

DOR BIOPHARMA INC
Form 424B3
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Registration No. 333-103114

PROSPECTUS

DOR BIOPHARMA, INC.

5,297,732 SHARES

COMMON STOCK

Our common stock is traded on the American Stock Exchange under the symbol "DOR." The closing sale price of our common stock on May 28, 2003 was \$0.94 per share.

AN INVESTMENT IN SHARES OF OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD CAREFULLY CONSIDER THE "RISK FACTORS" BEGINNING ON PAGE 1 BEFORE YOU DECIDE WHETHER TO INVEST IN SHARES OF OUR COMMON STOCK.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is May 29, 2003

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You should rely only on the information contained or incorporated by reference in this prospectus and in any prospectus supplement. We have not authorized

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anyone else to provide you with different information, and if you receive any unauthorized information you should not rely on it. We have not authorized the selling stockholders to make an offer of these shares in any place where the offer is not permitted. You should not assume that the information in this prospectus, any supplement or any document incorporated by reference is accurate as of any date other than the date of that document.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and the documents incorporated by reference. This summary does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus and the documents incorporated by reference carefully, including the risk factors and the financial statements and related notes.

OUR BUSINESS

We are a pharmaceutical company specializing in the development of oral and nasal delivery of vaccines and drugs. Through collaborations, we are developing a proprietary oral and nasal vaccine delivery technology called the Microvax(TM) system, which we are applying to vaccines intended to protect individuals against biological agents that may be used in war or acts of terrorism, including nasal vaccines against ricin toxins and anthrax and an oral delivered vaccine against botulinum toxin. In addition to our biodefense vaccines, we are developing orBec(R), an oral therapeutic product, that is currently in a pivotal Phase III clinical trial for the treatment of intestinal graft-vs-host disease, a life threatening complication of bone marrow transplantation. In addition, we are looking at other indications for which patients may benefit from the unique characteristics of orBec(R). We are also developing oral drug delivery systems, named the LPM(TM), PLP(TM) and LPE(TM) systems, for the delivery of proteins and water insoluble drugs. We have preclinical animal data demonstrating the oral delivery of the drug leuprolide, a FDA approved injectable anticancer product. We also have preclinical animal data demonstrating the oral delivery of the drug paclitaxel, a FDA approved injectable anticancer product.

Our business strategy is to (1) identify, acquire and exploit rights to new technologies and compounds relating to biodefense and orally delivered compounds to treat gastrointestinal disorders; (2) enhance the value of those technologies through collaborative research and development with leading institutions; (3) market our therapeutics drugs through licensing agreements with major pharmaceutical companies; and (4) market our biodefense vaccine products directly to the U.S. and European governmental agencies.

We have assembled a management team with significant industry experience that oversees the human clinical trials necessary to establish preliminary evidence of effectiveness and seek partnerships with pharmaceutical and biotechnology companies for late-stage development and marketing of our product candidates. We also supplement our management team through a network of consultants and contractors. By operating in this manner, we believe we can efficiently utilize our capital resources to advance our drug and vaccine products to market. We operate through various subsidiary companies: DOR Vaccines, Inc., which is the successor in interest to Innovaccines Corporation, our former joint venture, and formed the basis of our biodefense business initiative; Enteron Pharmaceuticals, Inc., which holds the intellectual property relating to orBec(R); and Oradel Systems, Inc., which formed the basis of our biotherapeutics initiative and holds the intellectual property relating to the LPM(TM) drug delivery system. We plan to continue to develop our later stage product opportunities, while seeking to manage our earlier stage product

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pipeline through collaborative licensing arrangements.

During 2002, our management and board of directors implemented a restructuring plan in which we reduced our headcount and capital expenditures. As part of this plan we acquired our joint venture Innovaccines Corporation from Elan Pharmaceuticals, Plc., which had been developing the Microvax(TM) vaccine delivery system since 1998. This acquisition provided us with a vaccine delivery platform to enter the biodefense vaccine industry. In September 2002, we began development of our first biodefense initiative to develop a vaccine against ricin toxin, one of the agents that potentially could be used in biological warfare. In further refocusing our development plan, we began an initiative to acquire the

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rights to key vaccines, as well as additional delivery technologies. To date, we have focused these efforts on negotiating licenses for the delivery technology related to a nasal vaccine for anthrax and a novel vaccine for botulinum toxin. In our restructuring plan, we have continued clinical evaluation of orBec(R), our lead product, which is currently being evaluated in a multi-center pivotal Phase III trial for the treatment of intestinal graft-vs-host disease.

THE OFFERING

This prospectus relates to the offer and sale from to time of up to 5,297,732 shares of our common stock by the selling stockholders. Of the shares registered for resale through this prospectus, 5,103,432 shares were issued or are issuable in connection with our December 2002 private placement as follows: (1) 3,093,569 shares were sold to investors in the private placement; (2) 1,546,789 shares are issuable upon exercise of warrants, exercisable until December 31, 2007 at a price of \$0.75 per share, sold to investors in the private placement; (3) 310,787 shares are issuable upon exercise of warrants, exercisable until December 31, 2007 at a price of \$0.35 per share, issued as consideration for placement services rendered in connection with the private placement, and (4) 152,286 shares are issuable upon exercise of warrants, exercisable until December 31, 2007 at a price of \$0.75 per share, issued as consideration for placement services rendered in connection with the private placement. Of the remaining 194,300 shares registered for resale through this prospectus, 160,000 shares are issuable upon exercise of warrants, exercisable until December 14, 2007 at prices ranging from \$0.35 to \$0.55 per share, issued to certain of our consultants, and 34,300 shares of common stock were issued to a consultant, in each case as payment for consulting services rendered to us.

