters, dealers or agents involved in the sale of securities described in that prospectus supplement and any applicable fee, commission or discount arrangements with them.

### COMMON STOCK

We may issue shares of our common stock either alone or underlying other registered securities convertible into or exercisable or exchangeable for shares of our common stock. Holders of our common stock are entitled to receive dividends declared by our board of directors out of funds legally available for the payment of dividends, subject to rights, if any, of preferred stock holders. Currently, we do not pay a dividend. The holders of our common stock are entitled to one vote per share and are not entitled to cumulative voting rights for the election of our directors. The holders of our common stock have no preemptive rights.

11

### PREFERRED STOCK AND DEPOSITARY SHARES

We may issue preferred stock, in one or more series, alone or underlying other registered securities convertible into or exercisable or exchangeable for shares of our preferred stock. Our board of directors or a committee designated by the board will determine the dividend, voting and conversion rights and other provisions of the preferred stock at the time of sale. Each series of preferred stock will be more fully described in the particular prospectus supplement that will accompany this prospectus, including redemption provisions, rights in the event of liquidation, dissolution or the winding up of Northfield, voting rights and conversion rights. We may also issue fractional shares of preferred stock that will be represented by depository shares and depository receipts. Each particular series of depository shares will be more fully described in the prospectus supplement that will accompany this prospectus.

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

### WARRANTS

We may issue warrants for the purchase of common stock, preferred stock, depositary shares or debt securities. We may issue warrants independently or together with other securities. The specific terms of any warrants will be described in the prospectus supplement that will accompany this prospectus.

### STOCK PURCHASE CONTRACTS

We may issue stock purchase contracts, including contracts obligating holders to purchase from us, and us to sell to the holders, a specified number of securities, at a future date or dates, or similar contracts issued on a "prepaid" basis, which in each case are referred to herein as "stock purchase contracts." The price per share of securities and the number of shares of securities may be fixed at the time the stock purchase contracts are issued or may be determined by reference to a specific formula set forth in the stock purchase contracts. The stock purchase contracts will require either the stock purchase price be paid at the time the stock purchase contracts are issued or that payment be made at a specified future date. The stock purchase contracts also may require us to make periodic payments to the holders of the stock purchase contracts or vice versa, and such payments may be unsecured or refunded on some basis. The specific terms of any stock purchase contracts will be described in the prospectus supplement that will accompany this prospectus.

### DEBT SECURITIES

#### General

We may issue secured or unsecured obligations in the form of either senior or subordinated debt. The senior debt securities and the subordinated debt securities are together referred to in this prospectus as "debt securities." The senior unsecured debt securities will have the same rank as all of our other unsecured unsubordinated debt. The subordinated debt securities generally will be entitled to payment only after payment of our senior debt. Senior debt generally includes all debt for money borrowed by us, except debt that is stated in the instrument governing the terms of that debt to be not senior to, or to have the same rank in right of payment as, or to be expressly junior to, the senior debt securities. We may issue debt securities that are convertible into or exchangeable for shares of common stock or other securities or property.

The senior and subordinated debt securities will be issued under separate indentures between a trustee and us. We have summarized the general features of the debt securities to be governed by the indentures. These indentures have been filed as exhibits or will be incorporated by reference into the registration statement that we have filed with the SEC of which this prospectus is a part. We encourage you to read these indentures. Instructions on how you can get copies of these documents are provided above in "Where You Can Find More Information."

12

#### General Indenture Provisions that Apply to Senior and Subordinated Debt

The following general indenture provisions will apply to any senior and subordinated debt securities:

- each indenture allows debt to be issued in series with terms particular to each series;
- neither indenture limits the amount of debt that we may issue



## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

or generally provides holders any protection should we engage in a highly leveraged transaction;

- the indentures allow us to merge or to consolidate with another U.S. entity or convey, transfer or lease our properties and assets substantially as an entirety to another U.S. entity, as long as certain conditions are met. If these events occur, the other company will be required to assume our responsibilities on the debt securities, and we will be released from all liabilities and obligations, except in the case of a lease;
- the indentures provide that the trustee and we may generally amend the indenture with the consent of holders of a majority of the total principal amount of the debt outstanding in any series to change certain of our obligations or your rights concerning the debt. However, to change the payment of principal, interest or adversely affect the right to convert or certain matters, every holder in that series must consent; and
- we may discharge the indentures and defease restrictive covenants by depositing sufficient funds with the trustee to pay the obligations when due, as long as certain conditions are met. The trustee would pay all amounts due to you on the debt from the deposited funds.

