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IMMTECH INTERNATIONAL INC  
Form 10-K/A  
July 20, 2004

United States  
Securities and Exchange Commission  
Washington, D.C. 20549

FORM 10-K/A

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the fiscal year ended March 31, 2004.

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the transition period from [ ] to [ ].

Commission file number 000-25669

IMMTECH INTERNATIONAL, INC.  
(Exact Name of Registrant as Specified in Its Charter)

Delaware	39-1523370
-----	
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
150 Fairway Drive, Suite 150, Vernon Hills, Illinois	60061
-----	
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (847) 573-0033

Securities registered pursuant to Section 12(b) of the Act:

None

-----  
(Title of class)

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value \$0.01 per share

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(Title of class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (ss.229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes  No

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The aggregate market value of our common stock held by non-affiliates of the registrant, computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common stock as of July 19, 2004, was \$78,184,192.

As of July 19, 2004, the total number of shares of the registrant's common stock outstanding was 9,915,324 shares.

## DOCUMENTS INCORPORATED BY REFERENCE

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None.

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FORWARD-LOOKING STATEMENTS

Certain statements contained in this annual report and in the documents incorporated by reference herein constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements frequently, but not always, use the words "may," "intends," "plans," "believes," "anticipates" or "expects" or similar words and may include statements concerning our strategies, goals and plans. Forward-looking statements involve a number of significant risks and uncertainties that could cause our actual results or achievements or other events to differ materially from those reflected in such forward-looking statements. Such factors include, among others described in this annual report, the following: (i) we are in an early stage of product development, (ii) the possibility that favorable relationships with collaborators cannot be established or, if established, will be abandoned by the collaborators before completion of product development, (iii) the possibility that we or our collaborators will not successfully develop any marketable products, (iv) the possibility that advances by competitors will cause our product candidates not to be viable, (v) uncertainties as to the requirement that a drug product be found to be safe and effective after extensive clinical trials and the possibility that the results of such trials, if completed, will not establish the safety or efficacy of our drug product candidates, (vi) risks relating to requirements for approvals by governmental agencies, such as the Food and Drug Administration, before products can be marketed and the possibility that such approvals will not be obtained in a timely manner or at all or will be conditioned in a manner that would impair our ability to market our product candidates successfully, (vii) the risk that our patents could be invalidated or narrowed in scope by judicial actions or that our technology could infringe upon the patent or other intellectual property rights of third parties, (viii) the possibility that we will not be able to raise adequate capital to fund our operations through the process of commercializing a successful product or that future financing will be completed on unfavorable terms, (ix) the possibility that any products successfully developed by us will not achieve market acceptance and (x) other risks and uncertainties that may not be described herein. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I.

ITEM 1. BUSINESS

A. Business Overview

Immtech International, Inc. is a pharmaceutical company advancing the development and commercialization of oral drugs to treat infectious diseases, and neoplastic (cancer) and metabolic (diabetes) disorders. We have drug development programs that include treatments for fungal infections,

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malaria, tuberculosis, diabetes, Pneumocystis carinii pneumonia ("PCP") and tropical diseases, including African sleeping sickness (trypanosomiasis) and leishmaniasis. We recently signed an agreement with CombinatoRx, Inc. to evaluate our first drug DB289 (in combination with other drugs on the market) for anticancer activity; currently CombinatoRx is using a drug similar in structure to DB289 as a combination partner in Phase II

clinical trials for the treatment of solid tumors. We hold worldwide patents and patent applications, and licenses and rights to license technology, primarily from a scientific consortium that has granted us exclusive rights to commercialize products from, and license rights to, the technology. Our scientific consortium includes scientists from The University of North Carolina at Chapel Hill ("UNC"), Georgia State University ("Georgia State"), Duke University ("Duke University") and Auburn University ("Auburn University") (collectively, the "Scientific Consortium").

Our strategy is to develop oral drugs effective against infectious diseases and neoplastic and metabolic disorders utilizing a dicationic technology platform. Infectious diseases in the global population have increased significantly during the past 20 years and are the most common cause of death worldwide according to the World Health Organization ("WHO"). Relatively few new drugs for treatment of infectious diseases have been brought to market during this period. New antibiotics are needed to overcome the problems of multi-drug resistance and the increasing number of new pathogens that are causing diseases in the world. Neoplastic and metabolic disorders, including cancer and diabetes, cause illness and death worldwide. Scientists have struggled for decades to find effective treatments for both cancer and diabetes. In our initial laboratory studies, the dication platform demonstrated positive therapeutic activity to treat these two devastating disorders.

Since our formation in October 1984, we have engaged in pharmaceutical research and drug development, expanding our scientific capabilities and collaborative network, developing technology licensing agreements, and advancing the commercialization of our proprietary technologies, including the development of aromatic cations (which include dications) commencing in 1997. In addition to our internal resources, we use the expertise and resources of strategic partners and third parties in a number of areas, including (i) discovery research, (ii) pre-clinical and human clinical trials and (iii) manufacture of pharmaceutical drugs.

We intend to continue to work with our scientific and foundation partners (See "Products and Programs - Malaria" and "Products and Programs - African sleeping sickness" below) to validate our technology platform, illustrating dications' low toxicity, broad application, and oral deliverability. We believe we will be permitted to sell drugs in niche markets in certain African nations as we further develop drugs to target multi-billion dollar markets such as antifungal, TB, cancer and diabetes treatments. Because we demonstrated to the United States Food and Drug Administration ("FDA") DB289's potential to provide improvement over currently available alternative therapies for African sleeping sickness, the FDA granted "fast-track" designation to DB289 for treatment of African sleeping sickness. Fast-track designation may allow for accelerated FDA review of DB289 for treatment of African sleeping sickness, however, there is no guarantee that fast-track designation will result in faster product development or impact the likelihood and timing of product approval.

For the fiscal year ended March 31, 2004, we had revenues of

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approximately \$2,416,000 and a net loss of \$12,846,000 which consisted primarily non-cash compensation expense related to the vesting of common stock options and warrants issued during the year which was approximately \$7,501,000. Our management believes we have sufficient capital for operations through our next fiscal year. There is no guarantee that we will not need additional

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funds before then or that sufficient funds will be available after April 2005 to fund further operations.

A predecessor of our Company was incorporated under the laws of the State of Wisconsin on October 15, 1984, and subsequently merged into the current Delaware corporation on April 1, 1993. Our executive offices are located at 150 Fairway Drive, Suite 150, Vernon Hills, Illinois 60061, telephone number (847) 573-0033 or toll-free (877) 898-8038. Our common stock is listed on The American Stock Exchange under the ticker symbol "IMM". Trading on the AMEX commenced on August 11, 2003.

We file annual, quarterly and current reports, proxy statements and other documents with the United States Securities and Exchange Commission (the "SEC"), under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Our reports, proxy statements and other documents filed electronically with the SEC are available at the website maintained by the SEC at <http://www.sec.gov>. We also make available free of charge on or through our Internet website, <http://www.immtech-international.com>, our annual, quarterly and current reports, and, if applicable, amendments to those reports, filed or furnished pursuant to Section 13(a) of the Exchange Act, as soon as reasonably practicable after we electronically file such reports with the SEC. Information on our website is not a part of this report.

Generally, when we use the words "we," "our," "us," the "Company" or "Immtech" in this report, we are referring to Immtech International, Inc. and its subsidiaries.

### B. Products and Programs

We currently have three human clinical trials and several more laboratory development programs underway testing the safety and effectiveness of DB289 for various indications. We are able to coordinate the development of simultaneous treatment programs by building on the results of our African sleeping sickness Phase IIb safety and efficacy trial to initiate Phase II studies in malaria and PCP. Dosage and treatment regimen for certain indications vary in each trial; however, our safety data from Phase I trials and Phase II trials of DB289 for treatment of African sleeping sickness have allowed us to expedite development of the dication technology for new indications.

#### 1. Malaria

Malaria is the second most deadly infectious disease in the world and is a significant problem for over 2.4 billion people exposed to this mosquito-borne disease. Malaria affects 300 to 500 million people

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each year and is especially devastating to children under the age of five for whom the fatality rate is very high. It is estimated by the WHO that over a million children die every year from malaria. The Global Fund to Fight AIDS, Tuberculosis and Malaria and Medicines for Malaria Venture ("MMV"), both foundations supported by The Bill and Melinda Gates Foundation ("The Gates

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Foundation"), are supporting the development of new oral drugs for safe and effective treatment of patients with drug-resistant forms of malaria.

In November 2003, we received a grant of approximately \$668,000 from MMV to fund clinical studies and manufacturing of DB289 for treatment of malaria. Subject to reaching certain milestones, MMV has committed approximately \$8.2 million to fund further clinical testing of DB289 to treat malaria and to commercially license its use.

In 2003, we commenced and completed a Phase IIa clinical trial of DB289 targeting two strains of the malaria parasite (*Plasmodium vivax* and *Plasmodium falciparum*, the two most common human forms of malaria in the world). Our pre-clinical data and pharmacokinetics (pharmacokinetics is the study of the uptake, distribution and rate of movement of a drug in the body from the time it is absorbed until it is eliminated) studies conducted in humans indicated that sufficient levels of DB289 could be reached in the blood to have a therapeutic effect on malaria in humans. DB289 demonstrated positive activity against several non-human forms of malaria (used as surrogates for the human disease) in animal models of the disease. DB289 also showed positive activity in vitro against known drug-resistant strains of malaria, including chloroquine-resistant strains of malaria. Chloroquine is the drug most frequently used to treat malaria in developing countries.

In December 2003, we reported results of our Phase IIa malaria trial that was conducted in Thailand. The patients who participated in the malaria trial were treated with 100 mg capsules of DB289 twice per day for five consecutive days. The patients' blood samples were evaluated for parasites in the prescreening process to establish a baseline and checked every six hours for the first three days, every 12 hours for the next four days and on days 10, 14, 21 and 28. For purposes of this study, patients were considered to be cured if malaria parasites were eliminated at 28 days after treatment. All 32 patients treated cleared the malaria parasite and malaria symptoms (i.e., fever) disappeared within the treatment period; 50% of the patients cleared the malaria parasite within 24 hours of the first dose. DB289 was well tolerated with no significant adverse side-effects reported. All patients were followed and monitored for 28 days after treatment to ensure that the malaria parasite had been eliminated.

Out of the 32 patients in the malaria trial, nine were infected with *Plasmodium vivax* and 23 were infected with *Plasmodium falciparum* (the most deadly form of malaria contracted by humans). *P. vivax* infected patients usually have less severe symptoms, but reoccurrence is very high and a large percentage develop chronic forms of the disease. *P. falciparum* has more severe symptoms (including high fever), and causes over 2 million deaths per year. Chloroquine, the most commonly used treatment, has high levels of drug-resistance.

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The *P. falciparum* patients were treated with DB289 as a monotherapy (not in combination with any other drugs). Of the 23 patients treated for *P. falciparum*, approximately 95% (22 of 23 patients) cleared the malaria parasite (and were considered to be cured) in the 28 day trial period. Blood samples from two of the patients

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contained malaria parasites at the end of this trial; however, after more extensive testing the principal investigator (an independent third-party) concluded that one of the two failed patients had been infected with a new malaria infection and had cleared the original malaria parasite. Nine *P. vivax* patients were treated with DB289 for five days followed by oral Primaquine (drug combination therapy is used as standard therapy for *P. vivax* treatment). Eight of the nine patients treated with both drugs for *P. vivax* remained clear of any parasites on the 28th day of the trial without any significant adverse events or safety issues with the combination therapy; one patient showed some signs of relapse on the 28th day and was administered an additional one day regimen of oral Primaquine after which all malaria parasites were cleared.

Based on the results of the Phase IIa malaria trial in Thailand, we initiated several new trials in July, 2004; (1) a new study in Thailand will evaluate DB289 in combination with a synthetic analog of Artemisinin, (thereby potentially creating a new drug cocktail to treat malaria) and (2) a study in uninfected, normal volunteers to determine the maximum tolerable dose of DB289 in a three day treatment regimen. In addition, the study in uninfected, normal volunteers will include three different ethnic groups to compare metabolism of DB289 and to compare 5 day dosing to 3 day dosing. The combination study is designed to evaluate potential drug interactions between the Artemisinin synthetic analog and DB289 in patients with acute to moderate malaria. The study incorporates several dose levels and regimens (once daily versus twice daily dosing) and will be conducted in Thailand. The study design is set forth below.

Clinical Trial	Trial Design	End Points	Site
DB289 in combination with a synthetic analog of Artemisinin	<input type="checkbox"/> Phase II	<input type="checkbox"/> Drug interactions	Thailand
	<input type="checkbox"/> Oral Dosing 3 days	<input type="checkbox"/> Safety	
	<input type="checkbox"/> Artemisinin & DB289	<input type="checkbox"/> Parasite clearance	
		<input type="checkbox"/> Clinical improvement	
DB289 alone	<input type="checkbox"/> Phase I	<input type="checkbox"/> Maximum tolerable dose	France
	<input type="checkbox"/> Healthy volunteers	<input type="checkbox"/> Safety	
	<input type="checkbox"/> Single doses for 3 days	<input type="checkbox"/> Pharmacokinetics	
	<input type="checkbox"/> Compare 3 and 5 day dosing		
	<input type="checkbox"/> Different ethnic groups		

a. MMV Agreement

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On November 26, 2003, we entered into a Testing Agreement with MMV, a foundation established in Switzerland, and UNC pursuant to which we, with the support of MMV and UNC, are conducting a study of DB289 as a treatment for malaria. The studies to be performed include Phase II and Phase III

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human clinical trials, and drug development activities of DB289 alone, and in combination with other anti-malarial drugs, with the goal of obtaining regulatory approval of a product for the treatment of malaria.

