DOR BIOPHARMA INC
Form 424B3
October 30, 2003

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Registration No. 333-109724

PROSPECTUS

DOR BIOPHARMA, INC.

15,334,625 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 October 28, 2003 was $0.67 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 2 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 October 30, 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 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. This summary does not contain all of the information that you should consider before investing in our common stock. You should read this entire prospectus and the documents that are incorporated by reference carefully, including the risk factors and the financial statements and related notes.

We are a pharmaceutical company currently developing a topically active, oral steroid called orBec(R), which is 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 planning a Phase II clinical program to investigate other uses for orBec(R) including prevention of intestinal graft-vs.-host disease, as well as the treatment of inflammatory bowel diseases and irritable bowel syndrome. Additionally, we are developing, through collaborations with leading universities, biodefense vaccines, including injectable and nasal vaccines against ricin toxin and a nasally delivered vaccine against botulinum toxin. We have also developed oral drug delivery systems, named the LPM(TM), PLP(TM), and LPE(TM) which are 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. We are in the process of trying to license these technologies to third parties for further development and commercialization.

Our business strategy is to (1) enhance the value of our current products through further research and development, specifically preclinical and clinical testing towards regulatory approval; (2) identify, acquire and exploit rights to new technologies and compounds related to our current product lines; (3) market our therapeutic drugs through licensing agreements with major pharmaceutical companies; (4) market our biodefense vaccine products directly to the U.S. and European governmental agencies; and (5) work to develop additional promising compounds utilizing collaborations with third parties such as our licensors at the University of Texas Southwestern Medical Center and Thomas Jefferson University.

We have assembled an experienced management team that oversees the preclinical and human clinical trials necessary to establish proof of safety and efficacy for our current products. We supplement our management team through a network of consultants and contractors on an as needed basis. By operating in this manner, we believe we can efficiently utilize our capital resources to advance our drug and vaccine products to market.

THE OFFERING

This prospectus relates to the offer and sale from to time of up to 15,334,625 shares of our common stock by the selling stockholders. Of the shares registered for resale through this prospectus, 14,953,206 shares were issued or are issuable in connection with our July 2003 private placement as follows: (1) 6,796,912 shares were sold to investors in the private placement; (2) 6,796,912 shares are issuable upon exercise of warrants, exercisable until September 17, 2008 at a price of $0.8756 per share, sold to investors in the private placement; (3) 1,359,382 shares are issuable upon exercise of warrants, exercisable until September 17, 2008 at a price of $0.8756 per share, issued as consideration for placement services rendered in connection with the private placement. Of the remaining 381,419 shares registered for resale through this prospectus, 141,305 and 203,114 shares were issued in exchange for license rights and 37,000 shares of common stock were issued to a consultant, 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.

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 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 September 30, 2003, we have expended approximately $2.2 million developing our current product candidates for our clinical trials, and we currently have commitments to spend approximately $2.6 million over the next two years in connection with development of our oral delivery systems, licenses, employee agreements, and consulting agreements. 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 preclinical 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:

- that we will not be able to maintain our current research and development schedules;

- that we will encounter problems in clinical trials; or

- that the technology or product will be found to be ineffective or unsafe.

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:

- it is uneconomical or the market for the product does not develop or diminishes;

- we are not able to enter into arrangements or collaborations to manufacture and/or market the product;

- the product is not eligible for third-party reimbursement from government or private insurers;

- others hold proprietary rights that preclude us from commercializing the product;

- others have brought to market similar or superior products; or

- 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. 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. Clinical trials of our lead product candidate OrBec(R) began in 2001 and are expected to continue for at least nine more months. We do not expect to complete clinical testing of any of our product candidates within the next six 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, among other things, 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.

