

DOR BIOPHARMA INC  
Form S-3  
February 12, 2003

As filed with the Securities and Exchange Commission on February 12, 2003

Registration No. 333-\_\_\_\_\_

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM S-3  
REGISTRATION STATEMENT

Under  
The Securities Act of 1933

**DOR BioPharma, Inc.**  
(Exact name of Registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**41-1505029**  
(I.R.S. Employer  
Identification Number)

**Ballard Drive, Suite F, Lake Forest, IL, 60045, (847) 573-8990**  
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

**William D. Milling**  
**Controller, Treasurer and Corporate Secretary**  
**Ballard Drive, Suite F, Lake Forest, IL, 60045, (847) 573-8990**  
(Name, address, including zip code, and telephone number, including area code, of agent for service)

*Copies to:*

**Mark D. Wood, ESQ.**  
**Craig C. Bradley, ESQ.**  
Katten Muchin Zavis Rosenman  
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(312) 902-5200

**Approximate date of commencement of proposed sale to the public:** From time to time after the effective date of this registration statement.

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

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

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

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

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

| <b>Title of Each Class of Securities to be Registered</b> | <b>Amount to be Registered(1)</b> | <b>Proposed Maximum Offering Price Per Share(2)</b> | <b>Proposed Maximum Aggregate Offering Price(2)</b> | <b>Amount of Registration Fee</b> |
|---|-----------------------------------|---|---|-----------------------------------|
| Common Stock, \$0.001 par value per share                 | 5,297,731                         | \$1.56  | \$8,264,461   | \$761                             |

- (1) Pursuant to Rule 416(a) under the Securities Act of 1933, the number of shares of common stock registered hereby is subject to adjustment to prevent dilution resulting from stock splits, stock dividends or similar transactions.
- (2) Estimated solely for purposes of calculating the registration fee, pursuant to Rule 457 of Regulation C under the Securities Act of 1933, on the basis of the average of the high and low price of our common stock as reported on the American Stock Exchange on February 6, 2003.

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

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

**SUBJECT TO COMPLETION, DATED FEBRUARY 12, 2003**

### PROSPECTUS

**DOR BioPharma, Inc.**

**5,297,731 Shares**

**Common Stock**

This prospectus relates to the offer and sale from time to time of up to 5,297,732 shares of our common stock by selling stockholders. We will not receive any proceeds from the sale of these shares. The selling stockholders may sell the 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 prices, or at negotiated prices.

Common Stock

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Our common stock is traded on the American Stock Exchange under the symbol DOR. The closing sale price of our common stock on February 11, 2003 was \$1.38 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 , 2003

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|  | <b>PAGE</b> |
|--|-------------|
| RISK FACTORS   | 1           |
| CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS | 13          |
| DOR BIOPHARMA  | 15          |
| RECENT DEVELOPMENTS                                  | 15          |
| USE OF PROCEEDS                                      | 20          |
| SELLING STOCKHOLDERS                                 | 21          |
| PLAN OF DISTRIBUTION                                 | 25          |
| WHERE YOU CAN FIND MORE INFORMATION                  | 25          |
| LEGAL MATTERS  | 26          |
| EXPERTS  | 26          |

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.

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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 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**

*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.*

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Unless and until we are able to generate sufficient licensing revenue from our products, we will require additional funding to sustain our research and development efforts, provide for future clinical trials, and continue our operations. We cannot be certain whether we will be able to obtain additional required funding on terms satisfactory to our requirements, if at all. In addition, we have expended, and will continue to expend, funds developing our product candidates and for our clinical trials. We currently have commitments to spend additional funds in connection with development of our oral delivery systems, licenses, employee agreements and severance arrangements, and consulting agreements. 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 enter into financing arrangements on terms that we would not otherwise accept, 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.

***We have had significant losses and anticipate future losses.***

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 significant revenues from product sales or licensing. There can be no guarantee that we will ever generate product revenues sufficient to become profitable or to sustain profitability.

***Our biodefense division has only recently been established.***

Because we only recently established our biodefense division, we have little experience in developing, producing, or marketing biodefense products. Accordingly, this aspect of our business may not be successful and will be particularly susceptible to the risks and uncertainties described in these risk factors.

***If we are unsuccessful in developing our products, our ability to generate revenues may be significantly impaired.***

To be profitable, our organization must, alone or with corporate partners and collaborators, successfully research, develop and commercialize our technologies or product candidates. Current technologies and 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 any one of our technologies or product candidates:

1

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

that we will not be able to enter into human clinical trials because of scientific, governmental or financial reasons, or that we will encounter problems in clinical trials that will cause us to delay or suspend development of the technology or product candidate;

that results of our pivotal clinical trials may not be consistent with earlier clinical or pre-clinical study results;

that the technology or product will be found to be ineffective or unsafe;

that our dependence on others to manufacture the product may adversely affect our ability to develop and deliver the product on a timely and competitive basis; or

that, if we are to manufacture the product ourselves, we will be subject to similar risks regarding delays or difficulties encountered in manufacturing the product, will require substantial additional capital, and may be unable to manufacture the product in a manner that meets regulatory requirements or in a cost-effective manner.

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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. Similarly, it is possible that, for reasons including, but not limited to those set forth below, we may be unable to commercialize, or receive royalties from the sale of, any given technology, 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 commercialize 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;
- others have superior resources to market similar products or technologies; 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.***

Our proposed products offerings are subject to very stringent United States, federal, foreign, state and local government regulations, including, without limitation, the Federal Food, Drug and Cosmetic Act, the Environmental Protection Act, the Occupational Safety and Health Act, and state and local counterparts to such acts. Similar regulatory frameworks exist in other countries where we may seek to market our products. Prior to marketing any proposed product we may develop, such product must undergo an extensive regulatory approval process.