Under the terms of the agreement, MMV has committed to advance funds to the Company to pay for human clinical trials and regulatory preparation and filing costs to obtain approval to market DB289 for treatment of malaria. MMV will pay for regulatory approvals for DB289 in at least one internationally accepted regulatory body and at least one malaria endemic country. We have forecasted such costs to be approximately \$8.2 million. MMV has agreed to fund the forecasted amount based on progress achieved. Through the fiscal year ended March 31, 2004, MMV has funded \$668,000 for human clinical trials conducted from June to December 2003. Under this agreement, UNC will receive approximately \$50,000 for its work to evaluate synergistic qualities of other drugs that may be used in combination with DB289 as a malarial drug "cocktail".

b. Related MMV/UNC Agreement  
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In a related "Discovery Agreement" between MMV and UNC, MMV has agreed to fund a research program with a three year budget of approximately \$1.4 million. The goals of the Discovery Agreement are to design, synthesis and optimize new compounds for testing and evaluation of effectiveness for treatment of malaria. Immtech is a third party beneficiary of the Discovery Agreement and, pursuant to the terms of the Consortium Agreement (defined below), has the rights to develop and commercialize the discoveries resulting therefrom.

2. African Sleeping Sickness (Human trypanosomiasis)

African sleeping sickness is a parasitic disease that is spread by tsetse flies in sub-Saharan Africa. Doctors Without Borders estimates that the geographical range in sub-Saharan Africa where human African sleeping sickness occurs encompasses 36 countries, wherein over 60 million persons are at risk of contracting the disease. Existing treatments for African sleeping sickness can be highly toxic and cannot be administered orally. African sleeping sickness is fatal if left untreated.

WHO estimates that there are 500,000 to 750,000 active cases of human African sleeping sickness in central Africa. A WHO survey reports that an "epidemic situation" for African sleeping sickness exists in the sub-Saharan region of Africa which includes the countries of Angola, Sudan,

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Uganda and the Democratic Republic of the Congo ("DRC").

Human African sleeping sickness may take one of two forms depending upon the origin of the parasite that transmits the disease: (1) West African sleeping sickness is caused by *Trypanosoma brucei gambiense* and (2) East African sleeping sickness is caused by *Trypanosoma brucei rhodesiense*. Although DB289 has shown in

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in vitro and in vivo (animal) tests activity in both forms, thus far we have conducted human clinical trials of DB289 only as a treatment for the West African sleeping sickness strain found in the area of sub-Saharan Africa that has an ongoing epidemic.

In September 2002, we completed an open-label, non-controlled Phase IIa study of DB289 in the Democratic Republic of Congo ("DRC") for treatment of African sleeping sickness. Initial results showed that the compound was well tolerated with no significant adverse side-effects and over 93% of the patients (28 of 30) treated were cleared of the African sleeping sickness parasite (blood and lymph node samples taken 2 days after completion of treatment were parasite free). Patients evaluated at three and six months after treatment (21 of 27 due for follow-up returned for six month testing) remained parasite free with one relapse detected. Based upon the promising results of the Phase IIa clinical trial, The Gates Foundation made an additional grant of \$2.7 million to the UNC Scientific Consortium to accelerate Phase IIb/III clinical trials.

In April 2003 we commenced the first arm of a multi-arm, multi-site 350-patient Phase II/III randomized human clinical trial to treat African sleeping sickness with DB289 that may serve as the pivotal study to support approval. The Phase IIb arm of the study included the testing of 80 patients at two sites in the DRC where we administered twice daily dosing of 100 mg of DB289 for five days and the current extended regimen program in 30 patients who are receiving twice daily dosing of 100 mg of DB289 for ten days. We anticipate that the extended regimen program will conclude in 3rd calendar quarter 2004 at which time we intend to commence the Phase III arm of the study by adding three additional sites and adding 250 additional patients overall at the five testing sites. Assuming consistent positive results, we intend upon completion of the final report of the pivotal Phase IIb trial including the extended regimen program (expected 4th calendar quarter 2004) to schedule conferences with the FDA and other regulatory agencies to present our Phase IIb results and to finalize requirements to file an NDA under Accelerated Approval or similar other regulatory licensure program for DB289 to treat African sleeping sickness. We expect to file the above-described NDA or other regulatory licensure program upon completion of treatment of 200 patients, which may for safety review purposes, include some patients treated with DB289 for other indications.

In the initial stage of the randomized clinical trial (Phase IIb), half the patients in the study receive DB289 and half the patients receive pentamidine intramuscular injections (standard first line therapy). In February 2004 we completed the first 80 patients in the pivotal Phase IIb trial. The initial clinical trial commenced in two larger sites in Maluku and Vanga in the DRC where patients receive extensive safety monitoring. Patient monitoring included EKG monitoring, blood sampling to check clinical chemistry and hematology parameters and

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various other clinical measurements and tests, including the clearance of parasites from blood. The results from the initial 80 patients continued to show DB289 to be well tolerated with a favorable safety profile. In the patients treated at the Vanga site several patients did not clear the parasite from the lymph nodes. Based on this information, we opened a new extended regimen arm of the study with 30 patients using DB289 for 10 days (twice daily at 100 mg per dose); twice

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the duration of the prior treatment regimen. We expect that the new dose term will clear the small number of parasites found in the lymph nodes of those patients.

Once the extended regimen trial is completed, we plan to (i) open three additional clinical sites, two in the DRC and one in Angola, where we intend collectively with the two original sites to enroll 250 additional patients and (ii) designate this study a Phase III trial and obtain regulatory approval regarding such designation. (See trial design below) Concurrently, if we meet the designated end points in our extended regimen trial, we plan to file a New Drug Application, or NDA, with the FDA (or similar applications with regulatory agencies in foreign countries) for approval of DB289 in treating African sleeping sickness and to apply for an Accelerated Approval of our NDA (or similar accelerated approval under the foreign regulatory programs). The FDA has indicated that it would consider a NDA for DB289 to treat African sleeping sickness upon submission of safety and efficacy data on 200 patients. Accelerated Approval is often granted to drugs intended for compassionate use in treating serious or life-threatening diseases after completion of safety and efficacy studies (often Phase II). If approval is based upon Accelerated Approval or other recognized governments' similar accelerated approval programs continued testing, often including clinical Phase IV trials, is typically required to validate the surrogate endpoints used in the prior safety and efficacy trials. There can be no guarantee that we will be granted Accelerated Approval quickly or at all or, that if granted, such approval will not be later revoked. (See this section - "Governmental Regulation")

If our NDA for DB289 to treat African sleeping sickness receives approval from the FDA or another recognized government regulatory agency (pursuant to Accelerated Approval or otherwise), we intend to apply to the WHO to have DB289 listed on their Essential Medicines List. The WHO generally accepts NDA approvals for the Essential Medicines List from drug regulatory agencies in the United States, UK, European Union and Japan as well as other countries with established regulatory agencies. In most cases, inclusion on the list is the primary requirement to selling drugs in sub-Saharan Africa. We believe we will then be able to sell DB289 to treat African sleeping sickness while continuing to perform post-approval studies as and if required. In addition to listing on the WHO Essential Medicines List, the distribution of pharmaceutical drugs in sub-Saharan Africa requires individual approval from each country where the drugs are sold. Once approved, certain governmental and charitable agencies have expressed willingness to purchase DB289 from us and distribute the drug in the sub-Saharan nations for compassionate use. We anticipate three to six months' lead time to manufacture, receive export clearance and deliver our first drug shipment after receipt of a purchase order pursuant to the above plan, although there could be delays that result in longer lead times.

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We have engaged a large scale pharmaceutical contract manufacturer, Cambrex Charles City Inc., to produce DB289 for the clinical trials and commercial sales. We plan concurrently with process validation to seek final regulatory approval (as described above) to commercially distribute the product into approved countries.

All clinical trials of DB289 are being conducted under an Investigational New Drug ("IND") application with the FDA. In addition to an IND filed with the FDA,

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on April 23, 2004 the FDA granted "Fast-Track" drug development designation for use of DB289 to treat human African sleeping sickness. We believe our studies have demonstrated DB289's potential to treat human African sleeping sickness, a life-threatening disease for which no other oral treatment exists, without the serious side-effects associated with alternative (non-orally deliverable) therapies. Fast-track designation of DB289 to treat African sleeping sickness increases the likelihood that the FDA will grant Accelerated Approval of our NDA for DB289, however, there is no guarantee that fast-track designation will result in faster product development or impact the likelihood and timing of product approval.

We believe that our data to date suggests that DB289 can be used to treat human African sleeping sickness without the serious side-effects and high toxicity profile associated with pentamidine, the primary treatment in use in Africa. Pentamidine is usually administered intravenously, by intramuscular injection, or via inhalation and generally requires medical personnel and hospital or clinic facilities for delivery. The oral deliverability of DB289 can be particularly important in remote geographic areas where this disease is endemic and where access to medical personnel and facilities needed to deliver the current therapy are limited.

Our pivotal clinical trial design for using DB289 to treat human African sleeping sickness is set forth below:

Clinical Trial	Trial Design / Phase	End Points
DB289 Pivotal Trial		
o African sleeping sickness	o Oral dosing for 5 to 10 days (BID) o Randomized comparison to pentamidine o Phase IIb o 110 patients - stage 1 disease o Phase III o 250 patients - stage 1 disease	o Safety o Clearance of parasite from blood after treatment and 3, 6 months o Improvement of symptoms

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a. Gates Grant  
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In November 2000, The Gates Foundation awarded a \$15.1 million grant to a research group led by UNC to develop new drugs to treat African sleeping sickness and leishmaniasis, two life-threatening diseases endemic in sub-Saharan Africa. The research group led by UNC includes Immtech and five other universities and research centers around the world which collectively employ scientists and physicians considered to be the foremost experts in one or both of these diseases.

b. Gates Acceleration Grant  
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In June 2003, the Gates Foundation awarded an additional \$2.7 million grant to the UNC led research group to (i) expand the Phase IIb trial of

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DB289 for treatment of African sleeping sickness into the pivotal multi-arm, multi-site 350-patient Phase II/III randomized human clinical trial described above, (ii) implement an improved method of synthesizing DB289 to reduce drug manufacturing costs and (iii) improve DB289's formulation to facilitate increased drug absorption into the blood circulation. Pursuant to the terms of the Clinical Research Subcontract described below, ninety-one percent of this grant (\$2,466,475) is directed to Immtech. On June 26, 2003 we received \$1,025,201 to advance the goals set forth above.

c. Clinical Research Subcontract with UNC  
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On March 29, 2001, we entered into a clinical research subcontract ("Clinical Research Subcontract") with UNC to advance the work funded by The Gates Foundation \$15.1 million grant. Pursuant to the Clinical Research Subcontract, UNC is to pay to us \$9.8 million of the \$15.1 million grant in installments over a period not to exceed five years based on our achieving certain milestones (approximately \$7.7 million of which has been paid to us to date). Under the terms of the Clinical Research Subcontract, we are responsible for the oversight of Phase II and Phase III human clinical trials of the drug candidate DB289 for African sleeping sickness. The terms of the Clinical Research Subcontract require us to segregate the Clinical Research Subcontract funds from our other funds and to use the proceeds only for developing a drug for treatment of African sleeping sickness. We have or will receive The Gates Foundation grant funds under the Clinical Research Subcontract as follows: (a) \$4.3 million was received in fiscal year 2001 to fund Phase II clinical trials to test DB289's effectiveness against African sleeping sickness in approximately 30 patients, (b) \$1.4 million was paid to us in September 2002 upon the successful

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completion of our Phase IIa clinical trial, (c) \$2.0 million was paid to us in December 2002 upon the delivery of the final Phase IIa report in respect of the Phase II clinical trial and (d) \$2.1 million is scheduled to be paid to fund Phase IIb and Phase III clinical trials to test compound DB289's effectiveness against African sleeping sickness on a larger, more diverse group of patients in calendar year 2005.

The Clinical Research Subcontract will continue in effect until November 17, 2005, unless otherwise terminated by a material breach by either party.

### 3. PCP pneumonia

In 2002, we received approval from the FDA and the Ministry of Health in Peru to commence a pilot Phase IIa clinical trial of DB289 to treat *Pneumocystis carinii* pneumonia ("PCP"). PCP is a fungus that overgrows the air sacs in the lungs of immunosuppressed patients, causing pneumonia that can be life-threatening. We conducted a proof of concept trial in 8 patients with acquired immune disease syndrome ("AIDS") who had failed standard therapy. The patients were each given 50 mg of DB289 twice per day for 21 days; the treatment regimen was completed in February

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2003. At the conclusion of the study, all patients showed improved lung function and, during the 21 days of treatment, normal lung function returned to three of the patients.

In July 2003, we commenced a second Phase IIb human clinical trial in Peru in 30 AIDS patients with PCP who had previously failed other therapies to treat PCP with a dosage of 100 mg twice per day (a higher dose than the pilot study). The initial data from 19 patients who have completed the trial indicates that all patients returned to normal lung function within 12 days. The higher dosage regimen appears to significantly increase the number of patients who clear the infection (demonstrate improved lung function) and decreased the time in which the infection is cleared.