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 COMMERCIALLY 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, the University of Texas Southwestern Medical Center, The University of Texas Medical Branch at Galveston, Thomas Jefferson University, Southern Research Institute, the University of Alabama Research Foundation, and George B. McDonald MD for the rights to commercialize key product candidates. 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 Ministry of Defense of the United Kingdom, the University of Texas Southwestern Medical Center and the University of Texas Medical Branch--Galveston, under which we plan to license issued patent and pending patent applications for technologies relating to nasal delivery of vaccines, and use of orBec(R) for Irritable Bowel Syndrome. Although these letters of intent and option agreements provide for defined business terms, we may not be able to come 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 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 may 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. 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 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.

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 nasally administered ricin 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 and our licensors have filed various patent applications covering the uses of our product candidates, patents may not be issued from the patent applications already filed or from applications that we might 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 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; Geoff Green, our Vice President of Clinical Operations; William Milling, our Controller, Treasurer and Corporate Secretary; Robert Brey, our Vice President of Research and Development; and Robin Simuncek, our Clinical Project Manager and Administrative Assistant. We depend upon these 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 little 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, these few employees on whom our business depends have very limited experience in managing and operating our business. Dr. Ellison was hired in March 2003; Mr. Green was hired in July 2003; Mr. Milling was hired in September 2002; and Mr. Brey was hired in December 2002. In addition, Alexander Haig, our Chairman of the Board was appointed in January 2003. Because of this inexperience in operating our business, there is significant uncertainty as to how our management team will perform. Furthermore, 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.

RISKS RELATED TO THE OFFERING

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, when ricin was discovered in an apartment in London and we announced that we had retained Mr. Haig as our chairman of the board on January 7, 2003; our stock price went from $0.58 per share to $1.05 per share in one day and has fluctuated between $0.70 per share and $1.57 per share from that date through September 30, 2003. From July 1, 2000 through September 30, 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, including a high of $2.10 per share and low of $0.11 per share since the beginning of 2002. 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 43,406 shares per day from January 1, 2001 to September 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.

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 the American Stock Exchange's continued listing requirements will increase from $4 million to $6 million for fiscal years ending 2003 and beyond. Moreover, our net equity of $2.3 million as of June 30, 2003 did not satisfy the $4 million minimum stockholders' equity requirement applicable to calendar quarters ending during 2003, and we received notification from the

AMEX that we were no longer in compliance with their minimum listing requirements. On August 4, 2003 we submitted a compliance plan, and the AMEX has accepted our plan and given us 18 months to regain compliance per our plan. If, however, we do not conform to our plan, or if after the 18 month period we are not in compliance with the minimum listing requirements, we may be delisted from the AMEX. Furthermore, we cannot assure you that we will continue to satisfy other requirements necessary to remain listed on the AMEX or that the AMEX will not take additional actions to delist our common stock. If for any reason, our stock were to be delisted from the AMEX, 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 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:

- warrants to purchase a total of approximate 6.7 million shares of our common stock at a current weighted average exercise price of approximately $2.17.

- conversion rights and dividend rights of preferred stock, consisting of 124,126 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 $6.58 per share;

- anti-dilution rights under the above warrants and preferred stock, which can permit purchase of additional shares and/or lower exercise/conversion prices under certain circumstances; and

- options to purchase approximately 7,200,000 shares of common stock of a current weighted average exercise price of approximately $0.75.

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.

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

Of the 15,334,625 shares of our common stock registered for public resale pursuant to this prospectus and listed under the column "Shares Available for Sale Under This Prospectus" on the table set forth below, 14,953,206 shares were issued or are issuable in connection with our July 2003 private placement, in which we sold shares at $0.796 per share receiving a warrant, to purchase a share of common stock for $0.8756, for each share purchased, this placement was completed on July 18, 2003 subject to shareholder approval of this financing and an amendment to our Certificate of Incorporation increasing authorized shares of common stock to 100,000,000 at our annual meeting September 15, 2003. Both motions passed at our annual meeting, and the distribution of the shares from this placement are: (1) 6,796,912 shares were sold to investors in the private placement; (2) 6,796,912 shares are issuable upon exercise of warrants, exercisable until September 17, 2008 at a price of $0.8756 per share, sold to investors in the private placement; (3) 1,359,382 shares are issuable upon exercise of warrants, exercisable until September 17, 2008 at a price of $0.8756 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 July 2003 private placement.