The regulatory process includes 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. Delays or denials of marketing approval are regularly encountered due to the submission of data deemed unacceptable or incomplete by the FDA or other similar regulatory agencies, or due to regulatory policy for product approvals. These delays may be encountered both domestically and abroad. The regulatory related risks with respect to any of our products include the following:

2

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- that the FDA or other regulatory agencies will not approve the product or will not do so on a timely basis;
- that the FDA or other regulatory agencies may not approve the process or facilities by which the product is manufactured;
- that the FDA's policies will change and/or additional government regulations and policies will be instituted, both of which could prevent or delay regulatory approval of the product; and/or
- that government regulations will delay or prevent the product's marketing for a considerable period of time and impose costly procedures upon our activities; or
- that we will be unable to obtain, or will be delayed in obtaining, approval of the product in other countries, as the approval process varies from country to country and the time needed to secure approval may be longer than that required for FDA approval.

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At least initially, we intend, to the extent possible, to rely on licensees to obtain regulatory approval for marketing our products. Failure by us or by our licensees to adequately demonstrate the safety and efficacy of any of our product candidates under development could delay, limit or prevent regulatory approval of the product, which may require us to reduce or discontinue development, commercialization or clinical testing of some or all of our product candidates.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in conducting advanced human clinical trials, even after obtaining promising results in earlier trials. Furthermore, the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Accordingly, we may be unable to, or experience difficulties and delays in obtaining, necessary governmental clearances and approvals to market a product. Also, even if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which the product may be marketed.

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.

***Even if orBec® is approved, its profitability may be limited.***

Our business may not become profitable even if and when orBec®, our lead product candidate, is approved for commercialization by the FDA or similar foreign regulatory agencies, because the market for the use of orBec® for the treatment of intestinal GVHD is relatively small. We have initiated clinical studies to examine whether or not orBec® is effective and safe when used to treat disorders other than intestinal GVHD, but we do not know whether these studies will in fact demonstrate safety and efficacy, or if they do, whether we will succeed in receiving regulatory clearance to market orBec® for additional indications. If the results of these studies are negative or if adverse experiences are reported in these clinical studies or otherwise in connection with the use of orBec® by patients, this could undermine physician and patient comfort with the product, limit the commercial success of the product, and impact the acceptance of orBec® in the intestinal GVHD market. Furthermore, new technology is being developed for bone marrow transplants that could reduce or eliminate instances of intestinal GVHD resulting from bone marrow transplants, and therapeutic alternatives to bone marrow transplants may become available. Any such developments could significantly decrease the market for orBec®.

3

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***We may not be able to develop the new corporate partnerships we need to develop and commercialize our products.***

In order for us to successfully develop and commercialize our product candidates, we may need to enter into collaboration agreements with partners to help research and develop our product candidates and to fund all or part of the costs thereof. We may not be able to enter into such collaboration agreements, or the terms of the collaboration agreements may not be favorable to us. Our inability to enter into collaboration 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 collaborative partners, if any, rights to license and commercialize pharmaceutical and related products developed under these collaborative agreements, and these rights would limit our flexibility in considering alternatives for the commercialization of these products. Under these agreements, we may rely on our collaborative partners to conduct research efforts and clinical trials on, obtain regulatory approvals for, and manufacture market and commercialize certain of our product candidates. Although we believe that our collaborative partners will have an economic motivation to commercialize the pharmaceutical and related products that they may license, the amount and timing of resources devoted to these activities generally will be controlled by each partner.

We have no manufacturing capabilities and therefore expect that we will need to rely on third-party manufacturers or suppliers of our products. We may not be able to identify any such manufacturers or suppliers, and even if we are able to do so, we may not be able to enter into manufacturing or supply agreement with them on terms that are favorable to us, if at all. We will be required to rely on contract manufacturers and suppliers for the foreseeable future to produce quantities of products and

substances necessary for research and development, pre-clinical trials, human clinical trials and product commercialization. The products may not be able to be manufactured or supplied at a cost or in quantities necessary to make them commercially viable. Third-party manufacturers or suppliers may not be able to meet our needs with respect to timing, quantity and quality for the products. If we are unable to contract for a sufficient supply of required products and substances on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our research and development, pre-clinical and clinical testing would be delayed, thereby delaying the submission of products for regulatory approval or the market introduction and subsequent sale of the products. Moreover, contract manufacturers that we may use must adhere to current Good Manufacturing Practices regulations enforced by the FDA through its facilities inspection program. If the facilities of the manufacturers cannot pass a pre-approval plant inspection, the FDA pre-market approval of our products will not be granted.

Additionally, if we receive approval from the FDA for our product candidates, the commercialization of these products will depend upon our ability to enter into marketing agreements with companies that have sales and marketing capabilities or to recruit, develop, train and deploy our own sales force. We currently intend to sell our products in the United States and internationally in collaboration with one or more marketing partners. We may not be able to enter into any collaboration to commercialize products in a timely manner or on commercially reasonable terms, if at all. We do not currently have a sales force, or possess the resources or experience necessary to market any of our product candidates ourselves, if they are approved. 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.

4

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***Our product development and commercialization efforts may not be successful.***

Our proprietary product candidates, which have not received regulatory approval, are in various stages of development. If the initial results from any of the evaluations for these product candidates are poor, those results could seriously harm our business and our ability to raise additional capital that may be necessary to continue research and development for our oral delivery technology. In addition, product candidates resulting from our research and development efforts are not expected to be available commercially for several years, if at all.

The products we are currently developing will require significant additional laboratory and clinical testing and investment for the foreseeable future. Our product candidates may not show sufficient efficacy in animal models to justify continuing research into clinical testing stages or may not prove to be effective in clinical trials or may cause serious harmful side effects. In addition, our product candidates, if approved, may prove impracticable to manufacture in commercial quantities at a reasonable cost and/or with acceptable quality. Any of these results could seriously harm our business.