The selling stockholders may sell these shares in the over-the-counter market or otherwise, at market prices prevailing at the time of sale, at prices related to the prevailing market price, or at negotiated prices. We will not receive any proceeds from the sale of shares by the selling stockholders.

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RISK FACTORS

You should carefully consider the risks, uncertainties and other factors described below before you decide whether to buy shares of our common stock. Any of the factors could materially affect our business, financial condition and/or operating results and could negatively impact the value of your investment. Also, you should be aware that the risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we do not

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yet know of, or that we currently think are immaterial, may also impair our business operations. The trading price of the common stock offered in this prospectus could decline, and you may lose all or part of your investment. You should also refer to the other information contained in and incorporated by reference into this prospectus including our financial statements and the related notes.

RISKS RELATED TO OUR BUSINESS AND OUR INDUSTRY

WE HAVE HAD SIGNIFICANT LOSSES AND ANTICIPATE FUTURE LOSSES; IF ADDITIONAL FUNDING CANNOT BE OBTAINED, WE MAY REDUCE OR DISCONTINUE OUR PRODUCT DEVELOPMENT AND COMMERCIALIZATION EFFORTS AND WE MAY BE UNABLE TO CONTINUE OUR OPERATIONS.

We are a development stage company that has experienced significant losses since inception and have a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. All of our products are currently in development, preclinical studies or clinical trials, and we have not generated any revenues from sales or licensing of these products. Through March 31, 2003, we have expended approximately \$1.7 million developing our current product candidates and for our clinical trials, and we currently have commitments to spend approximately \$1.1 million over the next two years in connection with our current clinical trials. Additional funds will need to be spent on development of our oral delivery systems, biodefense vaccine products and licenses. Unless and until we are able to generate licensing revenue from orBec(R), our leading product candidate, or another one of our product candidates, we will require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. We may not be able to obtain additional required funding on terms satisfactory to our requirements, if at all. If we are unable to raise additional funds when necessary, we may have to reduce or discontinue development, commercialization or clinical testing of some or all of our product candidates or take other cost-cutting steps that could adversely affect our ability to achieve our business objectives. If additional funds are raised by our issuing equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by our issuing debt, we may be subject to limitations on our operations.

IF WE ARE UNSUCCESSFUL IN DEVELOPING OUR PRODUCTS, OUR ABILITY TO GENERATE REVENUES WILL BE SIGNIFICANTLY IMPAIRED.

To be profitable, our organization must, along with corporate partners and collaborators, successfully research, develop and commercialize our technologies or product candidates. Our current product candidates are in various stages of clinical and pre-clinical development and will require significant further funding, research, development, preclinical and/or clinical testing, regulatory approval and commercialization testing, and are subject to the risks of failure inherent in the development of products based on innovative or novel technologies. Specifically, each of the following is possible with respect to orBec(R) or any of our other product candidates:

- o that we will not be able to maintain our current research and development schedules;
- o that we will encounter problems in clinical trials; or
- o that the technology or product will be found to be ineffective or unsafe.

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If any of the risks set forth above occurs, or if we are unable to obtain the necessary regulatory approvals as discussed below, we may not be able to successfully develop our technologies and product candidates and our business will be seriously harmed. Furthermore, for reasons including those set forth below, we may be unable to commercialize or receive royalties from the sale of orBec(R) or any other technology we develop, even if it is shown to be effective, if:

- o it is uneconomical or the market for the product does not develop or diminishes;
- o we are not able to enter into arrangements or collaborations to manufacture and/or market the product;
- o the product is not eligible for third-party reimbursement from government or private insurers;
- o others hold proprietary rights that preclude us from commercializing the product;
- o others have brought to market similar or superior products; or
- o the product has undesirable or unintended side effects that prevent or limit its commercial use.

OUR BUSINESS IS SUBJECT TO EXTENSIVE GOVERNMENTAL REGULATION, WHICH CAN BE COSTLY, TIME CONSUMING AND SUBJECT US TO UNANTICIPATED DELAYS.

All of our product offerings, as well as the processes and facilities by which they are manufactured, are subject to very stringent United States, federal, foreign, state and local government laws and regulations, including the Federal Food, Drug and Cosmetic Act, the Environmental Protection Act, the Occupational Safety and Health Act, and state and local counterparts to these acts. These laws and regulations may be amended, additional laws and regulations may be enacted, and the policies of the FDA and other regulatory agencies may change.

The regulatory process applicable to our products requires pre-clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years and require the expenditure of substantial capital and other resources. For example, clinical trials of orBec(R) began in 2001 and are expected to continue for at least one more year. We may be unable to obtain, or we may experience difficulties and delays in obtaining, necessary domestic and foreign governmental clearances and approvals to market a product. Also, even if regulatory approval of a product is granted, that approval may entail limitations on the indicated uses for which the product may be marketed. We do not expect to complete clinical testing of any of our product candidates within the next 6 months.

Following any regulatory approval, a marketed product and its manufacturer are subject to continual regulatory review. Later discovery of problems with a product or manufacturer may result in restrictions on such product or manufacturer. These restrictions may include withdrawal of the marketing approval for the product. Furthermore, the advertising, promotion and export of a product are subject to extensive regulation by governmental authorities in the United States and other countries. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and/or criminal prosecution.