Of the remaining 381,419 shares of our common stock registered for public resale pursuant to this prospectus and listed under the column "Shares Available for Sale Under This Prospectus" on the table set forth below, 141,305 shares were issued to Thomas Jefferson University in payment for a license to their botulinum technology, and 203,114 shares were issued to The Board of Regents of the University of Texas system and their designees in exchange for a license to their ricin technology, and 37,000 shares were issued to Robert Langer Ph.D. in exchange for consulting services. These shares of our common stock are included in this prospectus pursuant to the registration rights we granted in connection with these license agreements and the engagement of this consultant.

The following table sets forth 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 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)	NUMBER OF SHARE OF COMMON STOCK TO BE OWNED AFTER COMPLETIO OF THE OFFERING
David W Ruttenberg	62,814	*	62,814	-
Roger and Margaret Coleman JTWROS	125,628	*	125,628	-
Eugenia VI Venture Holdings LTD	1,256,280	3.57%	1,256,280	-
OrbiMed Advisors LLC (2)	5,026,000	13.55%	5,026,000	-
Bruno Widmer	62,814	*	62,814	-
The Osterweis Revocable trust	125,628	*	125,628	-
Keys Foundation	1,256,280	3.57%	1,256,280	-
Ronald Marchand Jr & Margaret Marchand	25,124	*	25,124	-
A.M. Pappas (3)	753,768	2.16%	753,768	-
Greg Dawe	62,814	*	62,814	-
Perceptive Life Sciences Master Fund	753,768	2.16%	753,768	-
BNB Associates Investments, L.P.	125,628	*	125,628	-
John P. Ritchie & Marianne Ritchie JTWROS	31,406	*	31,406	-
Capital Ventures International	1,256,280	3.57%	1,256,280	-
Chris M. Shaughnessy	31,406	*	31,406	-
James W. Robertson	31,406	*	31,406	-
Dirk Goldwasser	251,256	*	251,256	-
Michael Bollag	125,628	*	125,628	-
Joel Good	31,406	*	31,406	-
David J. Bershad	125,628	*	125,628	-
David J. Rupert	62,814	*	62,814	-
Imprimis Investors L.L.C.	628,140	1.80%	628,140	-

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)	NUMBER OF SHARE OF COMMON STOCK TO BE OWNED AFTER COMPLETIO OF THE OFFERING
Simon Family Trust	62,814	*	62,814	-
Tis Prager	188,442	*	188,442	-
Source One	125,628	*	125,628	-
Richard A. Jacoby	62,814	*	62,814	-
Spectrum Galaxy Fund LTD. RE Primo Capital Growth Fund	125,628	*	125,628	-

Heritage Finance and Trust Company	251,256	*	251,256	-
Sagres Group Ltd.	306,220	*	251,256	54,964
Steve H. Kanzer (4)	1,824,925	5.15%	251,256	1,573,669
Ross D. Ain	62,814	*	62,814	-
Nicholas Stergis (5)	757,132	2.02%	150,752	606,385
Kosta J. Moustakas & William J. Moustakas JTWROS	82,938	*	82,938	-
Steven P. Geras	10,000	*	10,000	-
Evan & Dina Myrianthopoulos JTWROS(6)	336,342	*	120,888	215,454
Larry Rosen	10,000	*	10,000	-
Ken Alberstadt	3,926	*	3,926	-
James S. Kuo M.D.	5,000	*	5,000	-
Alexander Myrianthopoulos	27,000	*	27,000	-
Elisabeth & Vasili Myrianthopoulos JTWROS	82,000	*	82,000	-
Thomas Jefferson University	141,305	*	141,305	-
The Board of Regents of the University of Texas system	160,460	*	160,460	-
Roxana G. Baluma (7)	20,311	*	20,311	-
Joan E. Smallshaw (7)	18,280	*	18,280	-
Michelle Vitteta (7)	4,063	*	4,063	-
Robert Langer	37,000	*	37,000	-
Wayde Walker	8,000	*	8,000	-
Richard A. Brewster	600	*	600	-
Kevin R. Wilson	4,400	*	4,400	-
Rafael Vasquez	200	*	200	-
William Poon	600	*	600	-
Theodore T. Wdowiak	200	*	200	-
Shraga Y. Faskowitz	400	*	400	-
Matthew D. Eitner	200	*	200	-
Nathaniel R. Clay	200	*	200	-
Daniel H. Schneiderman	200	*	200	-
Brian Smith	200	*	200	-