Our current clinical trial protocol for testing of DB289's safety and effectiveness against PCP is set forth below:

Clinical Trial	Trial Design / Phase	End Points
DB289		
o PCP	<ul style="list-style-type: none"><li>o Phase IIb</li><li>o Patients who failed standard treatment</li><li>o Oral dosing for 21 days</li><li>o Twice daily dosages of 100mg</li></ul>	<ul style="list-style-type: none"><li>o Safety</li><li>o Improvement in lung function (fungal clearance)</li><li>o Improvement in clinical symptoms</li></ul>

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### 4. Antifungal Program

Scientific Consortium scientists from Duke University, UNC and Georgia State have identified several compounds with the potential to treat both *Candida* and *Aspergillus*, two fungal infections that in the aggregate account for approximately 90% of the systemic fungal infection that make up the \$4 billion annual anti-fungal drug market (as estimated by DataMonitor). In vitro studies have identified 20-30 dications that display both broad based and selective antifungal activity against *Candida*, *Aspergillus* and *Cryptococcus*, including activity against fungi which had previously been shown to be drug resistant. Our objective in 2004 is to select an oral drug candidate for the treatment of fungal infections and begin preclinical safety and pharmacology studies required prior to human trials.

The market for an effective antifungal drug was estimated by DataMonitor in 2003 to be approximately \$4 billion annually and growing rapidly due to the increasing number of patients who are susceptible to fungal diseases, such as patients undergoing cancer chemotherapy, patients with HIV and those who have undergone organ transplants. In addition, the frequency of nosocomial infection (infection acquired while being treated in a hospital) caused by fungi has increased drastically and is now the third most common cause of sepsis, replacing *Escherichia coli* ("E. coli"). Sepsis is an infection that quickly overwhelms the immune system and can lead to sudden death. Recently, strains of fungi have developed that are resistant to currently available treatments. There is a significant opportunity for new oral drugs effective against specific strains of fungi as well as drugs with broad spectrum effectiveness across fungal strains.

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Duke University researchers have developed an animal model of *Candida* and *Aspergillus* and are testing compounds in this model. In addition, we have a contract with Case Western University ("Case Western") to test in animal models of fungal infections compounds believed to have potential to treat fungal infections. We and consortium scientists, after several years of testing, have selected approximately ten lead dication compounds for testing in Case Western's animal models. Case Western is evaluating dose responses for a number of our compounds to determine which of the lead compounds will be the best to move forward into preclinical development.

### 5. Tuberculosis

Tuberculosis ("TB") is the world's number one killer among infectious diseases and is the cause of over two million deaths per year, according to the WHO and the U.S. Centers for Disease Control (the "CDC"). The CDC reports that about two billion people, including fifteen million Americans, are infected with TB. The disease is spreading rapidly in developing countries in Asia, Africa and South America, and is becoming increasingly problematic in developed countries and in Eastern Europe. Japan has declared TB as its most threatening disease. An alarming increase in TB cases is also developing in the United States. The combination of the rapid spread of TB and the appearance of multi-drug resistant strains ("MDR") of the TB organism make TB a major health threat

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throughout the world. TB is a difficult infection to treat given that the bacteria is often sequestered in various tissues and organs of the body. The organisms that cause the disease can "hide" inside white blood cells where the organisms are protected against antibiotic drugs. To be effective, a drug must eliminate the TB organisms from the lungs, tissues, and infected white blood cells.

WHO and the National Institutes of Health ("NIH") have significantly increased research efforts to discover drugs to treat TB. Their research is focused on developing oral drugs that are effective against drug resistant strains of TB and the creation of therapies to shorten the treatment period required to eradicate the disease. Their overall target is to reduce the current nine- to eighteen-month treatment period down to two- to six- months.

NIH laboratories screened over 500 of our dication compounds looking for potential drug candidates for treatment of TB. The NIH screening program identified approximately 10 to 15 dications with in vitro activity comparable or superior in performance to drugs currently available to treat TB. We moved our screening and animal testing program to the University of Illinois-Chicago ("UIC") which is directed by Dr. Scott G. Franzblau, to develop new drugs to combat the common and MDR strains of Mycobacterium TB. Dr. Franzblau is a leading expert in TB treatment. Prior to running the TB program at UIC, Dr. Franzblau led the NIH-funded anti-TB screening program at the National Hansen's Disease Center at Louisiana State University. The in vitro screening program at UIC identified seven new compounds which displayed excellent activity which have been selected for in vivo screening. The UIC laboratory is evaluating these newly identified compounds and several from the NIH screening program in acute and latent animal models of TB. We believe that the final test results will assist us in selecting a compound this year that will move into pre-clinical studies required prior to human trials.

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### 6. Pharmaceutical Cancer Program

We have provided under a confidentiality, material transfer and testing agreement with CombinatoRx of Boston, Massachusetts certain of our aromatic cationic compounds, including DB289 and DB075, to be tested for activity against certain cancers. CombinatoRx previously tested various combinations of drugs not normally associated with cancer treatments for effectiveness against cancer and has had promising results. Several of our aromatic dication compounds have similar medicinal properties to those used by CombinatoRx in its earlier tests. Our compounds, however, do not appear to have the adverse side-effects and delivery difficulties generally associated with those other pharmaceuticals tested by CombinatoRx. We and CombinatoRx believe that our aromatic cationic compounds' broad-based activities and unique mechanism of action will demonstrate, through CombinatoRx's studies, activity in oncology. CombinatoRx's studies will include in vitro assays and in vivo models and will test our compounds in combination with CombinatoRx's proprietary anti-cancer technology.

### C. Technology

#### 1. Dications

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Our pharmaceutical program focuses on the development and commercialization of oral drugs to treat fungal, parasitic, bacterial and viral diseases and certain neoplastic and metabolic disorders, including cancer and diabetes. Aromatic dications are chemical structures that have two positively charged ends that are held together by a linker; at the atom level, they look like molecular barbells. In addition, a new class of monocations have been made with excellent activity in specific target diseases, these compounds have a single positive charge on one end and a linker. The positive charges as one mechanism of action allow our compounds to bind to negatively charged segments of deoxyribonucleic acid ("DNA"). Dication drugs bind in the minor groove of DNA and to certain receptors, blocking the activity of enzymes needed for microbial growth. The key site on an organism's DNA is an area where enzymes interact with the organism's DNA as part of their normal life cycle. Structurally, dications are chemical molecules that have two positively charged ends held together by a chemical linker. The composition of the dications, with positive charges on the ends and linkers of different length, shape and binding curvature allows specific dication binding.

Pentamidine (a dicationic drug on the market) was the prototype drug used by scientists at UNC to develop our proprietary library of aromatic compounds. While having broad based activity against many diseases including fungal infections and cancer, pentamidine can only be administered intravenously, by intramuscular injection, or via inhalation. Pentamidine is difficult and costly to administer outside of a hospital setting due to its narrow therapeutic dosage margin of safety and efficacy.

Scientists at UNC discovered that much of pentamidine's toxicity was the result of bi-products formed when the drug breaks down within the body. This discovery by the scientists led to the design of new compounds which did not break down in the same way. Additional modifications to the structures of these compounds improved on

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their binding activity and enhanced the applicability of this class as antibiotics over other anti-infectious agents, while lowering toxicity and increasing oral deliverability.

Scientific Consortium members have thus far designed and synthesized over 2,200 well-defined aromatic cationic compounds. These compounds have all been tested in a wide variety of assays and animal models of various diseases. UNC and Georgia State continue to improve methods for making cationic molecules in computer models that help to develop medicinally efficacious compounds. One or more of the universities comprising the Scientific Consortium have patents covering the molecular structure of the compounds, as well as in some cases particular uses of a compound for potential treatment of an infection or disease.

Members of the Scientific Consortium have laboratory testing systems for screening dications for activity against specific microorganisms (using both laboratory and animal models). Our scientists have over 25 years of experience in making dication compounds and have developed proprietary computer models which help our scientists rationally

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design the next generation of compounds. Generally, patents for the aromatic cation structures and uses are issued to the scientist who invents or discovers the new compound and/or proves its unique applicability for particular diseases. Then, pursuant to the scientist's employment arrangements, the patents are assigned to the employing university, and, through the License Agreement (see "The Scientific Consortium - Consortium Agreement and License" below), to us through an exclusive worldwide license to commercialize such compounds and uses.

a. DB289

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DB289 is an aromatic dication that utilizes prodrug oral delivery technology to deliver the active drug into blood circulation by swallowing a pill. In May 2001, we completed Phase I safety trials of DB289 in human volunteers. The single and multi-dose trials demonstrated that DB289 was well tolerated by the volunteers.

The study was designed to evaluate the safety and pharmacokinetics (pharmacokinetics is the study of a drug's effect on the body from the time it is absorbed until it is eliminated) of three dosage levels of DB289 administered twice a day over a period of six days. In addition to the safety studies, the volunteers who were given the active drug participated in a secondary study to determine whether food affected absorption through the digestive system. The studies showed that DB289 passed easily through the digestive membrane and the drug was active (as designed) for several hours in the bloodstream. In addition, volunteers tested at the highest dosage levels in the multi-dose segment of the trial did not display any specific side-effects, and the post-test EKGs, clinical chemistry and hematology parameters of those volunteers were all within normal ranges. The drug concentration levels in the blood were similar to levels that showed positive activity in animal models in malaria, PCP and African sleeping sickness.

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b. Prodrug Formulation

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One of our most significant research developments was the discovery of technology to make dication drugs orally deliverable. This proprietary technology temporarily masks the positive charges of the dication, enabling the active compound to move easily across digestive membranes into blood circulation. Once the drug is in blood circulation, the masking charges are removed by naturally occurring enzymes thereby releasing the active drug. Until now, the inability to deliver active compounds across the digestive membrane into the bloodstream had reduced the attractiveness of aromatic cations/dications as effective antibiotics. Our scientists have patented four prodrug synthesis methods allowing for oral delivery and making this entire class of compounds significantly more attractive for commercial development.

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On February 26, 2003, Scientific Consortium members were granted a patent by the U.S. Patent Office entitled "Prodrugs for Antimicrobial Amidines" for a new proprietary technology to synthesize and manufacture dication and other compounds with prodrug technology. This patent protects a substantially advanced process for economically producing oral drugs designed to treat infectious diseases and metabolic disorders such as fungal infections, malaria, tuberculosis, diabetes, Pneumocystis carinii pneumonia and tropical diseases, including African sleeping sickness (trypanosomiasis) and leishmaniasis. Application of prodrug technology is not limited to our products, and we are investigating the potential to sub-license the prodrug process to other drug manufacturers for use on other compounds designed to be ingested orally and then activated in the blood stream.

### 2. The Scientific Consortium

The Scientific Consortium responsible for the invention and development of dication technology includes scientists from UNC, Georgia State, Duke University and Auburn University (collectively, the "Scientific Consortium").

#### a. Consortium Agreement and License

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On January 15, 1997, we entered into a Consortium Agreement with UNC and Pharm-Eco Laboratories, Inc. ("Pharm-Eco") (to which each of Georgia State, Duke University and Auburn University agreed shortly thereafter to become a party). The Consortium Agreement provided that dications developed by the Scientific Consortium-members were to be exclusively licensed to us for global commercialization. As contemplated by the Consortium Agreement, on January 28, 2002, we entered into a License Agreement with the Scientific Consortium whereby we received the exclusive license to commercialize all future technology and compounds ("future compounds") developed or invented by one or more of the Scientific Consortium scientists after January 15, 1997, and which also incorporated into such License Agreement our

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license with the Scientific Consortium with regard to compounds developed on or prior to January 15, 1997 ("current compounds").

Pursuant to the Consortium Agreement, Pharm-Eco agreed to transfer to us the worldwide exclusive license to use, manufacture, have manufactured, promote, sell, distribute or otherwise dispose of any and all products based directly or indirectly on dications developed by the Scientific Consortium on or prior to January 15, 1997 and previously licensed (together with related technology and patents) to Pharm-Eco. In March 2001, Pharm-Eco assigned the license to us. The January 28, 2002, License Agreement grants to us a similar worldwide exclusive license covering products based on dicationic technology developed by the Scientific Consortium after January 15, 1997 and incorporates the exclusive license assigned to us by Pharm-Eco in March 2001. The Consortium Agreement has provided us with rights to the Scientific Consortium's library of over 2,000 well-defined aromatic cationic

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compounds/dications and to all future technology to be designed by the Scientific Consortium. The Scientific Consortium scientists are considered to be among the world's leading experts in infectious diseases, computer modeling of dicationic pharmaceutical drugs and computer-generated drug designs.