Our products, if approved, may not be immediately used by doctors unfamiliar with our product applications. Either our commercialization partner or us may be required to implement an aggressive education and promotion plan with doctors in order to gain market recognition, understanding and acceptance of our products. Any such effort may be time consuming and costly and might not be successful.

***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. Our clinical trial and product liability and general liability insurance 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 are subject to U.S. government funding decisions and other risks associated with the biodefense industry.***

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We are subject to risks associated with operating in the biodefense industry. 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, and may be affected by changes in U.S. government policies resulting from various political and military developments. In addition, individuals or groups intent upon utilizing bioweapons may attempt to disrupt or delay development and production of our biodefense products through acts of terrorism or otherwise.

***We use hazardous materials in our business; any claims relating to improper handling, storage, or disposal of these materials could be costly.***

Our research and development processes involve the controlled use of hazardous materials, including hazardous chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We cannot fully eliminate the risk of accidental contamination or discharge of such materials and any resulting injury. We could be subject to civil damages in the event of improper or unauthorized release of, or exposure of individuals to, hazardous materials. In addition, we could be sued for injury or contamination that results from our use of hazardous materials or their use by third parties or our collaborators. Federal, state, and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. Compliance with these laws and regulations may be expensive, and current or future laws and regulations relating to hazardous materials may impair our research, development and/or commercialization efforts, including those undertaken by our collaborative partners.

5

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***We may not be able to compete 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. Numerous companies are attempting to develop technologies to treat GVHD.

Competition is also intense in the therapeutic area of inflammatory bowel disease, or IBD, including Crohn's disease and ulcerative colitis. Other drugs used to treat IBD include another oral site-active corticosteroid called budesonide, which is being marketed by AstraZeneca in Europe and Canada under the tradename of Entocort®. In Italy, Cheisi Pharmaceuticals markets an oral formulation of Beclomethasone dipropionate, the active ingredient of orBec® for ulcerative colitis and may seek marketing approval for their product in countries other than Italy, including the United States.

Numerous other companies are known to be developing vaccine products for biodefense that might compete with our product candidates. We may not be successful in our efforts to sell innovative biodefense products to government agencies or convince any government agencies to fund the research and development of such innovative products. Other institutions, such as the US Army, separately conduct research and product development for military vaccines and may already have developed, or may at some point in the future develop, mucosally administered vaccines for biodefense purposes.

6

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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 liable for significant damages and be unable to commercialize our products if we are unable to protect our proprietary rights***

If we fail to adequately protect our intellectual property rights or face a claim of intellectual property infringement by a third party, then we could lose valuable intellectual property rights, be liable for significant damages or be prevented from commercializing products.

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. 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 certain 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 (PTO) 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 PTO may commence interference proceedings involving patents or patent applications, in which the question of first inventorship is contested. Accordingly, the patents owned by us or patents licensed to us in the future 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.

Any issued patents may not provide competitive advantages for the proposed products or may be successfully challenged or circumvented by competitors. In addition, others may independently develop similar products or duplicate any of our products. 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 may have to alter our products or processes, pay licensing fees or cease activities altogether because of patent rights of third parties.

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 such vaccine candidate. We may not be successful in our efforts to obtain a license under such patent on terms favorable to us, if at all.

7

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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 such 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.

***We depend on licenses from third parties.***

We rely on license agreements from several third parties for the rights to commercialize our product candidates. These agreements require that we meet certain milestones; our failure to meet those milestones allows the licensors to terminate the licenses, whereas our meeting those milestones triggers payment obligations on our part. Some of our license agreements are limited to certain fields of use and in some cases are nonexclusive. Our licensed patents and patent applications should therefore not be read to infer that we have complete freedom to operate or prevent others from operating under all of the issued

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claims contained in such licensed patents. We are in the process of negotiating amendments to certain of our existing licenses and negotiating new licenses to enhance our proprietary position and expand our line of product candidates. In connection with such amendments and new licenses, we expect that we will be required to make new commitments to such licensors. During the course of negotiations, commitments proposed by our existing or potential licensors may be considered so unfavorable to us that we may elect instead to terminate discussions. We may not be able to retain the rights granted under any of our existing licenses, existing licenses as amended, or new licenses. Pursuant to the Bayh-Dole Act of 1980 and other legislation, license agreements relating to inventions made under funding by the U.S. Government are required to contain provisions recognizing the right of the U.S. Government to utilize such inventions on a non-exclusive basis. Such march in rights, if invoked, may undermine our ability to prevent the U.S. Government from separately licensing to our competitors under our licensed patents.

***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, within certain guidelines, can 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. Also, the trend toward managed health care and the growth of health maintenance organizations in the United States may result in lower prices for our products, if approved and if and when commercially available, than we currently expect.

### **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 many factors, including, but not limited to:

actual or anticipated fluctuations in our results of operations;

announcements of innovations by us or our competitors;

8

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introduction of new products by us or our competitors;

additions or departures of key personnel;

commencement of litigation;

developments with respect to intellectual property rights;

conditions and trends in the pharmaceutical and drug delivery industries;

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changes in estimates of the development, future size and growth rate of our markets;

general market conditions; and

future sales of our common stock.

The market price of our common stock may also be affected by our ability to meet or exceed the expectations of analysts or investors or our own forecasts. In addition, the stock market has experienced significant price and volume fluctuations that affect the market price of our common stock, as well as that of the common stock of other biotechnology companies. These market fluctuations have sometimes been unrelated or disproportionate to the operating performance of these companies. Any significant stock market fluctuations in the future, whether due to our actual performance or prospects or not, could result in a significant decline in the market price of our common stock. In the past, following periods of volatility in the market price of a company's securities, securities class action has often been instituted against that company. If any securities litigation is initiated against us, we could incur substantial costs and our management's attention and resources could be diverted from our business.