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)	NUMBER OF SHARE OF COMMON STOCK TO BE OWNED AFTER COMPLETIO OF THE OFFERING
Richard G. Michalski	200	*	200	-
Michael L. Jerz	200	*	200	-
Matt McGovern	800	*	800	-
Evan Klein	800	*	800	-
Richard F. Sands	26,770	*	26,770	-
William Corcoran	16,348	*	8,229	8,119
Scott Katzmann	367,745	*	297,842	69,903
Michael Rosenman	49,748	*	49,748	-
Peter Kash	123,131	*	24,874	98,257
Jashua Kazamil	24,874	*	24,874	-

Lindsay A. Rosenwald	6,250,020	16.67	367,340	5,882,680
John Knox	8,181	*	5,000	3,181
Basil Christakos	5,000	*	5,000	-
David Tanen	21,932	*	15,000	6,932-
Stephen Rocamboli	19,050	*	15,000	4,050-
Hannah Vogler	10,000	*	10,000	-

* Less than 1%.

(1) Includes shares of common stock issuable upon the exercise of warrants as follows: David W. Ruttenberg, 31,407 shares; Roger and Margaret Coleman JTWROS, 62,814 shares; Eugenia VI Venture Holdings LTD, 628,141 shares; OrbiMed Advisors LLC, 2,513,000 shares; Bruno Widmer, 31,407 shares; The Osterweis Revocable Trust, 62,814 shares; Keys Foundation, 628,141 shares; Ronald Marchand Jr. and Margaret Marchand, 12,563 shares; A.M. Pappas, 376,984 shares; Greg Dawe, 31,407 shares; Perceptive Life Sciences Master Fund, 376,884 shares; BNB Associates Investments L.P., 62,814 shares; John P. Ritchie and Marianne Ritchie JTWROS, 15,704 shares; Capital Ventures International, 628,141 shares; Chris M. Schaughnessy, 15,704 shares; James W. Robertson, 15,704 shares; Dirk Goldwasser, 125,628 shares; Michael Bollag, 62,814 shares; Joel Good, 15,704 shares; David J. Bershad, 62,814 shares; David J. Rupert, 25,000 shares; Imprimis Investors L.L.C., 314,070 shares; Simon Family Trust, 31,407 shares; Tis Prager, 94,220 shares; Source One, 62,814 shares; Richard A. Jacoby, 31,407 shares; Spectrum Galaxy Fund LTD, 62,814 shares; Heritage Finance and Trust Company, 125,628 shares; Sagres Group, 167,294 and 125,628 shares; Steve H. Kanzer, 349,398 and 125,628 shares; Ross D. Ain, 31,407 shares; Nicholas Stergis, 245,946 and 150,742 shares; Steven P Geras, 10,000 shares; Kosta J Moustakas & William J Moustakas JTWROS, 82,469 shares; Larry Rosen, 5,000 shares; Ken Alberstadt, 1,963 shares; James S Kuo, 2,500 shares; Alexader Myrianthopoulos, 13,500 shares; Elisabeth & Vasili Myrianthopoulos JTWROS, 41,000 shares; Evan & Dina Myrianthopoulos JTWROS, 125,898 and 60,444 shares; Wayde Walker, 8,000 shares; Richard A. Brewster, 600 shares; Kevin R. Wilson, 4,400 shares; Rafael Vasquez, 200 shares; William Poon, 600 shares; Theodore T. Wdowiak, 200 shares; Shraga Y. Faskowitz, 400 shares; Matthew D. Eitner, 200 shares; Nathaniel R. Clay, 200 shares; Daniel H. Schneiderman, 200 shares; Brian Smith, 200 shares; Richard G. Michalski, 200 shares; Michael L. Jerz, 200 shares; Matt McGovern, 800 shares; Evan Klein, 800 shares; Richard F. Sands, 216,770 shares; William Corcoran, 16,348 and 8,229 shares; Scott