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WE WILL BE DEPENDENT ON GOVERNMENT FUNDING, WHICH IS INHERENTLY UNCERTAIN, FOR THE SUCCESS OF OUR BIODEFENSE OPERATIONS.

We are subject to risks specifically associated with operating in the biodefense industry, which is a new and unproven business area. We do not anticipate that a significant commercial market will develop for our biodefense products. Because we anticipate that the principal potential purchasers of our products, as well as potential sources of research and development funds, will be the U.S. government and governmental agencies, the success of our biodefense division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments.

OUR PRODUCTS, IF APPROVED, MAY NOT BE COMMERCIALY VIABLE DUE TO HEALTH CARE CHANGES AND THIRD PARTY REIMBURSEMENT LIMITATIONS.

Recent initiatives to reduce the federal deficit and to change health care delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price controls on pharmaceuticals, and other fundamental changes to the health care delivery system. Any changes of this type could negatively impact the commercial viability of our products, if approved. Our ability to successfully commercialize our product candidates, if they are approved, will depend in part on the extent to which appropriate reimbursement codes and authorized cost reimbursement levels of these products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

WE MAY NOT BE ABLE TO RETAIN RIGHTS LICENSED TO US BY THIRD PARTIES TO COMMERCIALIZE KEY PRODUCTS OR TO DEVELOP THE THIRD PARTY RELATIONSHIPS WE, NEED TO DEVELOP, MANUFACTURE AND MARKET OUR PRODUCTS.

We currently rely on license agreements from Southern Research Institute, the University of Alabama Research Foundation, Thomas Jefferson University and George B. McDonald for the rights to commercialize key product candidates. These agreements require that we use our best efforts to commercialize at least two products in the next 5 years. Our failure to meet the requirement would allow the licensors to terminate the licenses, whereas our meeting this milestone would trigger payment obligations on our part. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, or at all. We have also entered into letters of intent or option agreements with the Ministry of Defense of the United Kingdom, the University of Texas Southwestern Medical Center and the University of Texas Medical Branch at Galveston, under which we plan to license issued patent and pending patent applications for technologies relating to botulinum toxin, intranasal anthrax and ricin vaccines. Although these letters of intent and option agreements provide for defined business terms, we may not be able to come

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to definitive agreements with the institutions and, as a result, may not obtain critical intellectual property rights on which we expect to rely.

Furthermore, we currently have very limited product development capabilities and no manufacturing, marketing or sales capabilities. For us to research, develop and test our product candidates, we need to contract with outside researches, in most cases with or through those parties that did the original research and from whom we have licensed the technologies. If products are successfully developed and approved

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for commercialization, then we will need to enter into collaboration and other agreements with third parties to manufacture and market our products. We may not be able to induce the third parties to enter into these agreements, and, even if we are able to do so, the terms of these agreements may not be favorable to us. Our inability to enter into these agreements could delay or preclude the development, manufacture and/or marketing of some of our product candidates or could significantly increase the costs of doing so. In the future, we may grant to our development partners rights to license and commercialize pharmaceutical and related products developed under the agreements with them, and these rights might limit our flexibility in considering alternatives for the commercialization of these products. Furthermore, third-party manufacturers or suppliers may not be able to meet our needs with respect to timing, quantity and quality for the products.

Additionally, if we do not enter into relationships with third parties for the marketing of our products, if and when they are approved and ready for commercialization, we would have to build our own sales force. Such a marketing and sales force would be particularly relevant to our biotherapeutic products, which we intend to market to a broad customer base. Development of an effective sales force would require significant financial resources, time and expertise. We may not be able to obtain the financing necessary to establish a sales force in a timely or cost effective manner, if at all, and any sales force we are able to establish may not be capable of generating demand for our product candidates, if they are approved.

WE MAY SUFFER PRODUCT AND OTHER LIABILITY CLAIMS; WE MAINTAIN ONLY LIMITED PRODUCT LIABILITY INSURANCE, WHICH MAY NOT BE SUFFICIENT.

The clinical testing, manufacture and sale of our products involves an inherent risk that human subjects in clinical testing or consumers of our products may suffer serious bodily injury or death due to side effects, allergic reactions or other unintended negative reactions to our products. As a result, product and other liability claims may be brought against us. We currently have clinical trial and product liability insurance with limits of liability of \$5 million, which may not be sufficient to cover our potential liabilities. Because liability insurance is expensive and difficult to obtain, we may not be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Furthermore, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity.

WE MAY NOT BE ABLE TO COMPETE SUCCESSFULLY WITH OUR COMPETITORS IN THE BIOTECHNOLOGY INDUSTRY.

The biotechnology industry is intensely competitive, subject to rapid change and sensitive to new product introductions or enhancements. Virtually all of our existing competitors have greater financial resources, larger technical staffs, and larger research budgets than we have, as well as greater experience in

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developing products and conducting clinical trials. Our competition is particularly intense in the gastroenterology and transplant areas and is also intense in the therapeutic area of inflammatory bowel disease. We face intense competition in the area of biodefense from various public and private companies and universities, as well as governmental agencies, such as the U.S. Army, which may have their own proprietary technologies that may directly compete with our technologies. In addition, there may be other companies that are currently developing competitive technologies and products or that may in the future develop technologies and products that are comparable or superior to our technologies and products. We may not be able to compete successfully with our existing and future competitors.