Since it commenced trading on the American Stock Exchange on August 6, 1998, our common stock has been thinly traded until 2003. An active trading market for our common stock may not continue to develop.

### ***Our stock may not remain listed on the American Stock Exchange.***

Because we continue to incur losses from continuing operations in fiscal 2002, the stockholders' equity standard applicable to us of AMEX's continued listing requirements for the first, second, and third quarters of 2003 will be \$4 million, increasing to \$6 million for the fourth quarter 2003 fiscal years ending 2003 and beyond. Although not yet applicable, our current net equity would not allow it to meet these increased requirements. If, for this reason or for any other reason, our stock were to be delisted from the American Stock Exchange, we cannot assure you that we would 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, an active trading market may not exist for our common stock.

### ***Our business could be harmed by our failure to retain our current personnel.***

We have only four employees: David Kent, our Chief Executive Officer and President; William Milling, our Controller, Treasurer and Corporate Secretary; Robert Brey, our Vice President and Research and Development; and Robin Simuncek, our Clinical Project Manager and Administrative Assistant. We depend upon these four employees to manage the day-to-day activities of our business. Accordingly, the loss of any of our personnel or our inability to attract and retain other qualified employees in a timely manner may have a negative impact on our operations. Even if we lose the services of just one or two employees, our business could be adversely affected.

### ***Our management team lacks experience running our business.***

Our current management team has only recently been established, and has limited experience in managing and operating our business. Mr. Kent was hired in January 2003; Mr. Milling was hired in September 2002; Mr. Brey was hired in December 2002 after previously serving as a consultant. We will not be successful if this new management team cannot effectively manage and operate our business.

### ***We have certain relationships that may present potential conflicts of interest.***

Our Vice-Chairman of the Board of Directors, Steve H. Kanzer, is Chairman and Chief Executive Officer of Accredited Ventures, Inc. (Accredited) that in the regular course of its business, identifies, evaluates and pursues investment opportunities

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in biomedical and pharmaceutical products, technologies and companies. However, Accredited is under no obligation to make any additional products or technologies available to us. In addition, certain of 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. Accredited provided placement services in connection with our December 2002 private placement and received warrants to purchase 161,826 shares of our common stock as compensation for services as selected dealer.

### *Certain directors, officers and stockholders have significant influence.*

Our directors, executive officers and principal stockholders and certain of their affiliates have the ability to influence the election of directors and most other stockholder actions. This may discourage or prevent any proposed takeover of us, including transactions in which stockholders might otherwise receive a premium for their shares over the then current market prices. Such stockholders may also influence corporate actions, including influencing elections of directors and significant corporate events.

### *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 2,139,813 shares of common stock at a current exercise price of \$1.8209 per share, issued in connection with an October 1997 private placement of our common stock;

warrants to purchase 230,770 shares of common stock at a current exercise price of \$10.00 per share;

warrants to purchase 43,334 shares of common stock at a current exercise price of \$1.6914 per share, held by Aries Select Ltd. and warrants to purchase 23,334 shares of common stock at a current exercise price of \$1.6914 per share, held by Aries Select I LLC, both issued on May 19, 1997 pursuant to a senior line of credit that has been subsequently retired;

warrants to purchase 452,383 shares of common stock at a current exercise price of \$5.91 per share, issued in connection with the April 2000 private placement of our common stock;

warrants to purchase 226,190 shares of common stock at a current exercise price of \$5.25 per share, issued to Paramount Capital, Inc., as the finder in connection with the April 2000 private placement of our common stock;

conversion rights and dividend rights of preferred stock, consisting of 108,443 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

10

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options to purchase approximately 4,100,000 shares of common stock issued to participants in our stock option plan. with a current weighted average exercise price of approximately \$1.69;

warrants to purchase 207,070 shares of our common stock at a current exercise price of \$8.11 per share, pertaining to the conversion of Corporate Technology Development, Inc. warrants into our warrants, pursuant to the plan of merger and reorganization;

warrants to purchase 1,699,075 shares of our common stock at a current exercise price of \$0.75 per share issued in connection with the December 2002 private placement of our common stock;

warrants to purchase 310,787 shares of our common stock at a current exercise price of \$0.35 per share issued in connection with our December 2002 private placement;

warrants to purchase 160,000 shares of our common stock at a current exercise prices ranging from \$0.35 to \$0.58 issued to certain of our consultants; and

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.

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.

***We may issue equity securities in the future whose terms and rights are superior to those of our common stock.***

Our certificate of incorporation authorizes the issuance of up to 4,500,000 shares of preferred stock, including 108,443 shares that are currently outstanding. Shares of preferred stock may be issued by our board of directors from time to time in one or more series for the consideration and with the rights and preferences as our board of directors decides. Any shares of preferred stock we may issue in the future could be given voting and conversion rights that could dilute the voting power and equity of holders of shares of our common stock and have preferences over the common stock with respect to dividends and in liquidation.

***Provisions in our charter and Delaware law may discourage takeover attempts which could preclude our stockholders from receiving a change of control premium.***

Our certificate of incorporation could make it more difficult for a third party to acquire control of us because it gives our board of directors the ability to issue shares of preferred stock with rights as they deem appropriate without stockholder approval. In addition, Delaware law contains an anti-takeover provision that could have the effect of delaying or preventing changes in control that a stockholder may consider favorable. This provision prohibits us from engaging in a business combination with any significant stockholder for a period of three years from the date the person became a significant stockholder unless specific conditions are met.