The Consortium Agreement provides that we are required to pay to UNC on behalf of the Scientific Consortium reimbursement of patent and patent-related fees, certain milestone payments and royalty payments based on revenue derived from the Scientific Consortium's dication technology. Each month on behalf of the inventor scientist or university, as the case may be, UNC submits to us an invoice for payment of patent-related fees related to current compounds or future compounds incurred prior to the invoice date. For the fiscal year ended March 31, 2004, we reimbursed UNC \$473,567 for such patent and patent-related costs, and in the past, we have reimbursed to UNC approximately \$1,413,000 in the aggregate in patent and patent-related costs. We are also required to make milestone payments in the form of issuance of 100,000 shares of our common stock to the Consortium when we file our initial New Drug Application ("NDA") or an Abbreviated New Drug Application ("ANDA") based on Consortium technology and are required to pay to UNC on behalf of the Scientific Consortium (other than Duke University) (i) royalty payments of up to 5% of our net worldwide sales of "current products" and "future products" (products based directly or indirectly on current compounds and future compounds, respectively) and (ii) a percentage of any fees we receive under sublicensing arrangements. With respect to products or licensing arrangements emanating from Duke University technology, we are required to negotiate in good faith with UNC (on behalf of Duke University) royalty, milestone or other fees at the time of such event, consistent with the terms of the Consortium Agreement.

Under the License Agreement, we must also reimburse the cost of obtaining patents and assume liability for future costs to maintain and defend patents so long as we choose to retain the license to such patents.

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### D. Our Subsidiaries

#### 1. Immtech Hong Kong Limited

On January 13, 2003, we entered into an agreement with an investor who owned, through Lenton Fibre Optics Development Limited ("Lenton"), a Hong Kong company, a 1.6+ acre commercial real estate parcel located in a "free-trade zone" called the Futian Free Trade Zone, Shenzhen, in the People's Republic of China ("PRC"). Under the agreement, we purchased an 80% interest in Lenton by issuing to the investor 1,200,000 unregistered shares of our common stock, \$0.01 par value. We subsequently resold to the investor our interest in Lenton and the parcel of land in exchange for 100% ownership in the improved property described below under Super Insight Limited and Immtech Life Science Limited. In connection with the sale of Lenton, we acquired 100% ownership of Immtech Hong Kong Limited ("Immtech HK"), including Immtech HK's interest in Immtech Therapeutics Limited.

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Subsequently, though a sublicense agreement, we transferred to Immtech HK our rights to develop and license university technology in certain Asian countries and to commercialize resulting products granted to us under the Consortium Agreement. We intend to use Immtech HK as a vehicle to further sublicense rights to develop specific indications to indirect subsidiaries that will partner with investors who fund development costs of those indications. Immtech HK is a Hong Kong company.

a. Immtech Therapeutics Limited  
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Immtech Therapeutics Limited ("Immtech Therapeutics") provides assistance to healthcare companies seeking access to China to conduct human clinical trials and to manufacture and/or distribute pharmaceutical products in China.

Immtech Therapeutics is majority owned by Immtech HK and its minority owners are Centralfield International Limited (a British Virgin Island (BVI) company and wholly-owned subsidiary of TechCap Holdings Limited) and Bingo Star Limited (BVI). TechCap has assets and resources in China upon which Immtech Therapeutics may draw. Bingo Star Limited has substantial financial and medical expertise and resources located in Hong Kong and China. Immtech Therapeutics is a Hong Kong company.

2. Super Insight Limited (BVI)

On November 28, 2003, we purchased (i) from an investor 100% of Super Insight Limited ("Super Insight") and its wholly-owned subsidiary, Immtech Life Science Limited ("Immtech Life Science") and (ii) from Lenton Fiber Optics Development Limited, a 100% interest in Immtech HK. As payment for the acquisition, we transferred to the investor our 80% interest in Lenton and cash. Super Insight is a British Virgin Islands company.

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a. Immtech Life Science Limited  
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Immtech Life Science owns two floors of a newly-constructed building (the "Property") located in the Futian Free Trade Zone, Shenzhen, in the PRC in which Immtech intends to house a pharmaceutical production facility for manufacture of its products. The Property comprises Level One and Level Two of a building named the Immtech Life Science Building. The duration of the land use right associated with the building on which the Property is located is 50 years which expires May 24, 2051.

Under current law, we will enjoy reduced tax on the business located on the Property because the local government has granted incentives to business in high technology industrial sectors locating in the Futian Free Trade Zone. Our intended pharmaceutical manufacture use qualifies for the tax incentives. Immtech Life

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Science is a Hong Kong company.

### E. Manufacturing

#### 1. The Scientific Consortium

Scientific Consortium members, specifically the combinatorial chemistry laboratory at Georgia State and the synthetic chemistry laboratory at UNC, have the capability to produce and inventory small quantities of the aromatic cations under license to us. To date, Georgia State and UNC have produced and supplied the dications requested in the quantities required under various testing agreements with third parties. We believe that Scientific Consortium members will continue to produce and deliver small quantities of compounds as needed for testing and commercialization purposes.

#### 2. Third Party Sources

On October 23, 2003 we entered into an agreement with Cardinal Health PTS, Inc. (Cardinal Health) to develop prototype formulations of DB289 to improve oral bioavailability DB289. Once the formulation is perfected by Cardinal Health we intend to engage Cardinal Health to produce commercial quantities of good manufacturing practices ("GMP") grade with raw materials to be produced by another third party. Cardinal Health is the second largest producer of pharmaceuticals and other medical supplies in the United States.

In February 2004, we entered into an agreement with Cambrex Charles City Inc. to improve the synthesis method for DB289, find methods to reduce the cost of manufacturing DB289, and to prepare the drug for production of commercial quantities of bulk GMP drug for clinical trials and sale. Cambrex is a global, diversified life sciences company dedicated to providing innovative products and services to accelerate drug discovery, development, and the manufacture of human therapeutics.

#### 3. Our China Facility

See disclosure above under the heading Immtech Life Science Limited.

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### F. Strategy

Our strategy is to develop oral drugs that are effective against infectious diseases and neoplastic and metabolic disorders by utilizing the aromatic cation/dicationic platform technology. Infectious diseases in the global population have increased significantly during the past 20 years and are the most common cause of death worldwide according to the WHO. Relatively few new drugs for treatment of infectious diseases have been brought to market during this period. New antibiotics are needed to overcome the problems of multi-drug resistance and the increasing number of new pathogens that are causing diseases in the world. Neoplastic (cancer) and metabolic (diabetes) disorders cause illness and death worldwide. Scientists have struggled for decades to find effective treatments for both cancer and diabetes. Our initial laboratory studies

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have demonstrated that the dication platform may be effective in treating these two devastating disorders. Scientists at the National Institutes of Health ("NIH") concluded from cancer screens that over 47 dication compounds showed evidence of efficacy in vitro to inhibit tumor growth in cellular assays of cancer and studies at UNC using a series of dications have shown that certain dications have a propensity to bind to imidazoline receptors and cause the release of insulin from pancreas cells which is believed could be helpful in the treatment of Type II diabetes.

We believe we have been successful in developing a drug with a lower toxicity profile than pentamidine that is orally available using our dication and prodrug technologies. We have leveraged our scientific partners and foundation funding while advancing our technology and human clinical trials in niche markets such as African sleeping sickness, as well as, in larger markets like malaria. We have advanced our pipeline in both antifungal and TB drugs, and established new programs in cancer, diabetes and neurological disorders. We plan to generate our first revenue by selling drugs into these niche markets with appropriate regulatory approval.

We intend to proceed with the development and commercialization of aromatic cations/dications for drug products pursuant to our agreement with the Scientific Consortium as follows:

- o Generate revenues by sales of human drug products to governments and foundations expedited through the FDA's Accelerated Approval program and/or other governments' similar programs;
- o Conclude Phase IIb trials of DB289 for treatment of malaria and prepare for Phase III pivotal trial;
- o Utilize the FDA's Fast-Track designation of DB289 for treatment of African sleeping sickness to potentially expedite licensing and commercialization through Accelerated Approval of our NDA or otherwise;
- o Generate shareholder value by developing our pipeline of prodrugs targeting fungal infections, cancer, diabetes and TB;
- o Develop through our subsidiary Immtech HK a diabetes program with a financial partner;

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- o Create business relationships with pharmaceutical and biotechnology companies interested in developing oral products to treat diseases such as fungal, cancer and diabetes;
- o Develop business relationships to advance our compounds as agents with animal health indications; and
- o Co-develop a pharmaceutical cancer program with a financial or pharmaceutical partner.

Our strategy is to commercialize aromatic cations/dications

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and our prodrug technology and generate revenues first in niche markets by selling drugs for serious or life-threatening diseases where indications provide meaningful therapeutic benefits over existing therapies. We intend when feasible to apply for and utilize FDA Fast-track and Accelerated Approval or corollary foreign accelerated approval programs. We will continue to work with academic institutions and foundations to support our drug development programs. We seek to simultaneously develop treatments for infectious diseases, such as TB and fungal infections, and neoplastic and metabolic disorders like cancer and diabetes with substantial markets that afflict large populations of people. We believe our first product candidates demonstrate the power and versatility of the indication and prodrug platform technologies. We believe our experience with these compounds in human clinical trials will help us expedite acceptance and obtain regulatory approval of our product candidates in other markets. We will continue to manage and oversee the programs and the results of research performed by members of the Scientific Consortium and to use business-sponsored research programs, government and foundation grants, strategic joint ventures and other forms of collaborative programs to advance product commercialization. We consider our current collaborative relationships significant to the successful development of our business. We believe that our collaborations and use of grant funds minimize shareholder dilution while advancing drugs rapidly toward commercialization. We plan to enter into additional arrangements in the future to develop, manufacture and market not only the product candidates on which we are currently focused, but also those indications which the Scientific Consortium members are developing for other indications.

### G. Research and Development

Our current and future success will depend in large part on our ability to commercialize products based upon the platform technology for developing indications currently licensed to Immtech through the Consortium Agreement and future indications for which we have the exclusive worldwide rights to license from the Scientific Consortium.

During the past three fiscal years, we estimate that we have spent approximately \$581,000, \$1,111,000 and \$893,000, respectively, in fiscal years ended March 31, 2002, 2003 and 2004, on Company sponsored research and development and approximately \$3,377,000, \$1,459,000 and \$2,400,000, respectively, in fiscal years ended March 31, 2002, 2003 and 2004, on research and development sponsored by others. All research and development activity for

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fiscal years ended March 31, 2002, 2003 and 2004 has been in support of our pharmaceutical commercialization effort.

### H. Patents and Licenses

Our pharmaceutical compounds, including DB289 and DB075, are protected by multiple patents secured by members of the Scientific Consortium. We consider the protection of our proprietary technologies and products to be important to the success of our business and rely on a combination of patents, licenses, copyrights and trademarks to protect these technologies and products. To date, we have obtained exclusive

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licensing rights to 217 dication patents and patent applications, 138 of which have been issued in the United States and in various global markets as of July 2004. In addition to the 217 dication patents and patent applications previously mentioned we own seven additional patents. Generally, U.S. patents have a term of 17 years from the date of issue for patents issued from applications submitted prior to June 8, 1995, and 20 years from the date of filing of the application in the case of patents issued from applications submitted on or after June 8, 1995. Patents in most other countries have a term of 20 years from the date of filing the patent application. 143 of our licensed patents and patent applications, which includes 42 licensed U.S. patents and patent applications, were submitted after June 8, 1995, including patents covering DB289, DB075 and our latest prodrug formulation processes.

Our policy is to file patent applications and defend the patents licensed to us covering the technology we consider important to our business in all countries where such protection is available and feasible. We intend to continue to file and defend patent applications we license or develop. Although we pursue and encourage patent protection and defend our patents and those licensed to us, obtaining patents for pharmaceutical drugs and their specific uses involves complex legal and factual questions and consequently involves a high degree of uncertainty. In addition, others may independently develop similar products, duplicate our potential products or design around the claims of any of our potential products. Because of the time delay in patent approval and the secrecy afforded the U.S. patent applications, we do not know if other applications, which might have priority over our applications, have been filed. We also rely on trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position.

Publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries by at least several months. As a result, there can be no assurance that patents will be issued from any of our patent applications or from applications licensed to us. The scope of any of our issued patents may not be sufficiently broad to offer meaningful protection. In addition, our issued patents or patents licensed to us could be successfully challenged, invalidated or circumvented so that our patent rights would not create an effective competitive barrier. We also rely in part on trade secret, copyright and trademark protection of our intellectual property. We protect our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. Employees and consultants sign agreements to assign to us their interests in patents and copyrights arising from their work for us. Key employees also agree not to engage in unfair competition with us after their employment by using our confidential information. We have additional secrecy measures as well. However, these agreements can be breached and, if they were, there might not be an adequate remedy

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available to us. Also, a third party could learn our trade secrets through means other than by breach of our confidentiality agreements, or our trade secrets could be independently developed by our competitors.

### 1. Patents

Patents and patent applications for the chemical substance and

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use of pharmaceutical compounds to treat infections caused by PCP, TB, Cryptosporidium parvum, Giardia lamblia, Leishmania mexicana amazonensis, Trypanosoma brucei rhodesienses, various fungi, Plasmodium falciparum, HCV, BVDV and HIV have been filed by the scientists of the Scientific Consortium members. We have exclusively licensed, or have the right to exclusively license, any of such patents for commercialization. We are obligated to reimburse or pay for patent protection of any such drugs that we license for commercialization. Patents and patent applications also protect certain processes for making prodrugs and the uses of compounds to detect and treat specific diseases as well as a patent for a new method for making chemical compounds that form dimers when they are bound to DNA. Dimers are two identical chemical molecules that attach to a DNA's key site in series to cover a larger section (double) of a DNA's key site.