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WE MAY BE UNABLE TO COMMERCIALIZE OUR PRODUCTS IF WE ARE UNABLE TO PROTECT OUR PROPRIETARY RIGHTS AND WE MAY BE LIABLE FOR SIGNIFICANT COSTS AND DAMAGES IF WE FACE A CLAIM OF INTELLECTUAL PROPERTY INFRINGEMENT BY A THIRD PARTY.

Our success depends in part on our ability to obtain and maintain patents, protect trade secrets and operate without infringing upon the proprietary rights of others. For example, we currently hold the rights to a patent for our Microvax(TM) technology in the field of mucosally and orally administered vaccines. In the absence of patent and trade secret protection, competitors may adversely affect our business by independently developing and marketing substantially equivalent or superior products and technology, possibly at lower prices. We could also incur substantial costs in litigation and suffer diversion of attention of technical and management personnel if we are required to defend ourselves in intellectual property infringement suits brought by third parties, with or without merit, or if we are required to initiate litigation against others to protect or assert our intellectual property rights. Moreover, any such litigation may not be resolved in our favor.

Although we have filed various patent applications covering the uses of our product candidates, we may not be issued patents from the patent applications already filed or from applications we may file in the future. Moreover, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions, and recently has been the subject of much litigation. Any patents we have obtained, or may obtain in the future, may be challenged, invalidated or circumvented. To date, no consistent policy has been developed in the United States Patent and Trademark Office regarding the breadth of claims allowed in biotechnology patents.

In addition, because patent applications in the United States are maintained in secrecy until patents issue, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we and our licensors are the first creators of inventions covered by any licensed patent applications or patents or that we or they are the first to file. The Patent and Trademark Office may commence interference proceedings involving patents or patent applications, in which the question of first inventorship is contested. Accordingly, the patents owned or licensed to us may not be valid or may not afford us protection against competitors with similar technology, and the patent applications licensed to us may not result in the issuance of patents.

It is also possible that our patented technologies may infringe on patents or other rights owned by others, licenses to which may not be available to us. We are aware of at least one issued U.S. patent assigned to the U.S. Government relating to one component of one of our vaccine candidates that we may be required to license in order to commercialize those vaccine candidates. We may not be successful in our efforts to obtain a license under such patent on terms

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favorable to us, if at all. We may have to alter our products or processes, pay licensing fees or cease activities altogether because of patent rights of third parties.

In addition to the products for which we have patents or have filed patent applications, we rely upon unpatented proprietary technology and may not be able to meaningfully protect our rights with regard to that unpatented proprietary technology. Furthermore, to the extent that consultants, key employees or other third parties apply technological information developed by them or by others to any of our proposed projects, disputes may arise as to the proprietary rights to this information, which may not be resolved in our favor.

OUR BUSINESS COULD BE HARMED IF WE FAIL TO RETAIN OUR CURRENT PERSONNEL OR IF THEY ARE UNABLE TO EFFECTIVELY RUN OUR BUSINESS.

We have only five employees: Dr. Ralph Ellison, our Chief Executive Officer and President; Steve Kanzer, our Vice Chairman; William Milling, our Controller, Treasurer and Corporate Secretary; Robert Brey, our Vice President of Research and Development; and Robin Simunceck, our Clinical Project Manager and an Administrative Assistant. Mr. Ellison was hired in March 2003, following the resignation of David M. Kent, our former Chief Executive Officer for personal reasons; Mr. Kanzer became our Vice Chairman in January 2003; Mr. Milling was hired in September 2002; and Mr. Brey was hired in

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December 2002. In addition, Alexander Haig, our non-employee Chairman of the Board was appointed in January 2003. We depend upon the five employees to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them, even though they have very limited experience in managing or operating our business, or our inability to attract and retain other qualified employees in a timely manner, would likely have a negative impact on our operations. Furthermore, because of their inexperience in operating our business, there is significant uncertainty as to how our management team will perform. Our management team may need to devote a significant amount of time to learning about our business and its markets, which could limit their effectiveness in managing our business for a period of time. We will not be successful if this new management team cannot effectively manage and operate our business.

WE HAVE RELATIONSHIPS THAT PRESENT CONFLICTS OF INTEREST.

Our Vice Chairman of the Board of Directors, Steve H. Kanzer, is Chairman and Chief Executive Officer of Accredited Ventures, Inc., which in the regular course of its business, identifies, evaluates and pursues investment opportunities in biomedical and pharmaceutical products, technologies and companies. However, Accredited is under no obligation to make any additional products or technologies available to us. Therefore, we may lose to Accredited opportunities of which Mr. Kanzer is aware that would be beneficial to our business. In addition, our officers and directors and officers or directors appointed in the future may from time to time serve as officers, directors or consultants of other biopharmaceutical or biotechnology companies and those companies may have interests that conflict with our interests. As a result of our recent management changes, which highlighted some of the actual and potential conflicts, we have not yet developed policies to address the conflicts of interest, but we plan to do so in the near future.

RISKS RELATED TO THE OFFERING

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OUR STOCK PRICE IS HIGHLY VOLATILE AND OUR STOCK IS THINLY TRADED

The market price of our common stock, like that of many other development stage public pharmaceutical and biotechnology companies, has been highly volatile and may continue to be so in the future due to a wide variety of factors, which include, actual or anticipated fluctuations in our results of operations, announcements of innovations by us or our competitors, additions or departures of key personnel or general market conditions. For example, on January 7, 2003, when ricin was discovered in an apartment in London and we announced that we had retained Mr. Haig as our Chairman of the Board, our stock price went from \$0.58 per share to \$1.05 per share in one day and has fluctuated between \$0.80 per share and \$1.57 per share from that date through May 28, 2003. From July 1, 2000 through May 28, 2003, the per share price of our common stock ranged from a high of \$9.44 per share to a low of \$0.11 per share. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance.