**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.

**DOR BIOPHARMA, INC.**

We are a pharmaceutical company specializing in the oral and mucosal delivery of drugs and vaccines. Utilizing our proprietary Microvax<sup>®</sup> mucosal vaccine delivery technology, we are developing oral and intranasal synthetic (non-live) vaccines for bioterror threats, such as, ricin and anthrax. Such vaccines would have the ability to be stockpiled and rapidly deployed to military personnel, first responders and civilians. In addition to these benefits, we expect that our vaccine candidates will have the ability to confer mucosal immunity, the body's first line of defense against bioterror agents, while avoiding the safety concerns associated with the use of live vaccine pathogens.

In addition, our biotherapeutics division is developing oral and mucosal formulation of drugs that are traditionally delivered in non-oral formats. We anticipate that our oral and mucosal products will enhance patient quality of life, improve patient compliance to therapy and potentially reduce healthcare costs. Our lead product, orBec<sup>®</sup> (oral beclomethasone dipropionate), is currently in a pivotal phase III clinical trial for the treatment of intestinal graft-vs.-host disease. We are also currently testing orBec<sup>®</sup>'s usefulness in treating a large percentage of persons diagnosed with irritable bowel syndrome (IBS), a disease that is estimated to affect approximately 35 million persons in the U.S. alone.

**RECENT DEVELOPMENTS**

***Creation of Biodefense Division***

We formed our Biodefense Division in late 2002. Through our biodefense division, we are developing, along with our academic and manufacturing partners, novel synthetic and recombinant (non-live) subunit vaccines that may conveniently and rapidly confer full systemic and mucosal immunity, such as in the lungs against a series of biological agents that currently pose a significant bioterrorism or biowarfare threat. Our vaccines are based on the MicroVax<sup>®</sup> technology, a proprietary system that protects sensitive vaccine materials and permits their efficient delivery to the body's immune system.

There is growing concern about the potential use of biological agents in war or acts of terrorism accompanied by an increased realization that our country is poorly prepared to prevent or treat the human damage that can be caused by these agents. The use of these agents as weapons, even on a small scale, has the potential for huge social and economic disruption and massive diversion of local and national resources to combat the threat, treat primary disease and clean up environmental contamination. The Center for Disease Control (CDC) has identified and classified over thirty of these biological threats in Categories A-C, based on the severity of the threat as well as the seriousness of the diseases that could be caused by their use in bioterrorist or biowarfare acts. For a majority of these agents, there are no effective vaccines to prevent or no effective treatments following exposure. Even where vaccines do exist, their supply may be currently limited, as in the case of the smallpox vaccine, and their use could pose significant safety risks. A massive effort and expenditure to scale up and manufacture greater supplies of the vaccines that are now available in only limited quantities will be required to protect civilian and military populations.

We believe that vaccines to prevent the biological and human damage caused by these agents represent the best short and long-term alternative to dismantling the threat of their use. We envision a more rapid course to licensure for vaccines for these agents than the coverage applicable to our biotherapeutics products.

In many cases, the nature of the protective immune response in humans is not known or there have been no experimental vaccines that have proven to be safe and effective in preclinical animal studies. The National Institute of Health and other government agencies have recently increased their budgets for research and development into new vaccines, diagnostics and therapeutics for Category A-C biological agents. Recognizing that the course to vaccine development, manufacture and regulatory approval can be long and circuitous, we have initiated several programs for vaccine development based on our Microvax<sup>®</sup> vaccine delivery technology, with respect to vaccines where the Microvax<sup>®</sup> technology has proven to be safe and efficacious in preclinical animal studies. Based on promising preclinical results, we are preparing to enter into a manufacturing and testing stage for our Microvax<sup>®</sup> systems with several recombinant antigens. We have additionally selected for its first programs several biological agents from both category A and Category B in the CDC list, in which single recombinant antigens currently represent the best alternatives as antigen candidates.

### **MicroVax Vaccine Delivery Technology**

The MicroVax system is microencapsulation technology based on over ten years of research and development, which has been shown by many independent investigators to be effective in enhancing mucosal, cellular and systemic immune responses with numerous subunit and recombinant antigens and peptides. Antigens composed of proteins, peptides, whole killed, cells and viruses can be effectively entrapped within the matrix of microspheres composed of biodegradable polymers or simultaneously adsorbed to the particle surface. We have acquired exclusive license to the technology for the development of orally administered vaccines from the Southern Research Institute and the University of Alabama. The MicroVax technology is the subject of six patents issued in the US, two patents issued in Europe and equivalents in other countries.

### **Ricin Vaccine**

We are developing evaluation of a vaccine against the toxin ricin utilizing the MicroVax system can be administered orally or intranasally, utilizing a safe, detoxified recombinant ricin antigen. Ricin is a potent, easily produced plant toxin that could be deployed by aerosolization as a biological weapon. Ricin is a CDC category B biological agent. Inhaled ricin causes rapid lung damage that is irreversible and leads to death. There are no antidotes to ricin following exposure and no vaccine has been developed or licensed. Vaccine candidates based on inactivated ricin toxin have been tested experimentally, and recently researchers at the United States Army Medical Research Institute of Infectious Diseases successfully tested a prototype in the MicroVax system, showing protection in animals after nasal or oral vaccination. We are currently collaborating with the University of Texas Southwest Medical Center to develop the MicroVax technology with a safe, completely detoxified version of ricin A chain, which we consider the best option for further development. This vaccine antigen candidate has been recently described in the journal *Vaccine*. We have exercised an exclusive option with the University of Texas Southwestern Medical Center in Dallas to license patent applications pending in the United States and elsewhere pertaining to the use of novel recombinant ricin A chain mutants as vaccines to protect against aerosolized ricin. The exclusive option covers the development of intranasal, oral and inhalable vaccines that can be developed using the proprietary non-toxic mutants of ricin.