On February 26, 2003, Scientific Consortium members were granted a patent by the U.S. Patent Office entitled "Prodrugs for Antimicrobial Amidines" for a proprietary technology to synthesize and manufacture prodrugs. The patent protects a substantially advanced process for economically producing orally deliverable drugs. This newly patented process, licensed to Immtech under the Consortium Agreement, reduces the number of steps required to make dications orally available and thereby reduces the cost to manufacture prodrug enhanced drugs. We are investigating the potential to sub-license this new prodrug process to other drug manufacturers for use with their compounds designed to be taken orally and then activated in the blood stream.

### a. Patent Licenses

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Pursuant to the Consortium Agreement, licenses and options to license patents for the dications developed by the Scientific Consortium prior to January 15, 1997, which were previously licensed or optioned to Pharm-Eco, were transferred to us by Pharm-Eco as of March 2001. In accordance with the terms of the Consortium Agreement, we have obtained license rights to the patents covering the technology platform for making dicationic pharmaceutical drugs and to treat certain microbial infections with such products. To date, we have exclusively licensed 217 patents and patent applications, which includes 69 U.S. patents and patent applications. All of the patents on our dicationic product candidates have been filed by UNC jointly with the other academic institutions of the Scientific Consortium.

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### b. Patent Rights

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Since January 1997, as required under the Consortium Agreement, we have filed, together with Scientific Consortium members, approximately 110 patent applications, of which approximately 51 have been granted. The Consortium Agreement grants us the right to license for commercialization product candidates underlying the patents and patent applications for dications produced by the Scientific Consortium.

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### I. Governmental Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture, marketing and distribution of drug products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our product candidates.

We believe our first commercial drug products will be marketed outside of the United States and likely in sub-Saharan African nations. Our ability to market our drug products will depend on receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process generally includes all of the risks associated with FDA approval; however, the requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Community, or EC, registration procedures are available to companies wishing to market a product to more than one EC member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization typically will be granted.

Once regulatory approval is obtained for an indication, we intend to apply to the WHO to have the approved drug listed for such indication on the WHO's Essential Medicines List. The WHO generally accepts NDA approvals for the Essential Medicines List from drug regulatory agencies in the United States, UK, European Union and Japan as well as other countries with established regulatory agencies. In most cases, inclusion on the list is the primary requirement to selling drugs in the countries where we intend to sell DB289 to treat African sleeping sickness and other tropical diseases. We believe we will then be able to sell our products while continuing to perform post-approval studies as and if required.

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process required by the FDA before our product candidates may be marketed in the United States generally involves the following:

- o completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies, all performed in accordance with FDA's good laboratory practice, or GLP, regulations;
  
- o submission to the FDA of an investigational new drug, or IND, application which, must become effective before human clinical trials may begin;
  
- o performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug candidate for each proposed indication;

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- o submission to the FDA of a new drug application, or NDA;
- o satisfactory completion of an FDA preapproval inspection of the manufacturing facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice, or cGMP, regulations; and
- o FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our drug candidates will be granted on a timely basis, or at all.

Preclinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30 day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during drug development, and the FDA must grant permission before each clinical trial can begin. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center, and the IRB must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice, or GCP, regulations, including regulations governing informed consent.

Clinical Trials. For purposes of NDA submission and approval, human clinical trials are typically conducted in three sequential phases, which may overlap:

- o Phase I: Studies are initially conducted in a limited population to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as AIDS or cancer patients.
- o Phase II: Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the potential efficacy of the drug for specific targeted indications and to determine dose tolerance and optimal dosage.

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Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials. In some cases, a sponsor may decide to run what is referred to as a "Phase IIb" evaluation, which is a

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second, confirmatory Phase II trial that could, if positive and accepted by the FDA, serve as a pivotal trial in the approval of a drug candidate.

- o Phase III: These are commonly referred to as pivotal studies (however, as noted above in certain circumstances, Phase II trials can serve as pivotal). When Phase II evaluations demonstrate that a dose range of the drug has a therapeutic effect and an acceptable safety profile, Phase III trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically-dispersed clinical trial sites.
- o Phase IV: In some cases, FDA may condition approval of an NDA for a drug candidate on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval. Such post approval trials are typically referred to as Phase IV studies.

New Drug Application. The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. The NDA also must contain extensive manufacturing information. Once the submission has been accepted for filing, by law the FDA has 180 days to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it generally follows them. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data and/or an additional pivotal Phase III clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and FDA may interpret data differently than we or our collaborators interpret the data. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the drug reaches the market. In addition, the FDA may require testing, including Phase IV studies, and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a drug based on the results of these postmarketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require us to develop additional data or conduct additional preclinical studies and clinical trials.

Fast-track Designation. FDA's fast-track program is intended to facilitate the development and to expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition which demonstrate the potential to address unmet medical needs for the condition. Under the fast-track program, the sponsor of a new drug may request the FDA to

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designate the drug for a specific indication as a fast-track drug concurrent with or after the IND is filed for the product candidate. The FDA must determine if the drug qualifies for fast-track designation within 60 days of receipt of the sponsor's request.

If fast-track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the time period specified in the Prescription Drug User Fees Act, which governs the time period goals the FDA has committed to reviewing an application, does not begin until the complete application is submitted. Additionally, the fast-track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In some cases, a fast-track designated drug may also qualify for one or more of the following programs:

- o Priority Review. Under FDA policies, a drug is eligible for priority review, or review within a sixth month time frame from the time a complete NDA is accepted for filing, if the product provides a significant improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease. A fast-track designated drug would ordinarily meet the FDA's criteria for priority review. We cannot guarantee any of our products will receive a priority review designation, or if a priority designation is received, that review or approval will be faster than conventional FDA procedures, or that FDA will ultimately grant product approval.
- o Accelerated Approval. Under the FDA's accelerated approval regulations, the FDA is authorized to approve drugs that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments based upon either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on the basis of an effect on a clinical endpoint other than patient survival. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. A drug approved on this basis is generally subject to rigorous postmarket compliance requirements, including the completion of Phase IV or post-approval studies to validate the surrogate endpoint or to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to validate a surrogate endpoint or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drugs approved under accelerated regulations are subject to prior review by the FDA.

When appropriate, we and our collaborators intend to seek fast-track designation and/or accelerated approval for our drug candidates, including DB289. On April 23, 2004, the FDA designated DB289 for the treatment of African sleeping sickness as a fast-track product. We cannot predict whether any of our other drug candidates or proposed indications will obtain a fast-track and/or accelerated approval designation, or, if obtained, the ultimate impact, if any, of

the fast-track or the accelerated approval process on the timing or likelihood of FDA approval of any of our proposed products.

Satisfaction of FDA regulations and requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the drug or disease. Government regulation may delay or prevent marketing of drug candidates for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for new indications for our drug candidates on a timely basis, if at all. Even if a drug candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a drug may result in restrictions on the drug or even complete withdrawal of the drug from the market. Delays in obtaining, or failures to obtain, regulatory approvals for any of our drug candidates would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Other Regulatory Requirements. Any drugs manufactured or distributed by us or our collaborators pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to legal or regulatory action, such as Warning Letters, suspension of manufacturing, seizure of drug, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If our present or future third party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a drug from distribution, or withdraw approval of the NDA for that drug.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

Exports From the United States. The FDA regulates the export of unapproved drug products for use outside of the United States under the FDCA and its implementing regulations. The level of regulatory scrutiny the FDA applies to exports of unapproved drugs depends on a number of factors, including, among others, the country to which the investigational drug product is exported, whether that country has approved the drug for commercial sale within that jurisdiction, whether the exported drug is intended for use in a clinical trial or is intended to be sold commercially, and, if the drug is to be used in clinical testing, whether the manufacturer has obtained an IND from the FDA to conduct the clinical trial. Depending on the applicability of these factors, a manufacturer may be required to request and obtain authorization from the FDA prior to exporting an unapproved drug. We have requested and obtained several authorizations from FDA to export quantities of DB289 candidate for use in clinical trials abroad.

J. Competition

Competition in the pharmaceutical and biotechnology industries is intense. Factors such as scientific and technological developments, the procurement of patents, timely governmental approval for testing, manufacturing and marketing, availability of funds, the ability to commercialize product candidates in an expedient fashion and the ability to obtain governmental approval for testing, manufacturing and marketing play a significant role in determining our ability to effectively compete. Furthermore, our industry is subject to rapidly evolving technology that could result in the obsolescence of any product candidates prior to profitability.

Our competitors may have substantially greater financial, technical and human resources than we have and may be better equipped to develop, manufacture and market products. Many of our competitors have concentrated their efforts in the development of human therapeutics and developed or acquired internal biotechnology capabilities. We have utilized the Scientific Consortium as our research and development arm. In addition, many of these companies have extensive experience in pre-clinical testing and human clinical trials and in obtaining regulatory approvals. Our competitors may succeed in obtaining approval for products more rapidly than us and in developing and commercializing products that are safer and more effective than those that we propose to develop. Competitors, as well as academic institutions, governmental agencies and private research organizations, also compete with us in acquiring rights to products or technologies from universities, and recruiting and retaining highly qualified scientific personnel and consultants. The timing of market introduction of our potential products or of competitors' products will be an important competitive factor. Accordingly, the relative speed with which we can develop products, complete pre-clinical testing, human clinical trials and regulatory approval processes and supply commercial quantities to market will influence our ability to bring a product to market.

Our competition will be determined in part by the potential indications for which our products are developed and ultimately approved by regulatory authorities. We rely on our collaborations with the Scientific Consortium members and other joint venture partners to enhance our competitive edge by providing manufacturing, testing and

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commercialization support. Currently, DB289 is in clinical trials to treat African sleeping sickness, PCP, and malaria. Other drugs moving forward in our pipeline address markets for new drugs for use in

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treating fungal, TB, and diabetic diseases. The following table lists major competitors and their drugs by disease:

Malaria	PCP	African sleeping sickness	Antifungals
o Quinine (Watson Pharma.)	o Bactrim (Hoffman LaRoche)	o Pentamidine (Aventis)	o Fluconazole (Pfizer)
o Chloroquine (Sanofi-Synthelabo Inc.)	o Pentamidine (Aventis)	o Melarsoprol (Aventis)	o Itraconazole o Ketoconazole o Miconazole (Johnson & Johnson)
o Mefloquine (Hoffman LaRoche)		o Eflornithine (Aventis)	o Terbinafine (Novartis)
o Amodiaquine (Pfizer)		o Suramin (Bayer)	o Caspofungin (Merck)
			o Amphotericin B lipid complex (Fujisawa)

We are developing products to treat infectious diseases and metabolic disorders. Our drug development program closest to commercialization, a treatment for African sleeping sickness, has been funded in large part by a grant to a scientific consortium lead by UNC from The Gates Foundation. The Gates Foundation has chosen to support the African sleeping sickness program because there currently exists no effective treatment for the disease. We believe The Gates Foundation has financed this project because the likelihood that a major pharmaceutical company would develop a treatment for the disease is small because treatments for diseases that affect economically-challenged populations, without charitable assistance, are less profitable than treatments for diseases that affect more developed nations. Our efforts to develop aromatic dicationic prodrugs for treatment of African sleeping sickness contributes greatly to validating and advancing our technology platform and establishing pharmacological safety and dosage criteria for future compounds aimed at more

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mainstream markets.

We have listed in the table above, where applicable, current treatments and the names of the manufacturers of those products used to treat disease for which we are developing product candidates, however, each of the products listed has limitations in terms of effectiveness to treat the disease, toxicity, severity of side-effects, and/or difficulty of delivery (for example,

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pentamidine must be administered either intravenously or by inhalation. We therefore believe that competition for our product candidates for certain indications has yet to be developed or approved.

### EMPLOYEES

We currently have 13 employees, five of whom hold advanced degrees. Six work in support of clinical trials, research and development and regulatory compliance and the other seven work in general and administrative capacities which includes business development, investor relations, finance, legal and administration. Through our agreement with the Scientific Consortium, approximately 55 scientists are engaged in the research and development of the indications. We expect to add new employees in our regulatory and clinical development departments as our programs advance.

### RISK FACTORS

There is no assurance that we will successfully develop a commercially viable product; our most advanced product candidate is in Phase II human clinical trials.

We are at an early stage of human clinical trials, and in some cases pre-clinical, development activities required for drug approval and commercialization. Since our formation in October 1984, we have engaged in research and development programs, expanding our network of scientists and scientific advisors, licensing technology agreements and advancing the commercialization of the dication technology platform. We have generated no revenue from product sales, do not have any products currently available for sale, and none are expected to be commercially available for sale until after March 31, 2005, if at all. There can be no assurance that the research we fund and manage will lead to commercially viable products. Our most advanced programs are in the Phase II human clinical testing stage using our first compound DB289 for several indications including trypanosomiasis (African sleeping sickness), PCP pneumonia, and malaria and must undergo substantial additional regulatory review prior to commercialization.

We have a history of losses and an accumulated deficit; our future profitability is uncertain.

We have experienced significant operating losses since our inception and we expect to incur additional operating losses as we continue research and development, clinical trial and commercialization efforts. As of March 31, 2004, we had an accumulated deficit of approximately \$58,539,000. Losses from operations were approximately \$4,693,000 and \$12,866,000, for the fiscal years ended March 31, 2003 and March 31, 2004, respectively.

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We will need substantial additional funds in future years to continue our research and development; if financing is not available, we may be required to reduce spending for our research programs, cease operations or pursue other financing alternatives.