Since it commenced trading on the American Stock Exchange on August 6, 1998, our common stock has been thinly traded. The average trading volume for our common stock averaged approximately 36,907 shares per day from January 1, 2001 to April 30, 2003. The relatively illiquid market for our shares may have an adverse effect on the market price for our shares and on stockholders' ability to sell our common stock at the prevailing market price. A more active trading market for our common stock may not develop.

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OUR STOCK MAY NOT REMAIN LISTED ON THE AMERICAN STOCK EXCHANGE.

Because we continue to incur losses from continuing operations in fiscal 2003, the stockholders' equity standard applicable to us of AMEX's continued listing requirements will increase from \$4 million to \$6 million for fiscal years ending 2003 and beyond. Moreover, our net equity of \$3.3 million as of March 31, 2003 does not satisfy the \$4 million minimum stockholders' equity requirement applicable to calendar quarters ending during 2003. If, for this reason or for any other reason, our stock were to be delisted from the American Stock Exchange, we may not be able to list our common stock on another national exchange or market. If our common stock is not listed on a national exchange or market, the trading market for our common stock may be even more illiquid than it is already. Upon any such delisting, our common stock would become subject to the penny stock rules of the SEC, which generally are applicable to equity securities with a price of less than \$5.00 per share, other than securities registered on certain national securities exchanges or quoted on the Nasdaq system, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with bid and ask quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that, before a transaction in a penny stock that is not otherwise exempt from such rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. As a result of these requirements, if our common stock were to become subject to the penny stock rules, it is likely that the

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price of our common stock would decline and that our stockholders would find it more difficult to sell their shares.

INVESTORS MAY SUFFER SUBSTANTIAL DILUTION.

We have a number of agreements or obligations that may result in dilution to investors. These include:

- o warrants to purchase a total of approximate 5.2 million shares of our common stock at a current weighted average exercise price of approximately \$2.50.
- o conversion rights and dividend rights of preferred stock, consisting of 119,428 shares of Series B preferred stock (\$8.0 million original liquidation value) bearing an 8% cumulative payment-in-kind dividend and convertible at the liquidation value into common stock at \$7.38 per share;
- o anti-dilution rights under the above warrants and preferred stock, which can permit purchase of additional shares and/or lower exercise or conversion prices under certain circumstances; and
- o options to purchase approximately 6,078,000 shares of common stock at a current weighted average exercise price of approximately \$0.95.

To the extent that anti-dilution rights are triggered, or warrants, options or conversion rights are exercised, our stockholders will experience substantial dilution and our stock price may decrease.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the information incorporated by reference in it contains, or will contain, various "forward-looking statements" that are based on management's beliefs, as well as assumptions made by, and information currently available to, management, including statements regarding future economic performance, financial condition, liquidity and capital resources, acceptance of our products and services by the market and management's objectives. Where possible, we have tried, and will try, to identify the forward-looking statements by using words such as "anticipates," "expects," "believes," "estimates," "plans," "intends" and similar expressions. These statements are subject to various risks, uncertainties and other factors that could cause our actual results, performance and achievements to differ materially from those expressed in, or implied by, these statements. These risks, uncertainties and other factors include the risk factors discussed above, in any prospectus supplement and in any document incorporated by reference into this prospectus. You should not place any undue reliance on any forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to update any forward-looking statements to reflect new information, future events or developments or changes of circumstances or for any other reason.

USE OF PROCEEDS

Any net proceeds from any sale of shares of our common stock covered by this prospectus will be received by the selling stockholders. We will not receive any proceeds from the sale of shares by the selling stockholders.

SELLING STOCKHOLDERS

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Of the 5,297,732 shares of our common stock registered for resale through this prospectus and listed under the column "Shares Available for Sale Under This Prospectus" on the table set forth below, 5,103,432 shares were issued or are issuable in connection with our December 2002 private placement as follows: (1) 3,093,569 shares were sold to investors in the private placement; (2) 1,546,789 shares are issuable upon exercise of warrants, exercisable until December 31, 2007 at a price of \$0.75 per share, sold to investors in the private placement; (3) 310,787 shares are issuable upon exercise of warrants, exercisable until December 31, 2007 at a price of \$0.35 per share, issued as consideration for placement services rendered in connection with the private placement, and (4) 152,286 shares are issuable upon exercise of warrants, exercisable until December 31, 2007 at a price of \$0.75 per share, issued as consideration for placement services rendered in connection with the private placement. These shares of our common stock are included in this prospectus pursuant to registration rights we granted in connection with the December 2002 private placement.

Of the remaining 194,300 shares of our common stock registered for resale through this prospectus and listed under the column "Shares Available for Sale Under This Prospectus" on the table set forth below, 160,000 shares are issuable upon exercise of warrants, exercisable until December 14, 2007 at prices ranging from \$0.35 to \$0.58 per share, issued to certain of our consultants and 34,300 shares were issued to those consultants, in each case as payment for consulting services. These shares of our common stock are included in this prospectus pursuant to the registration rights we granted in connection with the engagement of these consultants.