14

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### **Anthrax Vaccine**

We are developing a vaccine against anthrax utilizing the MicroVax system that can be administered orally or intranasally utilizing with a recombinant anthrax antigen (PA), the protective antigen that is the principal component of the licensed anthrax vaccine (Biothrax®). Anthrax is a CDC category A biological agent. The current vaccine is associated with undesirable side effects and has to be administered by injections in a six dose regimen lasting up to a year. We believe that a mucosally administered vaccine will be safer and elicit protective antibodies at mucosal surfaces such as the lung, which could neutralize spores and prevent their systemic transfer and germination. Recently, a prototype MicroVax -PA vaccine has been evaluated and been shown to elicit protection in mice after two doses of an intranasally administered vaccine. We are developing further prototypes of MicroVax -PA and consider the current candidates to be the leading ones for the next generation of anthrax vaccines that could be self-administered mucosally with fewer doses than the current injected vaccines.

### **Other Biodefense Vaccines**

Once validated in preclinical models and in Phase I human clinical studies, the MicroVax technology is potentially applicable to a large number of other subunit, vaccines. We plan to develop other biodefense vaccines based on the MicroVax technology with corporate, government, and academic partners, including vaccines for plague, botulinum toxin and staphylococcal enterotoxin B, each of which poses a serious independent threat to biosecurity.

### ***Appointment of New Directors and Officers***

David M. Kent was appointed as our President and Chief Executive Officer in January 2003. From 1997 until September 2002, David M. Kent was a founder, director and Chief Financial Officer of Arriva Pharmaceuticals, Inc., a private

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biotechnology company focused on the development of recombinant alpha-1-antitrypsin. While at Arriva, he was successful in in-licensing intellectual property from a variety of corporate, private and public institutions. Mr. Kent was also instrumental in completing four private equity placements for Arriva totaling \$38 million. He also formed two corporate partnerships collectively valued at over \$60 million with Baxter Healthcare and Prometic Life Sciences. From 1996 until 1997, prior to founding Arriva, Mr. Kent was principal founder of Ventec, a venture capital firm focused on providing expansion capital for emerging growth companies, where he managed and co-led private equity financings totaling over \$24 million. From 1995 until 1996, he was a Senior Vice President at Lehman Brothers, London. From 1992 until 1995, he held various positions at Morgan Stanley, London, managing assets on behalf of client in excess \$600 million. From 1987 until 1992, he was a Vice President at Smith Barney, in its international corporate finance division. Mr. Kent received a B.A. in Economics and a B.A in History from Allegheny College in 1979.

Consistent with our new focus on biodefense, General Alexander M. Haig, Jr. joined us as Chairman of our Board of Directors in January 2003. General Haig graduated from the U.S. Military Academy in 1947, was commissioned a Second Lieutenant of the Army, and advanced through a variety of military assignments, including service in Japan, Korea, Europe and Vietnam. He attended Notre Dame University, pursued graduate studies in business administration at Columbia University and received a Master's Degree in International Relations from Georgetown University.

He served in the Pentagon from 1962 to 1965, where his positions included Military Assistant to the Secretary of the Army, and Deputy Special Assistant to the Secretary of Defense. He served in Vietnam in 1966 and 1967, receiving the Distinguished Service Cross for Heroism.

In January 1969, he was assigned to be Senior Military Advisor to the Assistant to the President for National Security Affairs. He was promoted to full General in 1972. During his four years in the White House ending in 1973, he made 14 trips to Southeast Asia as the personal emissary of the President to negotiate the Vietnam ceasefire and the return of the U.S. prisoners of war. He also coordinated preparations for President Nixon's historic visit to China.

15

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General Haig was serving as Vice Chief of Staff of the Army when President Nixon appointed him in May 1973 to rebuild the White House staff. Although this was to be a temporary position, the President subsequently named him White House Chief of Staff, at which point he retired from the military after 26 years of active service.

He served in the White House until October 1974, when President Ford recalled him to active duty as Commander-in-Chief, U.S. European Command. Two months later, General Haig was also appointed Supreme Allied Commander in Europe. In that position, he was responsible for the integrated military forces of the then 13-member nations of the North Atlantic Treaty Organization (NATO). He resigned his post effective June 30, 1979 and retired from the Army.

General Haig was elected President and Chief Operating Officer of United Technologies Corporation and a member of its Board of Directors on December 21, 1979.

Following his election on November 4, 1980, President-elect Ronald Reagan nominated General Haig to be his Secretary of State. The Senate subsequently confirmed General Haig, and he was sworn in as the Nation's 59th Secretary of State on January 22, 1981. He resigned from this position on July 5, 1982. He was an official candidate (1987-1988) for the nomination of the Republican Party for the presidency of the United States.

General Haig is currently Chairman of his own private firm, Worldwide Associates, Inc., based in Washington, DC. Worldwide Associates assists public and private corporations both domestically and abroad in developing and implementing marketing and acquisition strategies, in addition to providing strategic advice on the domestic and international political, economic and security environment affecting global commercial activities. Worldwide Associates is also involved in venture capital and international construction projects.

General Haig was a founding Director of America Online, Inc. He currently serves on the Board of Directors of Indevus Pharmaceuticals, Inc., MGM Mirage, Inc., Metro-Goldwyn-Mayer, Inc. and SDC International, Inc. He is senior advisor to several multinational corporations, including United Technologies Corporation. He is also the host of his own weekly television program, World Business Review.



*December 2002 Private Placement*

In December 2002, we completed a private placement of 3,093,569 shares of our common stock and warrants to purchase 1,546,789 shares of our common stock. In this private placement we received total proceeds of \$1,082,750. Purchasers in this private placement included David M. Kent, our Chief Executive Officer and President, and Steve H. Kanzer, Lawrence Kessel and Peter Salomon, each of whom is a member of our Board of Directors. In addition, we issued warrants to purchase 463,073 shares of our common stock to certain individuals and entities, including warrants to purchase 80,913 shares to Mr. Kanzer, in consideration for placement services rendered in connection with this private placement, through his broker/dealer Accredited Equities Inc. We also paid Mr. Kanzer approximately \$38,000 in cash commissions for these services.