### Events of Default

Each of the following is an event of default under the indentures:

- principal not paid when due;
- any sinking fund payment not made when due;
- failure to pay interest for 30 days;
- covenants not performed for 90 days after notice; and
- certain events of bankruptcy, insolvency or reorganization of Northfield.

A prospectus supplement may describe deletions of, or changes or additions to, the events of default.

### Remedies

Upon an event of default, other than a bankruptcy, insolvency or reorganization, the trustee or holders of 25 percent of the principal amount outstanding in a series may declare the outstanding principal, plus accrued interest, if any, immediately payable. However, the holders of a majority in principal amount may, under certain circumstances, rescind this action.

13

### Indenture Provisions that Apply Only to the Subordinated Debt Securities

The subordinated indenture provides that the subordinated debt securities will be subordinated to all senior debt as defined in the subordinated indenture.

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

### PLAN OF DISTRIBUTION

We may sell the offered securities in and outside the United States through underwriters, dealers or agents or directly to purchasers. The prospectus supplement will set forth the following information:

- the terms of the offering;
- the names of any underwriters, dealers or agents;
- the purchase price;
- the net proceeds to us;
- any delayed delivery arrangements;
- any underwriting discounts and other items constituting underwriters' compensation;
- the initial public offering price;
- any discounts or concessions allowed, reallocated or paid to dealers; and
- any commissions paid to agents.

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

During and after an offering through underwriters, the underwriters may purchase and sell the securities in the open market. These transactions may include over-allotment and stabilizing transactions and purchases to cover syndicate short positions created in connection with the offering. The underwriters may also impose a penalty bid, in which selling concessions allowed to syndicate members or other broker-dealers for the offered securities sold for their account may be reclaimed by the syndicate if the offered securities are repurchased by the syndicate in stabilizing or covering transactions. These activities may stabilize, maintain or otherwise affect the market price of the offered securities, which may be higher than the price that might otherwise prevail in the open market. If commenced, these activities may be discontinued at any time. If we use dealers in the sale of securities, we will sell the securities to them as principals. They may then resell those securities to the public at varying prices determined by the dealers at the time of resale. The dealers participating in any sale of our securities may be deemed to be underwriters within the meaning of the Securities Act with respect to any sale of those securities. We will include in the prospectus supplement the names of the dealers and the terms of the transaction.

We may sell the securities directly. In that event, no underwriters, dealers or agents would be involved. We may also sell the securities through

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

agents we designate from time to time. In the prospectus supplement, we will name any agent involved in the offer or sale of the offered securities, and we will describe any

14

commissions payable by us to the agent. Unless we inform you otherwise in the prospectus supplement, any agent will agree to use its reasonable best efforts to solicit purchases for the period of its appointment. We may sell the securities directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act with respect to any sale of those securities. We will describe the terms of any of these sales in the prospectus supplement.

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

Underwriters, dealers and agents participating in a sale of securities may be deemed to be underwriters as defined in the Securities Act, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions under the Securities Act.

### LEGAL MATTERS

The validity of the securities offered herein will be passed upon for us by Baker & McKenzie, Chicago, Illinois. If the securities are distributed in an underwritten offering, the underwriters will be advised by their own legal counsel with respect to any offering.

### EXPERTS

The financial statements of Northfield Laboratories Inc. as of May 31, 2002, and for each of the years in the three-year period ended May 31, 2002 and for the cumulative period from June 19, 1985 (inception) have been incorporated by reference herein and in the registration statement in reliance upon the report of KPMG LLP, independent certified public, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

With respect to the unaudited interim financial information of the periods ended August 31, 2002, November 30, 2002 and February 28, 2003, incorporated by reference herein, the independent certified public accountants have reported that they applied limited procedures in accordance with professional standards for a review of such information. However, their separate reports included in Northfield Laboratories Inc.'s quarterly reports on Form 10-Q for the quarters ended August 31, 2002, November 30, 2002 and February 28, 2003, incorporated by reference herein, state that they did not audit and they do not express an opinion on that interim financial information. Accordingly, the degree of reliance on their reports on such information should be restricted in light of the limited nature of the review procedures applied. The accountants are not subject to the liability provisions of Section 11 of the Securities Act of 1933 for their report on the unaudited interim financial information because that report is not a "report" or a "part" of the registration statement prepared or certified by the accountants within the meaning of Sections 7 and 11 of the Act.