Our operations to date have consumed substantial amounts of cash. Negative cash flow from operations is expected to continue in the foreseeable future. Without substantial additional financing, we may be required to reduce some or all of our research programs or cease

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operations. Our cash requirements may vary materially from those now planned because of results of research and development, results of pre-clinical and clinical testing, responses to our grant requests, relationships with strategic partners, changes in the focus and direction of our research and development programs, delays in the enrollment and completion of our clinical trials, competitive and technological advances, the FDA and foreign regulatory approval processes and other factors. In any of these circumstances, we may require substantially more funds than we currently have available or currently intend to raise to continue our business. We may seek to satisfy future funding requirements through public or private offerings of equity securities, by collaborative or other arrangements with pharmaceutical or biotechnology companies, issuance of debt or from other sources. Additional financing may not be available when needed or may not be available on acceptable terms. If adequate financing is not available, we may not be able to continue as a going concern or may be required to delay, scale back or eliminate certain research and development programs, relinquish rights to certain technologies or product candidates, forego desired opportunities or license third parties to commercialize our products or technologies that we would otherwise seek to develop internally. To the extent we raise additional capital by issuing equity securities, ownership dilution to existing stockholders will result.

We receive funding primarily from technology licensing, grants, research and development programs and from sales of our equity securities. To date we have directed most of such funds not used for general and administrative overhead toward our research and development and commercialization programs (including preparation of submissions to regulatory agencies for product licensing). Until one or more of our product candidates is approved for sale, our funding is limited to funds received from testing and research agreements, licensing of our technology and potential fees associated with interim leasing of our properties while we develop them for product manufacture.

We do not have employment contracts with any employees other than our CEO, T. Stephen Thompson.

We have an employment agreement with our CEO, T. Stephen Thompson that renews annually in April of each year unless 30 day prior notice of non-renewal is given by either party to the other. Mr. Thompson renewed his employment with us this year and has not expressed any indication that he desires to leave our employ or retire. All of our other employees are "at will" and may leave at any time, however, none have as of this date, expressed any intention to do so. We do not have "key-man" life insurance policies on any of our executives, including Mr. Thompson.

Most of our business' financial aspects, including investor relations, intellectual property control and corporate governance, are under the direct supervision of Cecilia Chan and Gary Parks. Together with Mr. Thompson, Ms. Chan and Mr. Parks hold institutional knowledge and business savvy that they

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utilize to assist us to forge new relationships and exploit new business opportunities without diminishing or undermining existing programs and obligations. Neither Ms. Chan nor Mr. Parks have employment contracts with us, however, neither has indicated any intention to retire or leave our employ.

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Some of our proprietary intellectual property is developed by scientists that are not employed by us.

Our business depends to a significant degree on the continuing contributions of our key management, scientific and technical personnel, as well as on the continued discoveries of scientists, researchers and specialists at The University of North Carolina at Chapel Hill, Georgia State, Duke University and Auburn University (collectively, the "Scientific Consortium") and other research groups that assist in the development of our product candidates. Substantial amounts of our proprietary intellectual property is developed by scientists who are employed by the universities that comprise the Scientific Consortium and other research groups. We do not have control over, knowledge of, or access to those employment arrangements. We have not been advised by any of the key members of our company, the scientific research groups or of the Scientific Consortium of their intention to leave their employ or the program.

There can be no assurance that the loss of certain members of management or the scientists, researchers and technicians from the Scientific Consortium universities would not materially adversely affect our business.

Additional research grants needed to fund our operations may not be available or, if available, not on terms acceptable to us.

We have funded our product development and operations as of March 31, 2004 through a combination of sales of equity instruments and revenue generated from research agreements and grants. As of March 31, 2004, our accumulated deficit was approximately \$58,539,000 of which approximately \$11,259,000 was funded either directly or indirectly with grant funds and payments from research and testing agreements.

In March 2001 we entered into a clinical research subcontract with UNC, funded by a \$15.1 million grant from The Gates Foundation to UNC for the study of African sleeping sickness and leishmaniasis, under which UNC is to pay to us \$9.8 million in installments over a period not to exceed five years subject to our achieving certain milestones. We entered into a second subcontract with UNC under which we are to receive over \$2.4 million based on a separate \$2.7 million grant from the Gates Foundation to UNC to accelerate the African sleeping sickness study.

In November 2003, we entered into a Testing Agreement with Medicines For Malaria Venture, a foundation established in Switzerland ("MMV") and UNC, pursuant to which we, with the support of MMV and UNC, are conducting a proof of concept study of DB289, including Phase II and Phase III human clinical trials, and will pursue drug development activities of DB289 alone, or in combination with other anti-malarial drugs, with the goal of obtaining marketing approval of a product for the treatment of malaria. Under the terms of the agreement, MMV has advanced to us \$668,000 for human clinical trials and has committed to fund additional budgeted amounts, subject to attainment of certain milestones, for additional clinical trials and regulatory preparation and filing costs for the approval to market DB289 for treatment of malaria by at least one internationally accepted regulatory body and one malaria endemic country. We forecast such costs to be approximately \$8.2 million over the next three years.

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We will continue to apply for new grants to support continuing research and development of our dication platform technology and other product candidates. The process of obtaining grants is extremely competitive and there can be no assurance that any of our grant applications will be acted upon favorably. Some charitable organizations may request licenses to our proprietary information or may impose price restrictions on the products we develop with grant funds. We may not be able to negotiate terms that are acceptable to us with such organizations. In the event we are unable to raise sufficient funds to advance our product developments with grant funds we may seek to raise additional capital with the issuance of debt or equity securities. There can be no assurance that we will be able to place or sell debt or equity securities on terms acceptable to us and, if we sell equity, existing stockholders will suffer dilution (see Risk Factors, this section, entitled "Shares eligible for future sale may adversely affect our ability to sell equity securities," and "Our outstanding options and warrants may adversely affect our ability to consummate future equity financings due to the dilution potential to future investors").

None of our product candidates have been approved for sale by any regulatory agency; approval is required before we can sell drug products commercially.

All of our product candidates, including DB289 and DB075, require additional clinical testing, regulatory approval and development of marketing and distribution channels, all of which are expected to require substantial additional investment prior to commercialization. There can be no assurance that any of our product candidates will be successfully developed, prove to be safe and effective in human clinical trials, meet applicable regulatory standards, be approved by regulatory authorities, be capable of being produced in commercial quantities at acceptable costs, be eligible for third party reimbursement from governmental or private insurers, be successfully marketed or achieve market acceptance. If we are unable to commercialize our product candidates in a timely manner we may be required to seek additional funding, reduce or cancel some or all of our development programs, sell or license some of our proprietary information or cease operations.

There are substantial uncertainties related to clinical trials that may result in the extension, modification or termination of one or more of our programs.

In order to obtain required regulatory approvals for the commercial sale of our product candidates, we must demonstrate through human clinical trials that our product candidates are safe and effective for their intended uses. Prior to conducting human clinical trials we must obtain governmental approvals from the host nation, approval from the U.S. to export our product candidate to the test site and qualify a sufficient number of volunteer patients that meet our trial criteria. If we do not obtain required governmental consents or if we do not enroll a sufficient number of patients in a timely manner or at all, our trial expenses could increase, results may be delayed or the trial may be cancelled.

We may find, at any stage of our research and development, that product candidates that appeared promising in earlier clinical trials do not demonstrate safety or effectiveness in later clinical trials and therefore do not receive regulatory approvals. Despite the positive results of our pre-clinical testing and human clinical trials those results may not be predictive of the results of later clinical trials and large-scale testing.

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Companies in the

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pharmaceutical and biotechnology industries have suffered significant setbacks in various stages of clinical trials, even after promising results had been obtained in early-stage human clinical trials.

Completion of human clinical trials may be delayed by many factors, including slower than anticipated patient enrollment, participant retention and follow up, difficulty in securing sufficient supplies of clinical trial materials or other adverse events occurring during clinical trials. For instance, once we obtain permission to run a human trial, there are strict criteria regulating who we can test. In the case of African sleeping sickness, we are subject to civil unrest in sub-Saharan Africa where local rebels could close clinics and dramatically reduce enrollment rates, and make it difficult to conduct trials. Political instability and the minimal infrastructure in the African countries where we conduct our trials may cause delays in enrollment and difficulty in the completion of trials. In another case, our PCP-trial could encounter difficulties in finding potential patients because our initial regimen requires patients to first fail other treatment programs in order to be eligible for our treatment.

Completion of testing, studies and trials may take several years, and the length of time varies substantially with the type, complexity, novelty and intended use of the product. Delays or rejections may be based upon many factors, including changes in regulatory policy during the period of product development. No assurance can be given that any of our development programs will be successfully completed, that any Investigational New Drug ("IND") application filed with the FDA (or any foreign equivalent filed with the appropriate foreign authorities) will become effective, that additional clinical trials will be allowed by the FDA or other regulatory authorities, or that clinical trials will commence as planned. There have been delays in our testing and development schedules due to the aforementioned conditions and funding and patient enrollment difficulties and there can be no assurance that our future testing and development schedules will be met.

We do not currently have pharmaceutical manufacturing capability, which could impair our ability to develop commercially viable products at reasonable costs.

Our ability to commercialize product candidates will depend in part upon our ability to have manufactured or develop manufacturing capability to manufacture our product candidates, either directly or through third parties, at a competitive cost and in accordance with FDA and other regulatory requirements. We currently lack facilities and personnel to manufacture our product candidates. There can be no assurance that we will be able to acquire such resources, either directly or through third parties, at reasonable costs, if we develop commercially viable products.

We have acquired a facility in which we intend to commence construction of a pharmaceutical manufacturing plant in the PRC with our subsidiary Immtech Hong Kong Limited. Operation of such a facility is subject to various governmental approvals, which may be difficult or impossible to obtain. There can be no guarantee that products manufactured at this facility will be accepted in all countries where we desire to sell our future products.

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We are dependent on third-party relationships for critical aspects of our business; problems that develop in these relationships may increase costs and/or diminish our ability to develop our product candidates.

We use the expertise and resources of strategic partners and third parties in a number of key areas, including (i) research and development, (ii) pre-clinical and human clinical trials and (iii) manufacture of pharmaceutical drugs. We have licensing and exclusive commercialization rights to a dicationic pharmaceutical platform and are developing drugs intended for commercial use based on that platform. This strategy creates risks by placing critical aspects of our business in the hands of third parties, whom we may not be able to control. If these third parties do not perform in a timely and satisfactory manner, we may incur costs and delays as we seek alternate sources of such products and services, if available. Such costs and delays may have a material adverse effect on our business if the delays jeopardize our licensing arrangements by causing us to become non-compliant with certain license agreements.

We may seek additional third-party relationships in certain areas, particularly in clinical testing, marketing, manufacturing and other areas where pharmaceutical and biotechnology company collaborators will enable us to develop particular products or geographic markets that are otherwise beyond our current resources and/or capabilities. There is no assurance that we will be able to obtain any such collaboration or any other research and development, manufacturing or clinical trial arrangements. Our inability to obtain and maintain satisfactory relationships with third parties may have a material adverse effect on our business by slowing our ability to develop new products, requiring us to expand our internal capabilities, increasing our overhead and expenses, hampering future growth opportunities or causing us to delay or terminate affected programs.

We are uncertain about the ability to protect or obtain necessary patents and protect our proprietary information; our ability to develop and commercialize our product candidates would be compromised without adequate intellectual property protection.

We have spent and continue to spend considerable funds to develop our product candidates and we are relying on the potential to exploit commercially without competition the results of our product development. Much of our intellectual property is licensed to us under various agreements including the Consortium Agreement. It is the primary responsibility of the discoverer to develop his, her or its invention confidentially, insure that the invention is unique, and to obtain patent protection. In most cases, our role is to reimburse patent related costs after we decide to develop any such invention. We therefore rely on the inventors to insure that technology licensed to us is adequately protected. Without adequate protection for our intellectual property we believe our ability to realize profits on our future commercialized product would be diminished. Without protection, competitors might be able to copy our work and compete with our products without having invested in the development.

There can be no assurance that any particular patent will be granted or that issued patents will provide us, directly or through licenses, with the intellectual property protection contemplated. Patents and licenses of patents can be challenged, invalidated or circumvented. It is also possible that competitors will develop similar products simultaneously. Our breach of any license agreement or the failure to obtain a license to any technology or process which may

be required to develop or commercialize one or more of our product candidates may have a material adverse effect on our business including the need for additional capital to develop alternate technology, the potential that competitors may gain unfair advantage and lessen our expectation of potential future revenues.

The pharmaceutical and biotechnology fields are characterized by a large number of patent filings, and a substantial number of patents have already been issued to other pharmaceutical and biotechnology companies. Third parties may have filed applications for, or may have been issued, certain patents and may obtain additional patents and proprietary rights related to products or processes competitive with or similar to those that we are attempting to develop and commercialize. We may not be aware of all of the patents potentially adverse to our interests that may have been issued to others. No assurance can be given that patents do not exist, have not been filed or could not be filed or issued, which contain claims relating to or competitive with our technology, product candidates, product uses or processes. If patents have been or are issued to others containing preclusive or conflicting claims, then we may be required to obtain licenses to one or more of such patents or to develop or obtain alternative technology. There can be no assurance that the licenses or alternative technology that might be required for such alternative processes or products would be available on commercially acceptable terms, or at all.