Katzmann, 367,745 and 297,842 shares; Michael Rosenman, 49,748 shares; Joshua Kazam, 123,131 and 24,874 shares; Peter Kash, 24,874 shares; Lindsay A. Rosenwald, M.D. 1,950,772 and 367,340 shares; John Knox. 8,181 and 5,000 shares; Basil Christakos, 5,000 shares; David Tanen, 21,932 and 15,000 shares; Stephen Rocamboli, 19,050 and 15,000; and Hannah Vogler, 10,000 shares.

(2) OrbiMed has control over shares being registered as follows: 480,000 shares and 480,000 warrants held by Caduceus Capital II L.P.; 70,000 shares and 70,000 warrants held by HFR SHC Aggressive Master Trust; 900,000

shares and 900,000 warrants held by Caduceus Capital Trust; 133,000 shares and 133,000 warrants held by PW Eucalypts Fund LTD and 933,000 shares and 933,000 warrants held by PW Eucalyptus Fund L.L.C.

(3) A.M. Pappas has control of shares being registered as follows: 125,628 shares and 125,628 warrants held by A.M. Pappas Emerging Life Science Equities II and 251,256 shares and 251,256 warrants held by A.M. Pappas Emerging Life Science Equities III.

(4) 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 Ventures, Inc. (Accredited), a merchant banking and venture capital firm specializing in biotechnology companies, which provided placement services in connection with our July 2003 private placement. The number of shares beneficially owned by Mr. Kanzer includes 666,800 shares immediately issuable upon exercise of options.

(5) Nicholas Stergis is employed by Accredited Equities, Inc., which served as a selected dealer to our placement agent for the private placement. As consideration for these placement services, we issued to Mr. Stergis warrants to purchase 75,376 shares of our common stock, exercisable until September 17, 2008 at a price of $0.8756 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. 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.

(6) Evan Myrianthopoulos has been a member of our Board of Directors since November 2002. Mr. Myrianthopoulos provided placement services in connection with our July 2003 private placement. As consideration for these services, we issued to Mr. Myrianthopoulos warrants to purchase 120,888 shares, exercisable until September 17, 2008 at a price of $0.8756 per share. The shares subject to these warrants are registered for resale in this prospectus (see footnote (1)).

(7) Designees of the Board of Regents of the University of Texas System.

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 that 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:

- a block trade in which a broker-dealer may resell a portion of the block, as principal, in order to facilitate the transaction;
- purchases by a broker-dealer, as principal, and resale by the broker-dealer for its account; or
- 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:

- 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;
- transfer its shares in other ways not involving market makers or established trading markets, including directly by gift, distribution or other transfer; or
- 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. 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. 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:

- Our annual report on Form 10-KSB for the year ended December 31, 2002;

- Our quarterly reports on form 10-QSB for the period ended March 31, 2003 and June 30, 2003;

- Our current report on form 8-K dated July 18, 2003; and

- 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.
1691 Michigan Avenue
Suite 435
Miami, Florida 33139
(305) 523-3993

LEGAL MATTERS

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

EXPERTS

The consolidated financial statements of DOR BioPharma, Inc. appearing in DOR BioPharma, Inc.'s Annual Report on Form 10-KSB for the year ended December 31, 2002, have been audited by Ernst & Young LLP, independent certified public accountants, as set forth in their report thereon, included therein and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.