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

PART II.

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The following table sets forth the expenses in connection with the issuance and distribution of the securities being registered, other than underwriting discounts and commissions. All of the amounts shown are estimated, except the SEC registration fee.

SEC registration fee	\$4,045
Legal fees and expenses	75,000
Printing and engraving	7,500
Fees of accountants	10,000
Miscellaneous	28,445
	-----
	125,000
	=====

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation may indemnify any person who was or is a party to or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request

15

of the corporation as a director, officer, employee of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceedings, had no reasonable cause to believe his conduct was unlawful, except that in a suit by or in the right of the corporation no indemnification may be made in respect of any claim, issue or matter as to which such person has been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery of the State of Delaware or the court in which such action or suit was brought has determined upon application that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity or such expenses deemed proper by the court.

Our certificate of incorporation provides that we must indemnify our directors, officers, employees and agents to the fullest extent permitted by Delaware law. Our certificate of incorporation additionally requires us to advance expenses incurred by our directors, officers, employees and agents to the fullest extent permitted by Delaware law in connection with any matter with respect to which such persons may be entitled to seek indemnification.

Our certificate of incorporation also provides that, to the fullest extent permitted by Delaware law, our directors will not be liable for monetary damages for breach of the directors' fiduciary duty of care to us or our stockholders. This provision does not eliminate the duty of care and, in

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

appropriate circumstances, equitable remedies such as an injunction or other forms of non-monetary relief will remain available under Delaware law. Each director will also continue to be subject to liability for breach of the director's duty of loyalty to us or our stockholders, for acts or omissions not in good faith or involving intentional misconduct or a knowing violation of law, for unlawful distributions to stockholders and for any transaction from which the director derives an improper personal benefit. In addition, this provision does not affect a director's responsibilities under any other laws, such as the federal securities laws or state or federal environmental laws.

We are a party to separate indemnification agreements with each of our directors and senior executive officers. These agreements require us to indemnify our directors and executive officers to the maximum extent permitted by law and to advance all expenses they may reasonably incur in connection with the defense of any claim or proceeding in which they may be involved as a party or witness. The agreements specify certain procedures and assumptions applicable in connection with requests for indemnification and advancement of expenses and also require us to continue to maintain directors and officers and fiduciary liability insurance for a six-year period following any change in control transaction. The rights provided to our directors and executive officers under their indemnification agreements are in addition to any other rights such individuals may have under our certificate of incorporation or bylaws, applicable law or otherwise.

We have purchased an insurance policy which insures our directors and officers against certain liabilities incurred by them in the discharge of their official functions, except for liabilities resulting from their own malfeasance. The insurance policy provides coverage in the amount of \$10,000,000 for annual aggregate claims.

17

### ITEM 16. EXHIBITS.

The exhibits listed below are filed or incorporated by reference as part of this registration statement.

NUMBER	DESCRIPTION
1.1*	Form of Underwriting Agreement.
3.1	Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on March 25, 1994, File No. 33-76856 (the "Registration Statement")).
3.2	Certificate of Amendment to Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.1.1 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended November 30, 1999).
3.3	Restated Bylaws of the Registrant (incorporated herein by reference to Exhibit 3.4 to the Registration Statement).

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

4.1**	Form of Senior Indenture.
4.2**	Form of Subordinated Indenture.
4.3**	Form of Senior Debt Security (included as Exhibit 4.1).
4.4**	Form of Subordinated Debt Security (included as Exhibit 4.2).
4.5*	Form of Certificate of Amendment.
4.6*	Form of Preferred Stock Certificate.
4.7*	Form of Deposit Agreement.
4.8*	Form of Depositary Receipt (included in Exhibit 4.7).
4.9*	Form of Warrant Agreement.
4.10*	Form of Warrant Certificate.
5.1**	Opinion of Baker & McKenzie.
10.1	Office Sublease dated as of April 20, 1993 between the Registrant and First Illinois Bank of Evanston, N.A., as Trustee (incorporated herein by reference to Exhibit 10.1 to the Registration Statement).