Because of the substantial length of time and expense associated with bringing new drug products to market through the development and regulatory approval process, the pharmaceutical and biotechnology industries place considerable importance on patent and trade secret protection for new technologies, products and processes. Since patent applications in the United States are confidential until patents are issued and since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we cannot be certain that we (or our licensors) were the first to make the inventions covered by pending patent applications or that we (or our licensors) were the first to file patent applications for such inventions. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions and, therefore, the breadth of claims allowed in pharmaceutical and biotechnology patents, or their enforceability, cannot be predicted. There can be no assurance that any patents under pending patent applications or any further patent applications will be issued. Furthermore, there can be no assurance that the scope of any patent protection will exclude competitors or provide us competitive advantages, that any of our (or our licensors') patents that have been issued or may be issued will be held valid if subsequently challenged, or that others, including competitors or current or former employers of our employees, advisors and consultants, will not claim rights in, or ownership to, our (or our licensors') patents and other proprietary rights. There can be no assurance that others will not independently develop substantially equivalent proprietary information or otherwise obtain access to our proprietary information, or that others may not be issued patents that may require us to obtain a license for, and pay significant fees or royalties for, such proprietary information.

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We rely on technology developed by others and shared with collaborators to develop our product candidates which puts our proprietary information at risk of unauthorized disclosure.

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We rely on trade secrets, know-how and technological advancement to maintain our competitive position. Although we use confidentiality agreements and employee proprietary information and invention assignment agreements to protect our trade secrets and other unpatented know-how, these agreements may be breached by the other party thereto or may otherwise be of limited effectiveness or enforceability.

We are licensed to commercialize technology from a dication platform developed by a Scientific Consortium, comprised primarily of scientists employed by universities in an academic setting. The academic world is improved by the sharing of information. As a business, however, the sharing of information whether through publication of research, academic lectures or general intellectual discourse among contemporaries is not conducive to protection of proprietary information. Our proprietary information may fall into the possession of unintended parties without our knowledge through customary academic information sharing.

At times we may enter into confidentiality agreements with other companies, allowing them to test our technology for potential future licensing, in return for milestone and royalty payments should any discoveries result from the use of our proprietary information. We cannot be assured that such parties will honor these confidentiality agreements subjecting our intellectual property to unintended disclosure.

The pharmaceutical and biotechnology industries have experienced extensive litigation regarding patent and other intellectual property rights. We could incur substantial costs in defending suits that may be brought against us (or our licensors) claiming infringement of the rights of others or in asserting our (or our licensors') patent rights in a suit against another party. We may also be required to participate in interference proceedings declared by the U.S. Patent and Trademark Office or similar foreign agency for the purpose of determining the priority of inventions in connection with our (or our licensors') patent applications.

Adverse determinations in litigation or interference proceedings could require us to seek licenses (which may not be available on commercially reasonable terms) or subject us to significant liabilities to third parties, and could therefore have a material adverse effect on our business by increasing our expenses and having an adverse effect on our business. Even if we prevail in an interference proceeding or a lawsuit, substantial resources, including the time and attention of our officers, would be required.

Confidentiality agreements may not adequately protect our intellectual property which could result in unauthorized disclosure or use of our proprietary information.

We require our employees, consultants and third-parties with whom we share proprietary information to execute confidentiality agreements upon the commencement of their relationship with us. The agreements generally provide that trade secrets and all inventions conceived by the individual and all confidential information developed or made known to the individual during the term of the relationship will be our exclusive property and will be kept

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confidential and not disclosed to third parties except in specified circumstances. There can be no assurance, however, that these agreements will provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure of such information. If our unpatented

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proprietary information is publicly disclosed before we have been granted patent protection, our competitors could be unjustly enriched and we could lose the ability to profitably develop products from such information.

Our industry has significant competition; our product candidates may become obsolete prior to commercialization due to alternative technologies thereby rendering our development efforts obsolete or non-competitive.

The pharmaceutical and biotechnology fields are characterized by extensive research efforts and rapid technological progress. Competition from other pharmaceutical and biotechnology companies and research and academic institutions is intense and other companies are engaged in research and product development for treatment of the same diseases that we target. New developments in pharmaceutical and biotechnology fields are expected to continue at a rapid pace in both industry and academia. There can be no assurance that research and discoveries by others will not render some or all of our programs or products non-competitive or obsolete.

We are aware of other companies and institutions dedicated to the development of therapeutics similar to those we are developing, including Aventis Pharmaceuticals, Inc., Hoffman-LaRoche Ltd., Sanofi-Synthelabo Inc., Pfizer Inc., and Bayer Corporation. Many of our existing or potential competitors have substantially greater financial and technical resources than we do and therefore may be in a better position to develop, manufacture and market pharmaceutical products. Many of these competitors are also more experienced performing pre-clinical testing and human clinical trials and obtaining regulatory approvals. The current or future existence of competitive products may also adversely affect the marketability of our product candidates.

In the event some or all of our programs are rendered non-competitive or obsolete, we do not currently have alternative strategies to develop new product lines or financial resources to pursue such a course of action.

There is no assurance that we will receive FDA or corollary foreign approval for any of our product candidates for any indication; we are subject to government regulation for the commercialization of our product candidates.

We have not made application to the FDA or any other regulatory agency to sell commercially or label any of our product candidates. We or our test collaborators have received licenses from the FDA to export DB289 for testing purposes and have been approved to conduct human clinical trials for various indications in each of the Democratic Republic of Congo, Angola, Thailand and Peru.

All new pharmaceutical drugs, including our product candidates, are subject to extensive and rigorous regulation by the federal government, principally the FDA under the Federal Food, Drug and Cosmetic Act ("FDCA") and other laws and by state, local and foreign

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governments. Such regulations govern, among other things, the development, testing, manufacture, labeling, storage, pre-market clearance or approval, advertising, promotion, sale and distribution of pharmaceutical drugs. If drug products are marketed abroad, they are subject to extensive regulation by foreign governments. Failure to comply with applicable regulatory requirements may subject us to administrative or judicially imposed sanctions such as civil penalties, criminal prosecution, injunctions, product seizure or detention,

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product recalls, total or partial suspension of production and FDA refusal to approve pending applications.

Each of our product candidates must be approved for each indication for which we believe it to be viable. We have not yet determined from which regulatory bodies we will seek approval for our product candidates or indications for which approval will be sought. Once determined, the approval process is subject to those agencies' policies and acceptance of those agencies' approvals, if obtained, in the countries where we intend to market our product candidates.

We have not received regulatory approval in the United States or any foreign jurisdiction for the commercial sale of any of our product candidates.

On April 23, 2004 the FDA granted fast-track designation for DB289, our first oral drug, for treatment of African sleeping sickness (trypanosomiasis). Fast-track designation means, among other things, that the FDA may accept initial late-stage data from us rather than waiting for the entire Phase III clinical trial data to be submitted together for consideration of approval to market the drug, however, there is no guarantee that fast-track designation will result in faster product development or licensing approval or that our product candidates will be approved at all.

The process of obtaining FDA or other required regulatory approvals, including foreign approvals, often takes many years and varies substantially based upon the type, complexity and novelty of the products involved and the indications being studied. Furthermore, the approval process is extremely expensive and uncertain. There can be no assurance that our product candidates will be approved for commercial sale in the United States by the FDA or regulatory agencies in foreign countries. The regulatory review process can take many years and we will need to raise additional funds to complete the regulatory review process for our current product candidates. The failure to receive FDA or other governmental approval would have a material adverse effect on our business by precluding us from marketing and selling such products and negatively impacting our ability to generate future revenues. Even if regulatory approval of a product is granted, there can be no assurance that we will be able to obtain the labeling claims (a labeling claim is a product's description and its FDA permitted uses) necessary or desirable for the promotion of such product. FDA regulations prohibit the marketing or promotion of a drug for unapproved indications. Furthermore, regulatory marketing approval may entail ongoing requirements for post-marketing studies if regulatory approval is obtained; we will also be subject to ongoing FDA obligations and continued regulatory review. In particular, we, or our third party manufacturers, will be required to adhere to Good Manufacturing Practices ("GMP"), which require us (or our third party manufacturers) to manufacture products and maintain records in a prescribed manner with respect to manufacturing, testing and quality control. Further, we (or our third party manufacturers) must pass a manufacturing facilities pre-approval inspection by the FDA or corollary agency before

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obtaining marketing approval. Failure to comply with applicable regulatory requirements may result in penalties, such as restrictions on a product's marketing or withdrawal of the product from the market. In addition, identification of certain side-effects after a drug is on the market or the occurrence of manufacturing problems could cause subsequent withdrawal of approval, reformulation of the drug, additional pre-clinical testing or clinical

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trials and changes in labeling of the product.

Prior to the submission of an application for FDA approval, our pharmaceutical drugs undergo rigorous pre-clinical and clinical testing, which may take several years and the expenditure of substantial financial and other resources. Before commencing clinical trials in humans in the United States, we must submit to the FDA and receive clearance of an IND. There can be no assurance that submission of an IND for future clinical testing of any of our product candidates under development or other future product candidates would result in FDA permission to commence clinical trials or that we will be able to obtain the necessary approvals for future clinical testing in any foreign jurisdiction. Further, there can be no assurance that if such testing of product candidates under development is completed, any such drug compounds will be accepted for formal review by the FDA or any foreign regulatory body or approved by the FDA for marketing in the United States or by any such foreign regulatory bodies for marketing in foreign jurisdictions.

Our most advanced programs are developing products intended for sale in countries that may not have established pharmaceutical regulatory agencies.

Some of the intended markets for our treatment of African sleeping sickness and malaria are in countries without developed pharmaceutical regulatory agencies. We plan in such cases to try first to obtain regulatory approval from a recognized pharmaceutical regulatory agency such as the FDA or one or more European agencies and then to apply to the targeted country for recognition of the foreign approval. Because the countries where we intend to market treatments for African sleeping sickness and malaria are not obligated to accept foreign regulatory approvals and because those countries do not have standards of their own for us to rely upon, we may be required to provide additional documentation or complete additional testing prior to distributing our products in those countries.

There is uncertainty regarding the availability of health care reimbursement for purchasers of our anticipated products; health care reform may negatively impact the ability of prospective purchasers of our anticipated products to pay for such products.

Our ability to commercialize any of our product candidates will depend in part on the extent to which reimbursement for the costs of the resulting drug or biologic will be available from government health administration authorities, private health insurers, charities and others. Many of our product candidates, including treatments for trypanosomiasis, malaria and tuberculosis, would be in the greatest demand in developing nations, many of which do not maintain comprehensive health care systems with the financial resources to pay for such drugs. We do not know to what extent governments, private charities, international organizations and others would contribute toward bringing newly developed drugs to developing nations. Even among drugs sold in developed countries, significant uncertainty exists as to the reimbursement status of newly approved health care products. There can be no assurance of the availability of

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third-party insurance reimbursement coverage enabling us to establish and maintain price levels sufficient for realization of a profit on our investment in developing pharmaceutical drugs and biologics. Government and other

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third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drug or biologic products approved for marketing by the FDA and by refusing, in some cases, to provide any coverage for uses of approved products for disease indications for which the FDA has not granted marketing approval. If adequate coverage and reimbursement levels are not provided by government and third-party payers for uses of our anticipated products, the market acceptance of these products would be adversely affected.

Health care reform proposals are continually introduced in the United States Congress and in various state legislatures and there is no guarantee that such proposals will not be introduced in the future. We cannot predict when any proposed reforms will be implemented, if ever, or the effect of any implemented reforms on our business. Implemented reforms may have a material adverse effect on our business by reducing or eliminating the availability of third-party reimbursement for our anticipated products or by limiting price levels at which we are able to sell such products. If reimbursement is not available for our products, health care providers may prescribe alternative remedies if available. Patients, if they cannot afford our products, may do without. In addition, if we are able to commercialize products in overseas markets, then our ability to achieve success in such markets may depend, in part, on the health care financing and reimbursement policies of such countries. We cannot predict changes in health care systems in foreign countries, and therefore, do not know the effects on our business of possible changes.

Shares eligible for future sale may adversely affect our ability to sell equity securities.

Sales of our common stock (including the issuance of shares upon conversion of preferred stock) in the public market could materially and adversely affect the market price of shares because prior sales have been executed at or below our current market price. We have outstanding four series of preferred stock that convert to common stock at prices equivalent to \$4.42, \$4.00, \$4.42 and \$9.00, respectively, for our series A, series B, series C and series D convertible preferred stock. Our obligation to convert the preferred stock upon demand by the holders may depress the price of our common stock and also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that we deem appropriate.

As of June 4, 2004, we had 9,905,324 shares of common stock outstanding, plus (1) 80,400 shares of series A convertible preferred stock, convertible into approximately 454,750 shares of common stock at the conversion rate of 1:5.656, (2) 19,925 shares of series B Convertible Preferred stock convertible into approximately 124,531 shares of common stock at the conversion rate of 1:6.25, (3) 67,252 shares of series C convertible preferred stock convertible into approximately 380,384 shares of common stock at the conversion rate of 1:5.656, (4) 200,000 shares of series D convertible preferred stock convertible into approximately 555,540 shares of common stock at the conversion rate of 1:2.778, (5) 964,057 options to purchase shares of common stock with a weighted-average exercise price of \$8.91 per share and (6) 2,885,312 warrants to purchase shares of common stock with a weighted-average exercise price of \$7.42. Of the shares outstanding, 7,297,511 shares of common stock are freely

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tradable without restriction. All of the remaining 2,607,813 shares are restricted from resale, except pursuant to certain exceptions under the Securities Act of 1933, as amended (the "Securities Act").