The following table sets forth, to our knowledge, the number of shares beneficially owned by each of the selling stockholders as of the date of this prospectus. We are not able to estimate the amount of shares that will be held by each selling stockholder after the completion of this offering because (1) the selling stockholders may sell less than all of the shares registered under this prospectus, (2) the selling stockholders may exercise less than all of their warrants, and (3) to our knowledge, the selling

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stockholders currently have no agreements, arrangements or understandings with respect to the sale of any of their shares. The following table assumes that all of the currently outstanding warrants will be exercised into common stock and all of the shares being registered pursuant to this prospectus will be sold. The selling stockholders are not making any representation that any shares covered by this prospectus will be offered for sale. Except as otherwise indicated, based on information provided to us by each selling stockholder, the selling stockholders have sole voting and investment power with respect to their shares of common stock.

| NAME OF SELLING STOCKHOLDER | NUMBER OF SHARES OF COMMON STOCK OWNED BEFORE THE OFFERING (1) | PERCENT OF COMMON STOCK OWNED BEFORE THE OFFERING | SHARES AVAILABLE FOR SALE UNDER THIS PROSPECTUS (1) | NUMB SHAR COMMON TO BE AF COMPLE THE OF |
|-----------------------------|--|--|---|---|
| ----- | ----- | ----- | ----- | ----- |

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| | | | | |
|----------------------------------|-----------|------|---------|----|
| Concordia Capital | 1,002,637 | 3.5% | 985,714 | 1 |
| Steve H. Kanzer (2) | 747,713 | 2.6% | 80,193 | 66 |
| Pharmainvestors, LLC (3) | 831,666 | 2.1% | 429,291 | 40 |
| Harris Kanzer (4) | 642,857 | 2.2% | 642,857 | |
| Odisseas Myrianthopoulos (5) | 225,000 | * | 225,000 | |
| David M. Kent (6) | 214,286 | * | 214,286 | |
| Alberto Guiterez | 214,286 | * | 214,286 | |
| Ralph M. Ellison (7) | 214,286 | * | 214,286 | |
| Martin Draper | 128,571 | * | 128,571 | |
| William Kanzer (8) | 214,286 | * | 214,286 | |
| Catherine Makary | 150,000 | * | 150,000 | |
| Mitchell Littman | | | | |
| and Sima Littman JTWROS | 107,143 | * | 107,143 | |
| Ivy Scheinholz | 90,000 | * | 90,000 | |
| Ed O'Donnell | 107,143 | * | 107,143 | |
| Daniel Kessel, M.D. (9) | 64,286 | * | 64,286 | |
| Lawrence and Shirley Kessel (10) | 214,286 | * | 64,286 | 16 |
| Charles Griffith | 64,286 | * | 64,286 | |
| Gilbert Goldstein | 51,429 | * | 51,429 | |
| Nicholas Stergis (11) | 563,528 | 2.0% | 80,913 | 43 |
| Nicholas and | | | | |
| Jennifer Stergis JTWROS | 42,857 | * | 42,857 | |
| Guilhem Canstagne | 42,857 | * | 42,857 | |
| Ken Alberstadt | 42,857 | * | 42,857 | |
| Dewey Tran | 22,500 | * | 22,500 | |
| Giuseppe Cavalieri | 42,857 | * | 42,857 | |
| Eva Weinberg (12) | 15,000 | * | 15,000 | |
| Peter Salomon (13) | 165,000 | * | 15,000 | 15 |
| John and Tiffany Ofenloch | 6,429 | * | 6,429 | |
| Louis Bianco | 214,286 | * | 214,286 | |
| James Bianco, M.D. | 214,286 | * | 214,286 | |
| Nicole Scheinholz | 15,000 | * | 15,000 | |
| Atlas Capital Services, LLC (14) | 195,669 | * | 195,669 | |
| Steven Pollan (15) | 35,619 | * | 35,619 | |
| Dan Myers (16) | 4,505 | * | 4,505 | |
| Redington, Inc. (17) | 164,300 | * | 164,300 | |
| Ibis Consulting Group, Inc. (18) | 30,000 | * | 30,000 | |
| Evan Myrianthopoulos (19) | 215,454 | * | 65,454 | 15 |

* Less than 1%.

(1) Includes shares of common stock issuable upon the exercise of warrants as follows: Concordia Capital 328,571 shares; Steve H. Kanzer 80,913 shares; Pharmainvestors, LLC 142,857 shares; Harris Kanzer 214,286 shares; Odisseas Myrianthopoulos 75,000 shares; David M. Kent 71,429 shares; Alberto Guiterez 71,429 shares; Ralph M. Ellison 71,429 shares; William Kanzer 71,429 shares; Catherine Makary 50,000 shares; Martin Draper 42,857 shares; Mitchell Littman and Sima Littman JTWROS 35,714 shares; Ivy Scheinholz 30,000 shares; Ed O'Donnell 35,714 shares; Daniel Kessel 21,429 shares; Lawrence and Shirley Kessel 171,249 shares; Charles Griffith 21,429 shares; Gilbert Goldstein 17,143 shares; Nicholas and Jennifer Stergis JTWROS 80,611 shares; Guilhem Canstagne 14,286 shares; Ken Alberstadt 14,286 shares; Dewey Tran 7,500 shares; Giuseppe Cavalieri 14,286 shares; Eva Weinberg 5,000 shares; Peter Salomon 5,000 shares; John and Tiffany

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Ofenloch 2,143 shares; Louis Bianco 71,429; James Bianco 71,429 shares; Nicole Scheinholz 5,000 shares; Atlas Capital Services, LLC 195,669 shares; Steven Pollan 35,619 shares; Dan Myers 4,505 shares; Reddington, Inc. 130,000 shares; Ibis Consulting Group, Inc. 30,000 shares; and Evan Myrianthopoulos 65,454 shares.