17

NUMBER	DESCRIPTION
10.2	Amendment to Lease dated as of January 7, 1998 between the Registrant and First Illinois Bank of Evanston, N.A. (incorporated herein by reference to Exhibit 10.1.1 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 1998).
10.3	Lease dated as of June 8, 1989 between the Registrant and OTR (incorporated by reference to Exhibit 10.2 to the Registration Statement).
10.4	Amendment to Lease dated as of May 6, 1998 between the Registrant and OTR (incorporated herein by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K for the Registrant's fiscal year ended May 31, 1998).
10.5	Third Amendment to Lease dated as of September 16, 1999 between the Registrant and

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

- OTR (incorporated by reference to Exhibit 10.4.1 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended November 30, 1999).
- 10.6 License Agreement dated as of March 6, 1989 between the Registrant and KabiVitrum AB (predecessor of Pharmacia Corporation) (incorporated herein by reference to Exhibit 10.6 to the Registration Statement)
- 10.7 License Agreement dated as of July 20, 1990 between the Registrant and Eriphyle BV (incorporated herein by reference to Exhibit 10.7 to the Registration Statement).
- 10.8 Northfield Laboratories Inc. 401(K) Plan (incorporated herein by reference to Exhibit 10.14 to the Registration Statement).
- 10.9 Northfield Laboratories Inc. Nonqualified Stock Option Plan for Outside Directors (incorporated herein by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K for the Registrant's fiscal year ended May 31, 1994).
- 10.10 Northfield Laboratories Inc. 1996 Stock Option Plan (incorporated herein by reference to Exhibit 10.5.1 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended November 30, 1997).
- 10.11 Northfield Laboratories Inc. 1999 Stock Option Plan (incorporated herein by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K for the

18

NUMBER	DESCRIPTION
	Registrant's fiscal year ended May 31, 1999).
10.12**	Northfield Laboratories Stock Option Plan for New Employees.
10.13**	Employment Agreement dated as of January 1, 2003 between the Registrant and Steven A. Gould, M.D.
10.14**	Employment Agreement dated as of January 1, 2003 between the Registrant and Jack Kogut.
10.15	Form of Indemnification Agreement -- Director and Executive Officer (incorporated herein by reference to Exhibit 10.18 to the

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 2001).

- 10.16 Form of Indemnification Agreement -- Director (incorporated herein by reference to Exhibit 10.19 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 2001).
- 10.17 Form of Indemnification Agreement -- Executive Officer (incorporated herein by reference to Exhibit 10.20 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 2001).
- 15.1\*\* Letter re unaudited interim financial information.
- 23.1\*\* Consent of Baker & McKenzie (contained in their opinion filed as Exhibit 5.1 to this Registration Statement).
- 23.2\*\* Consent of KPMG LLP.
- 25.1\* Form T-1 Statement of Eligibility of Trustee from Senior Indenture under the Trust Indenture Act of 1939.
- 25.2\* Form T-1 Statement of Eligibility of Trustee from Subordinated Indenture under the Trust Indenture Act of 1939.

\* To be filed by amendment or as an exhibit to a report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934.

\*\* Filed herewith.

19

ITEM 17. UNDERTAKINGS.

The Registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
- (a) to include any prospectus required by Section 10(a)(3) of the Securities Act;
- (b) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated



## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

- (c) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (1)(a) and (1)(b) do not apply if the registration statement is on Form S-3, Form S-8 or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or 15(d) of the Exchange Act that are incorporated by reference in the registration statement.

- (2) that, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof;
- (3) to remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering;
- (4) for purposes of determining any liability under the Securities Act, each filing of Registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at the time shall be deemed to be the initial bona fide offering thereof.
- (5) insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

**Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3**

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Evanston, State of Illinois, on the 25th day of June, 2003.

NORTHFIELD LABORATORIES INC.

By: /s/ Steven A. Gould, M.D.

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

We, the undersigned officers and directors of Northfield Laboratories Inc., hereby, severally constitute and appoint each of Steven A. Gould, M.D. and Jack J. Kogut our true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and registration statements filed pursuant to Rule 462 under the Securities Act of 1933, and to file the same with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto such attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that such attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities indicated and on the dates indicated:

Signature -----	Title -----	
/s/ Steven A. Gould, M.D. ----- Steven A. Gould, M.D.	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	Jun
/s/ Jack J. Kogut ----- Jack J. Kogut	Senior Vice President, Chief Financial Officer, Secretary and Treasurer (Principal Financial Officer)	Jun
/s/ Gerald S. Moss, M.D. ----- Gerald S. Moss, M.D.	Director	Jun
----- Bruce S. Chelberg	Director	Jun
/s/ Jack Olshansky ----- Jack Olshansky	Director	Jun
/s/ David A. Savner ----- David A. Savner	Director	Jun

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

-----  
John F. Bierbaum

Director

Jun

/s/ Paul M. Ness, M.D.  
-----

Director

Jun

Paul M. Ness, M.D.