16

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**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.

17

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**SELLING STOCKHOLDERS**

Of the 5,297,731 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, 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 public resale pursuant to 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 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 Shares of Common Stock To Be Owned After Completion of the Offering | Percent of Common Stock to be Owned After Completion of the Offering |
|----------------------------------|--|---|---|---|--|
| Concordia Capital                | 1,002,637  | 3.5%  | 985,714   | 16,923  | *  |
| Steve H. Kanzer (2)              | 1,573,669  | 5.5%  | 509,484   | 1,064,185   | 4.0%   |
| Pharma investors, LLC (3)        | 1,321,628  | 4.9%  | 1,321,628   | --  | --   |
| Odisseas Myrianthopoulos         | 225,000  | *   | 225,000   |   |  |
| David M. Kent (4)                | 214,286  | *   | 214,286   |   |  |
| Alberto Gutierrez                | 214,286  | *   | 214,286   |   |  |
| Ralph M. Ellison                 | 214,286  | *   | 214,286   |   |  |
| Martin Draper                    | 128,571  | *   | 128,571   |   |  |
| Milton Lippman                   | 107,143  | *   | 107,143   |   |  |
| Ed O'Donnell                     | 107,143  | *   | 107,143   |   |  |
| Lawrence and Shirley Kessel (5)  | 214,286  | *   | 64,286  | 161,920   | *  |
| Charles Griffith                 | 64,286   | *   | 64,286  |   |  |
| Gilbert Goldstein                | 51,429   | *   | 51,429  |   |  |
| Guilhem Canstagne                | 42,857   | *   | 42,857  |   |  |
| Ken Alberstadt                   | 42,857   | *   | 42,857  |   |  |
| Dewey Tran                       | 22,500   | *   | 22,500  |   |  |
| Giuseppe Cavalieri               | 42,857   | *   | 42,857  |   |  |
| Peter Salomon (6)                | 165,000  | *   | 15,000  | 150,000   | *  |
| Louis Bianco                     | 214,286  | *   | 214,286   |   |  |
| James Bianco                     | 214,286  | *   | 214,286   |   |  |
| Atlas Capital Services, LLC (7)  | 195,669  | *   | 195,669   |   |  |
| Steven Pollen (8)                | 35,619   | *   | 35,619  |   |  |
| Dan Myers (9)                    | 4,505  | *   | 4,505   |   |  |
| Redington, Inc. (10)             | 164,300  | *   | 164,300   |   |  |
| Ibis Consulting Group, Inc. (11) | 30,000   | *   | 30,000  |   |  |
| Evan Myrianthopoulos (12)        | 65,454   | *   | 65,454  |   |  |

\* Less than 1%.

- (1) Includes shares of common stock issuable upon the exercise of warrants as follows: Concordia Capital: 328,571 shares; Steve Kanzer: 223,770 shares; Pharma Investors, LLC: 495,486 shares, Odisseas Myrianthopoulos: 75,000 shares; David M. Kent 71,429 shares; Alberto Gutierrez: 71,429 shares; Ralph Ellison: 71,429 shares; Martin Draper: 42,857 shares; Milton Lippman: 35,714 shares; Ed O'Donnell: 35,714 shares; Lawrence and Shirley Kessel: 21,249 shares; Charles Griffith: 21,429 shares; Gilbert Goldstein: 17,143 shares; Guilhem Canstagne: 14,286 shares; Ken Alberstadt: 14,286 shares; Dewey Tran: 7,500 shares; Giuseppe Cavalieri: 14,286 shares; Peter Salomon: 5,000 shares; Louis Bianco: 71,429; James Bianco: 71,429 shares; Redington, 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 Ventures, Inc. (Accredited), a merchant banking and venture capital firm specializing in biotechnology companies, which provided placement services in connection with our December 2002 private placement. As consideration for the placement services provided by Accredited, 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

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by Mr. Kanzer includes 616,800 shares immediately issuable upon exercise of options.

19

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- (3) Keith Thornton has voting and power with respect to the shares held by Pharma investors, LLC.
- (4) David M. Kent has been our Chief Executive Officer and President since January 2003.
- (5) Lawrence Kessel has been a member of our Board of Directors since June 2002. The shares beneficially owned by him include 50,000 shares of common stock immediately issuable upon exercise of options.
- (6) 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.
- (7) Atlas Capital Services, LLC (Atlas) 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)).
- (8) Steve Pollen is an employee of Atlas. As consideration for the placement services provided by Atlas, we issued to Mr. Pollen 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)).
- (9) Dan Myers is an employee of Atlas. 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)).
- (10) 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.
- (11) 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)).

20

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- (12) Evan Myriantopoulos has been a member of our Board of Directors since June 2002. Mr. Myriantopoulos provided placement services in connection with our December 2002 private placement. As consideration for these services, we issued to Mr. Myriantopoulos 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)).

21

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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:

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, 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. 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

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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 fiscal year ended December 31, 2001, as amended by a Form 10-KSB/A filed on February 12, 2003;

Our quarterly reports on Form 10-QSB for the quarters ended March 31, 2002, June 30, 2002 and September 30, 2002;

Our current report on Form 8-K dated June 17, 2002; and

The description of our common stock contained in the Registration Statement on Form 8-Adated 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

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/A at December 31, 2001 and 2000, and the years then ended, and the cumulative period from February 15, 1985 (inception) to December 31, 2001, 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.