- (2) Steve H. Kanzer is our Vice Chairman of the Board of Directors, and from June 2002 until January 2003 was our Chairman of the Board and Interim President. He has been a member of our Board of Directors since 1996. Mr. Kanzer is also Chairman, Chief Executive Officer and sole stockholder of Accredited Equities, Inc. and Accredited Ventures, Inc., which are merchant banking and venture capital firms specializing in biotechnology companies and, which provided placement services in connection with our December 2002 private placement. As consideration for these placement services, we issued to Mr. Kanzer warrants to purchase 54,304 shares of our common stock, exercisable until December 31, 2007 at a price of \$0.35 per share, and warrants to purchase 26,609 shares, exercisable until December 31, 2007 at a price of \$0.75 per share. The shares subject to these warrants are registered for resale in this prospectus (see footnote (1)). The number of shares beneficially owned by Mr. Kanzer includes 616,800 shares immediately issuable upon exercise of options. The number of shares beneficially owned by Mr. Kanzer does not include 688,809 shares of common stock and 142,857 shares of common stock issuable upon the exercise of warrants held by Pharmainvestors, LLC (see footnote (3)).
- (3) Pharmainvestors, LLC, is a limited liability company incorporated under the laws of Nevis, West Indies, the sole member of which is an irrevocable trust of which Steve H. Kanzer is a beneficiary, but over which he has no control. Henry Schwartz is the sole trustee of the irrevocable trust. The shares beneficially owned by Pharmainvestors, LLC consist of 688,809 shares of common stock and 142,857 shares of common stock issuable upon the exercise of warrants. The shares subject to these warrants are registered for resale in this prospectus (see footnote (1)). Mr. Kanzer disclaims beneficial ownership of such shares.
- (4) Harris Kanzer is the father of our Vice Chairman of the Board, Steve H. Kanzer. They do not reside in the same household.
- (5) Odiseas Myrianthopoulos is the adult cousin of Evan Myrianthopoulos, one of the members of our board of directors. They do not reside in the same household.
- (6) David M. Kent was our Chief Executive Officer and President from January 2003 to February 2003.
- (7) Ralph M. Ellison has been our Chief Executive Officer and President since March 2003.
- (8) William Kanzer is the adult brother of our Vice Chairman of the Board, Steve H. Kanzer. They do not reside in the same household.
- (9) Dr. Daniel Kessel is the adult brother of Dr. Larry Kessel, one of the members of our board of directors. They do not reside in the same household.
- (10) Lawrence Kessel has been a member of our Board of Directors since June 2002. The shares beneficially owned by him include 150,000 shares of common stock immediately issuable upon exercise of options.
- (11) Nicholas Stergis is employed by Accredited Equities, Inc., which served as a selected dealer to our placement agent for the December 2002 private placement. As consideration for these placement services, we issued to Mr.

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Stergis warrants to purchase 54,304 shares of our common stock, exercisable until December 31, 2007 at a price of \$0.35 per share, and warrants to purchase 26,609 shares, exercisable until December 31, 2007 at a price of \$0.75 per share. The shares subject to these

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warrants are registered for resale in this prospectus (see footnote (1)). The number of shares beneficially owned by Mr. Stergis includes 129,552 shares of common stock issuable upon exercise of options. The number of shares beneficially owned by Mr. Stergis does not include 42,857 shares of common stock owned by Nicholas and Jennifer Stergis as joint tenants with right of survivorship.

- (12) Eva Weinberg is the adult sister of Dr. Peter Salomon, one of the members of our board of directors. They do not reside in the same household.
- (13) Dr. Peter Salomon has been a member of our Board of Directors since June 2002. The shares beneficially owned by him include 150,000 shares of common stock immediately issuable upon exercise of options.
- (14) Atlas Capital Services, LLC provided placement services in connection with our December 2002 private placement. As consideration for the placement services provided by Atlas, we issued to Atlas warrants to purchase 131,321 shares, exercisable until December 31, 2007 at a price of \$0.35 per share, and warrants to purchase 64,348 shares, exercisable until December 31, 2007 at a price of \$0.75 per share. The shares subject to these warrants are registered for resale in this prospectus (see footnote (1)).
- (15) Steve Pollan is an employee of Atlas Capital Services, LLC. As consideration for the placement services provided by Atlas, we issued to Mr. Pollan warrants to purchase 23,905 shares, exercisable until December 31, 2007 at a price of \$0.35 per share, and warrants to purchase 11,714 shares, exercisable until December 31, 2007 at a price of \$0.75 per share. The shares subject to these warrants are registered for resale in this prospectus (see footnote (1)).
- (16) Dan Myers is an employee of Atlas Capital Services, LLC. As consideration for the placement services provided by Atlas, we issued to Mr. Myers warrants to purchase 3,024 shares, exercisable until December 31, 2007 at a price of \$0.35 per share, and warrants to purchase 1,481 shares, exercisable until December 31, 2007 at a price of \$0.75 per share. The shares subject to these warrants are registered for resale in this prospectus (see footnote (1)).
- (17) Redington, Inc. serves as a consultant to the Company. We issued to Redington warrants to purchase 130,000 shares, exercisable until December 14, 2007 at prices ranging from \$0.35 to \$0.58 per share, as payment for consulting services. These warrants vest upon the Company's common stock attaining certain price levels, and the shares subject to these warrants are registered for resale in this prospectus. (see footnote (1)).
- (18) Ibis Consulting Group, Inc. serves as a consultant to the Company. We issued to Ibis warrants to purchase 30,000 shares, exercisable until December 14, 2004 at prices ranging from \$0.35 to \$0.58 per share, as payment for consulting services. The shares subject to these warrants are registered for resale in this prospectus (see footnote (1)).
- (19) Evan Myriantopoulos has been a member of our Board of Directors since