21

EXHIBIT INDEX

NUMBER	DESCRIPTION
1.1*	Form of Underwriting Agreement.
3.1	Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on March 25, 1994, File No. 33-76856 (the "Registration Statement")).
3.2	Certificate of Amendment to Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.1.1 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended November 30, 1999).
3.3	Restated Bylaws of the Registrant (incorporated herein by reference to Exhibit 3.4 to the Registration Statement).
4.1**	Form of Senior Indenture.
4.2**	Form of Subordinated Indenture.
4.3**	Form of Senior Debt Security (included as Exhibit 4.1).
4.4**	Form of Subordinated Debt Security (included as Exhibit 4.2).
4.5*	Form of Certificate of Amendment.
4.6*	Form of Preferred Stock Certificate.
4.7*	Form of Deposit Agreement.
4.8*	Form of Depositary Receipt (included in Exhibit 4.7).
4.9*	Form of Warrant Agreement.
4.10*	Form of Warrant Certificate.
5.1**	Opinion of Baker & McKenzie.
10.1	Office Sublease dated as of April 20, 1993 between the Registrant and First Illinois Bank of Evanston,

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

N.A., as Trustee (incorporated herein by reference to

1

NUMBER	DESCRIPTION
	Exhibit 10.1 to the Registration Statement).
10.2	Amendment to Lease dated as of January 7, 1998 between the Registrant and First Illinois Bank of Evanston, N.A. (incorporated herein by reference to Exhibit 10.1.1 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 1998).
10.3	Lease dated as of June 8, 1989 between the Registrant and OTR (incorporated by reference to Exhibit 10.2 to the Registration Statement).
10.4	Amendment to Lease dated as of May 6, 1998 between the Registrant and OTR (incorporated herein by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K for the Registrant's fiscal year ended May 31, 1998).
10.5	Third Amendment to Lease dated as of September 16, 1999 between the Registrant and OTR (incorporated by reference to Exhibit 10.4.1 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended November 30, 1999).
10.6	License Agreement dated as of March 6, 1989 between the Registrant and KabiVitrum AB (predecessor of Pharmacia Corporation) (incorporated herein by reference to Exhibit 10.6 to the Registration Statement)
10.7	License Agreement dated as of July 20, 1990 between the Registrant and Eriphyle BV (incorporated herein by reference to Exhibit 10.7 to the Registration Statement).
10.8	Northfield Laboratories Inc. 401(K) Plan (incorporated herein by reference to Exhibit 10.14 to the Registration Statement).
10.9	Northfield Laboratories Inc. Nonqualified Stock Option Plan for Outside Directors (incorporated herein by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K for the Registrant's fiscal year ended May 31, 1994).
10.10	Northfield Laboratories Inc. 1996 Stock Option Plan (incorporated herein by reference to Exhibit 10.5.1 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended November 30, 1997).

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form S-3

2

NUMBER	DESCRIPTION
10.11	Northfield Laboratories Inc. 1999 Stock Option Plan (incorporated herein by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K for the Registrant's fiscal year ended May 31, 1999).
10.12**	Northfield Laboratories Stock Option Plan for New Employees.
10.13**	Employment Agreement dated as of January 1, 2003 between the Registrant and Steven A. Gould, M.D.
10.14**	Employment Agreement dated as of January 1, 2003 between the Registrant and Jack Kogut.
10.15	Form of Indemnification Agreement -- Director and Executive Officer (incorporated herein by reference to Exhibit 10.18 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 2001).
10.16	Form of Indemnification Agreement -- Director (incorporated herein by reference to Exhibit 10.19 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 2001).
10.17	Form of Indemnification Agreement -- Executive Officer (incorporated herein by reference to Exhibit 10.20 to the Registrant's Quarterly Report on Form 10-Q for the Registrant's quarter ended February 28, 2001).
15.1**	Letter re unaudited interim financial information.
23.1**	Consent of Baker & McKenzie (contained in their opinion filed as Exhibit 5.1 to this Registration Statement).
23.2**	Consent of KPMG LLP.
25.1*	Form T-1 Statement of Eligibility of Trustee from Senior Indenture under the Trust Indenture Act of 1939.
25.2*	Form T-1 Statement of Eligibility of Trustee from Subordinated Indenture under the Trust Indenture Act of 1939.

\* To be filed by amendment or as an exhibit to a report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934.

\*\* Filed herewith.

3