23

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## PART II

### INFORMATION NOT REQUIRED IN PROSPECTUS

**ITEM 14. Other Expenses of Issuance and Distribution.**

The following table sets forth the estimated costs and expenses of the Registrant in connection with the offering described in the Registration Statement.

|   |          |
|---|----------|
| Securities and Exchange Commission registration fee | 761      |
| Legal fees and expenses                             | 10,000   |
| Accounting fees and expenses                        | 7,000    |
| Miscellaneous expenses                              | 2,239    |
|   | <hr/>    |
| Total expenses                                      | \$20,000 |
|   | <hr/>    |

**ITEM 15. Indemnification of Directors and Officers.**

Section 102(b)(7) of the Delaware General Corporation Law grants the Registrant the power to limit the personal liability of its directors to the Registrant or its stockholders for monetary damages for breach of a fiduciary duty. Article XI of the Registrant's Certificate of Incorporation, as amended, provides for the limitation of personal liability of the directors of the Registrant as follows:

A director of the Corporation shall have no personal liability to the Corporation or its stockholders for monetary damages for breach of his fiduciary duty as a director; provided, however, this Article shall not eliminate or limit the liability of a director (i) for any breach of the Director's duty of loyalty to the Corporation or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) for the unlawful payment of dividends or unlawful stock repurchases under Section 174 of the General Corporation Law of the State of Delaware; or (iv) for any transaction from which the Director derived an improper personal benefit. If the General Corporation Law is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware, as so amended.

Section 145 of the Delaware General Corporation Law grants to the Registrant the power to indemnify its directors, officers, employees and agents against liability arising out of their respective capacities as directors, officers, employees or agents. Article VII of the Registrant's Bylaws provides that the Registrant shall indemnify any person who is serving as a director, officer, employee or agent of the Registrant, or of another entity at the request of the Registrant, against judgments, fines, settlements and other expenses incurred in such capacity if such person acted in good faith and in a manner reasonably believed to be in, or not opposed to, the best interests of the Registrant and, with respect to any criminal action, had no reasonable cause to believe his conduct was unlawful. In the event of an action or suit by or in the right of the Registrant, no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable for negligence or misconduct in the performance of his duty to the Registrant unless and only to the extent that the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses as the court shall deem proper.

The Registrant has entered into indemnification agreements with its directors that would require the Registrant, subject to any limitations on the maximum permissible indemnification that may exist at law, to indemnify a director for claims that arise because of his capacity as a director.

II-1

The Registrant has a directors' and officers' liability insurance policy.

The above discussion is qualified in its entirety by reference to the Registrant's Certificate of Incorporation and Bylaws.

**ITEM 16. Exhibits**

| Exhibit<br>Number | Exhibit  |
|-------------------|--|
| 4.1               | Amended and Restated Certificate of Incorporation, incorporated by reference from Exhibit 3.1 to our quarterly Report on Form 10-QSB for the fiscal quarter ended June 30, 2001. |
| 4.2               | Amended and Restated Bylaws of the Company, incorporated by reference from Exhibit 1-3(c) to our Firm S-1 filed April 15, 1987.  |
| 5.1*              | Opinion of Katten Muchin Zavis Rosenman as to the validity of the common stock.  |
| 23.1*             | Consent of Ernst & Young, independent public accountants.  |
| 23.2*             | Consent of Katten Muchin Zavis Rosenman (contained in its opinion filed as Exhibit 5.1 hereto).  |
| 24.1*             | Powers of Attorney (included on the signature page hereto).  |

\* Filed herewith

**ITEM 17. Undertakings**

B. The Registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement to include any additional or changed material information on the plan of distribution.
- (2) To, for determining liability under the Securities Act of 1933, treat each post-effective amendment as a new registration statement relating to the securities offered therein, and the offering of the securities at that time to be the initial *bona fide* offering.
- (3) To file a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.

II-2

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- (4) Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the Act ) may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

II-3

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**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Lake Forest, State of Illinois, on the 11th day of February, 2003.

**DOR Biopharma, Inc.**

By: /s/ David M. Kent

David M. Kent  
President and Chief Executive Officer

**POWERS OF ATTORNEY**

Each person whose signature appears below hereby constitutes and appoints David Kent and William Milling, and each of them severally, acting along and without the other, his true and lawful attorneys-in-fact and agents, with full power of substitution, to sign on his behalf, individually and in each capacity stated below, all amendments and post-effective amendments to this registration statement and any registration statement registering additional securities pursuant to Rule 462(b) under the Securities Act of 1933, and to file the same, with all exhibits thereto and any other documents in connection therewith, with the Securities and Exchange Commission under the Securities Act of 1933, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully and to all intents and purposes as each might or could do in person, hereby ratifying and confirming each act that said attorneys-in-fact and agents may lawfully do or cause to be done by virtue thereof.

II-4

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**SIGNATURES**

Pursuant to the requirements of the 1933 Act, this registration statement has been signed below on February 11, 2003 by the following persons in the capacities indicated.

|                           |   |
|---------------------------|---|
| /s/ David M. Kent         | President and Chief Executive Officer<br>(principal executive officer)                        |
| David M. Kent             |   |
| /s/ William D. Milling    | Controller, Treasurer and Corporate Secretary<br>(principal financial and accounting officer) |
| William D. Milling        |   |
| /s/ Alexander M. Haig Jr. | Chairman of the Board   |
| Alexander M. Haig Jr.     |   |
| /s/ Steve H. Kanzer       | Vice Chairman of the Board  |
| Steve H. Kanzer           |   |



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/s/ Paul D. Rubin Director

Paul D. Rubin

/s/ Peter Salomon Director

Peter Salomon

/s/ Lawrence Kessel Director

Lawrence Kessel

/s/ Evan Myrianthopoulos Director

Evan Myrianthopoulos

Director

Arthur Asher Kornbluth

II-5

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**INDEX TO EXHIBITS**

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