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November 2002. Mr. Myrianthopoulos provided placement services in connection with our December 2002 private placement. As consideration for these services, we issued to Mr. Myrianthopoulos warrants to purchase 43,929 shares, exercisable until December 31, 2007 at a price of \$0.35 per share, and warrants to purchase 21,525 shares, exercisable until December 31, 2007 at a price of \$0.75 per share. The shares subject to these warrants are registered for resale in this prospectus (see footnote (1)). The number of shares beneficially owned by Mr. Myrianthopoulos includes 150,000 shares immediately issuable upon exercise of options.

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PLAN OF DISTRIBUTION

We are registering the shares of our common stock covered by this prospectus for the selling stockholders. As used in this prospectus, "selling stockholders" include any pledgees or donees who may later hold the shares, provided they are named in a prospectus supplement. We will pay the costs and fees of registering the shares of our common stock, but each selling stockholder will pay any brokerage commissions, discounts or other expenses relating to the sale of the shares.

Each selling stockholder may sell the shares of our common stock in the over-the-counter market or otherwise, at market prices prevailing at the time of sale, at prices related to the prevailing market prices, or at negotiated prices. In addition, each selling stockholder may sell some or all of its common shares through:

- o a block trade in which a broker-dealer may resell a portion of the block, as principal, in order to facilitate the transaction;
- o purchases by a broker-dealer, as principal, and resale by the broker-dealer for its account; or
- o ordinary brokerage transactions and transactions in which a broker solicits purchasers.

Each selling stockholder may negotiate and pay broker-dealers commissions, discounts or concessions for their services. Broker-dealers engaged by each selling stockholder may allow other broker-dealers to participate in resales. However, the selling stockholders and any broker-dealers involved in the sale or resale of the common shares may qualify as "underwriters" within the meaning of the Section 2(a)(11) of the Securities Act of 1933. In addition, the broker-dealers' commissions, discounts or concessions may qualify as underwriters' compensation under the Securities Act. If a selling stockholder qualifies as an "underwriter," it will be subject to the prospectus delivery requirements of Section 5(b)(2) of the Securities Act. We have informed each selling stockholder that the anti-manipulative provisions of Regulation M under the Securities Exchange Act of 1934 may apply to its sales in the market.

Furthermore, each selling stockholder may:

- o agree to indemnify any broker-dealer or agent against certain liabilities related to the selling of the shares, including liabilities arising under the Securities Act;
- o sell its shares in other ways not involving market makers or established trading markets; or

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- o sell its shares under Rule 144 under the Securities Act rather than under this prospectus, if the transaction meets the requirements of Rule 144.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly, and special reports, proxy statements, and other information with the SEC. You may read and copy any document we file at the SEC's public reference rooms at Judiciary Plaza Building, 450 Fifth Street, N.W., Room 1024, Washington, D.C. 20549, as well as at the SEC's regional offices at 175 West Jackson Street, Suite 900, Chicago, Illinois 60661 and 223 Broadway, New York, New York 10279. Copies of these materials may also be obtained from the SEC at prescribed rates by writing to the Public Reference Section of the SEC, 450 Fifth Street, N.W., Washington, D.C. 20549.

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You may obtain information about the operation of the SEC public reference room in Washington, D.C. by calling the SEC at 1-800-SEC-0330. Our filings are also available to the public from commercial document retrieval services and at the web site maintained by the SEC at "<http://www.sec.gov>."

This prospectus is part of a registration statement we have filed with the SEC. The SEC allows us to incorporate documents by reference. This means that we can disclose important information by referring you to another document we file separately with the SEC. The information incorporated by reference is considered to be part of this prospectus, except for any information superseded by information in this prospectus. The information we file later with the SEC will automatically update and supersede the information contained in this prospectus or incorporated by reference from earlier filings. 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 all of the securities covered by this prospectus have been sold or we have deregistered all of the securities then remaining unsold:

- o Our annual report on Form 10-KSB for the fiscal year ended December 31, 2002;
- o Our quarterly report on Form 10-QSB for the fiscal quarter ended March 31, 2003; and
- o The description of our common stock contained in the Registration Statement on Form 8-A dated August 4 1998 filed under the Securities Exchange Act of 1934, and all amendments and reports filed by us to update the description.

You may request a copy of these filings, at no cost, by writing or telephoning us at our principal executive offices at the following address and phone number:

Corporate Secretary
DOR Biopharma, Inc.
28101 Ballard Drive
Suite F
Lake Forest, Illinois 60045
(847) 573-8990

LEGAL MATTERS

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The legality of the securities offered hereby has been passed upon for us by Katten Muchin Zavis Rosenman, Chicago, Illinois.

EXPERTS

Ernst & Young LLP, independent auditors, have audited our consolidated financial statements included in our Annual Report on Form 10-KSB at December 31, 2002 and 2001, and the years then ended, and the cumulative period from February 15, 1985 (inception) to December 31, 2002, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.