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Our outstanding options and warrants may adversely affect our ability to consummate future equity financings due to the dilution potential to future investors.

We have outstanding options and warrants for the purchase of shares of our common stock with exercise prices currently below market which may adversely affect our ability to consummate future equity financings. The holders of such warrants and options may exercise them at a time when we would otherwise be able to obtain additional equity capital on more favorable terms. To the extent any such options and warrants are exercised, the value of our outstanding shares of our common stock will be diluted.

As of June 4, 2004, we have outstanding vested options to purchase 654,508 shares of common stock at a weighted-average exercise price of \$7.24 and vested warrants to purchase 2,875,312 shares of common stock with a weighted-average price of \$7.44.

Due to the number of shares of common stock we are obligated to sell pursuant to outstanding options and warrants described above, potential investors may not purchase our future equity offerings at market price because of the potential dilution such investors may suffer as a result of the exercise of the outstanding options and warrants.

The market price of our common stock has experienced significant volatility.

The securities markets from time to time experience significant price and volume fluctuations unrelated to the operating performance of particular companies. In addition, the market prices of the common stock of many publicly traded pharmaceutical and biotechnology companies have been and can be expected to be especially volatile. Our common stock price in the 52-week period ended June 10, 2004 had a low of \$5.35 and high of \$32.51. Announcements of technological innovations or new products by us or our competitors, developments or disputes concerning patents or proprietary rights, publicity regarding actual or potential clinical trial results relating to products under development by us or our competitors, regulatory developments in both the United States and foreign countries, delays in our testing and development schedules, public concern as to the safety of pharmaceutical drugs and economic and other external factors, as well as period-to-period fluctuations in our financial results, may have a significant impact on the market price of our common stock. The realization of any of the risks described in these "Risk Factors" may have a significant adverse impact on such market prices.

We routinely pay vendors in stock as consideration for their services; this may result in shareholder dilution, additional costs and difficulty retaining certain vendors.

In order for us to preserve our cash resources, we often pay vendors in shares, warrants or options to purchase shares of our common stock rather than cash. Payments for services in stock may materially and adversely affect our shareholders by diluting the value of outstanding shares of our common stock. In addition, in situations where we have agreed to register the shares issued to a vendor, this will generally cause us to incur additional expenses

associated with such registration. Paying vendors in shares, warrants or options to purchase shares of common stock may also limit our ability to contract with

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the vendor of our choice should that vendor decline payment in stock.

We do not intend to pay dividends on our common stock. Until such time as we pay cash dividends our stockholders must rely on increases in our stock price for appreciation.

We have never declared or paid dividends on our common stock. We intend to retain future earnings to develop and commercialize our products and therefor we do not intend to pay cash dividends in the foreseeable future. Until such time as we determine to pay cash dividends on our common stock, our stockholders must rely on increases in our common stock's market price for appreciation.

If we do not effectively manage our growth, our resources, systems and controls may be strained and our operating results may suffer.

We have recently added to our workforce and we plan to continue to increase the size of our workforce and scope of our operations as we continue our drug development programs and clinical trials, develop our manufacturing facility in the PRC, and move towards commercialization of our products. This growth of our operations will place a significant strain on our management personnel, systems and resources. We may need to implement new and upgraded operational and financial systems, procedures and controls, including the improvement of our accounting and other internal management systems. These endeavors will require substantial management effort and skill, and we may require additional personnel and internal processes to manage these efforts. If we are unable to effectively manage our expanding operations, our revenue and operating results could be materially and adversely affected.

Our continuing obligations as a public company under the changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002 and related regulations, will increase our expenses and administrative burden.

As a public company, we incur significant legal, accounting and other expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002 and related regulations implemented by the Securities and Exchange Commission and the National Association of Securities Dealers, are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

There are limitations on the liability of our directors, and we may have to indemnify our officers and directors in certain instances.

Our certificate of incorporation limits, to the maximum extent permitted under Delaware law, the personal liability of our directors for monetary damages for breach of their fiduciary duties as directors. Our bylaws provide that we will indemnify our officers and directors and may indemnify our

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employees and other agents to the fullest extent permitted by law. We have entered into indemnification agreements with our officers and directors containing provisions that are in some respects broader than the specific indemnification provisions under Delaware law. The indemnification agreements may require us, among other things, to indemnify such officers and directors against certain liabilities that may arise by reason of their status or service as directors or officers (other than liabilities arising from willful misconduct of a culpable nature), to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified and to obtain directors' and officers' insurance. Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify a director, officer, employee or agent made or threatened to be made a party to an action by reason of the fact that he or she was a director, officer, employee or agent of the corporation or was serving at the request of the corporation, against expenses actually and reasonably incurred in connection with such action if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. Delaware law does not permit a corporation to eliminate a director's duty of care and the provisions of our certificate of incorporation have no effect on the availability of equitable remedies, such as injunction or rescission, for a director's breach of the duty of care.

We believe that our limitation of director liability assists us to attract and retain qualified directors. However, in the event a director or the board commits an act that may legally be indemnified under Delaware law, we will be responsible to pay for such director(s) legal defense and potentially any damages resulting therefrom. Furthermore, the limitation on director liability may reduce the likelihood of derivative litigation against directors, and may discourage or deter stockholders from instituting litigation against directors for breach of their fiduciary duties, even though such an action, if successful, might benefit us and our stockholders. Given the difficult environment and potential for incurring liabilities currently facing directors of publicly-held corporations, we believe that director indemnification is in our and our

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stockholders best interests because it enhances our ability to retain highly qualified directors and reduce a possible deterrent to entrepreneurial decision-making.

Nevertheless, limitations of director liability may be viewed as limiting the rights of stockholders, and the broad scope of the indemnification provisions contained in our certificate of incorporation and bylaws could result in increased expenses. Our board of directors believes, however, that these provisions will provide a better balancing of the legal obligations of, and protections for, directors and will contribute positively to the quality and stability of our corporate governance. Our board of directors has concluded that the benefit to stockholders of improved corporate governance outweighs any possible adverse effects on stockholders of reducing the exposure of directors to liability and broadened indemnification rights.

Product liability exposure may expose us to significant liability.

We do not have pharmaceutical products for sale and we therefor do not carry product liability insurance. However, if we do commercialize drug products we will face risk of exposure to product liability and other claims and lawsuits in the event that the development or use of our technology or prospective products is alleged to have resulted in adverse effects. We may not

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be able to avoid significant liability exposure. We may not have sufficient insurance coverage and we may not be able to obtain sufficient coverage at a reasonable cost. An inability to obtain product liability insurance at acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of our products. A product liability claim could hurt our financial performance. Even if we avoid liability exposure, significant costs could be incurred, potentially damaging our financial performance. We do carry commercial general liability insurance and clinical trials insurance which covers our human clinical trial activities.

### ITEM 2. PROPERTIES

Our administrative offices and research laboratories are located at 150 Fairway Drive, Suite 150, Vernon Hills, Illinois 60061. We occupy approximately 9,750 square feet of space under a lease that expires on March 14, 2005. We are in the process of negotiating an extension on the current lease. Our rent for the Vernon Hills facility is \$12,800 per month through March 2005. We are also charged by the landlord a portion of the real estate taxes and common area operating expenses. Our New York offices are located at One North End Avenue, New York, New York 10282. We pay rent of approximately \$10,100 per month, on a month-to-month basis, for approximately 2,500 square feet of space for our New York office. (See Item 13. "Certain Relationships and Related Transactions.") We believe our current facilities are adequate for our needs for the foreseeable future and, in the opinion of our management, the facilities are adequately insured.

Our indirectly wholly-owned subsidiary, Immtech Life Science, owns two floors of a newly-constructed building located in the Futian Free Trade Zone, Shenzhen, in the PRC in which we intend to construct a pharmaceutical production facility for manufacture of our products. The property comprises the first two floors of an industrial building named the

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Immtech Life Science Building. The duration of the land use right associated with the building on which the property is located is 50 years which expires May 24, 2051.

### ITEM 3. LEGAL PROCEEDINGS

We are parties to the following legal proceedings:

Dale M. Geiss v. Immtech International, Inc. and Criticare Systems, Inc.  
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On January 14, 2002 plaintiff filed a complaint in the Circuit Court of the Nineteenth Judicial Circuit, Lake County, State of Illinois, against the Company and Criticare Systems, Inc. ("Criticare"). The Company filed two motions to dismiss, both of which were successful. Thereafter, the plaintiff amended his complaint for a third time. After engaging in preliminary discovery, plaintiff agreed to voluntarily dismiss his action. On February 10, 2004, the Court entered an Order granting plaintiff's motion to voluntarily dismiss the action without prejudice.

Immtech International, Inc., et al. v. Neurochem, Inc., et al.  
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On August 12, 2003, the Company filed a lawsuit in Federal District Court in New York against Neurochem, Inc. On January 23, 2004, the Company

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amended the complaint and added two additional plaintiffs, UNC and Georgia State, and an additional defendant, Neurochem (International) Limited. The Company's amended complaint alleges that Neurochem misappropriated the Company's intellectual property by filing a series of patent applications relating to compounds synthesized and developed by the Consortium, with whom Immtech has an exclusive license agreement. The misappropriated intellectual property was provided to Neurochem pursuant to a testing agreement under which Neurochem agreed to test the compounds to determine if they could be successfully used to treat Alzheimer's disease. Pursuant to the terms of the agreement, Neurochem agreed to keep all information confidential, not to disclose or exploit the information without Immtech's prior written consent, to advise Immtech before filing any patent applications and to provide the Company with all testing and evaluation data. The amended complaint alleges that Neurochem fraudulently induced the Company into signing the testing agreement, misappropriated valuable intellectual property, filed a series of fraudulent patent applications, breached numerous provisions of the testing agreement, fraudulently transferred all its rights in the patent applications to an offshore affiliate - Neurochem (International) Limited, blocking the development of the Consortium's compounds for the treatment of Alzheimer's disease. By engaging in these acts, plaintiffs allege that defendants have prevented the public from obtaining the potential benefit of new drugs for the treatment of Alzheimer's disease, which would be in competition to Neurochem's Alzhemed drug. The plaintiffs seek injunctive relief and monetary and punitive damages.

The defendants recently filed a motion with the court to compel arbitration, or in the alternative, to dismiss the amended complaint. After receiving legal memorandum from the parties and having heard oral argument, on April 8, 2004, the court ruled that an arbitrator, not the court, should decide the issue of whether the Company's claims against the defendants should be heard by the court or an arbitrator.

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The Company intends to file a motion with the arbitration panel arguing that language in the testing agreement specifically allows the Company the option to litigate its claims against Neurochem in court rather than through arbitration.

Gerhard Von der Ruhr et al. v. Immtech International, Inc. et. al.  
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On October 20, 2003, plaintiffs filed a complaint in the United States District Court for the Northern District of Illinois against the Company and certain officers and directors. On April 19, 2004, the Company and its officers and directors filed a motion with the court to dismiss the complaint. On May 17, 2004, plaintiffs filed opposition papers. Defendants have filed a reply brief and the motion is currently before the court. The Company believes that plaintiffs' claims are meritless and intends to vigorously defend this action.

#### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Matters submitted to a vote of the security holders at our Annual Meeting on January 7, 2004 at the American Stock Exchange in New York City have been disclosed in our quarterly report on Form 10-Q for the quarter ended December 31, 2003, filed with the SEC on February 17, 2004.

PART II.

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### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

#### Market Information

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Our common stock has been quoted on the American Stock Exchange under the symbol "IMM" since August, 11, 2003 (our common stock was quoted under the Symbol "IMMT" on the NASDAQ SmallCap Market from April 26, 1999 to March 29, 2000, on the NASDAQ National Market System from March 30, 2000 to March 8, 2002, on the NASDAQ SmallCap Market from March 9, 2002 to December 2, 2002, and on the NASDAQ OTC Bulletin Board from December 2, 2002 to August 11, 2003). Following are the reported high and low share trade prices as reported by IDD Information Services, NASDAQ Online and Lexis/Nexis for each of the quarters set forth below since the fiscal quarter ended March 31, 2002.

	High	Low
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2002		
Quarter ended March 31, 2002	\$ 7.400	\$ 4.000
Quarter ended June 30, 2002	\$ 5.990	\$ 2.800
Quarter ended September 30, 2002	\$ 5.150	\$ 2.390
Quarter ended December 31, 2002	\$ 3.800	\$ 2.120
2003		
Quarter ended March 31, 2003	\$ 4.850	\$ 1.580

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	High	Low
	-----	-----
Quarter ended June 30, 2003	\$ 7.000	\$ 4.150
Quarter ended September 30, 2003	\$18.820	\$ 5.700
Quarter ended December 31, 2004	\$32.510	\$ 9.000
2004		
Quarter ended March 31, 2004	\$19.500	\$10.110

#### Shareholders

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As of June 4, 2004, there were approximately 232 shareholders of record of our common stock and the number of beneficial owners of shares of common stock as of such date was approximately 2,854. As of June 4, 2004, there were approximately 9,905,324 shares of common stock issued and outstanding.

#### Dividends

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We have never declared or paid dividends on our common stock and we

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do not intend to pay any common stock dividends in the foreseeable future. Our Series A Convertible Preferred Stock, Series B Convertible Preferred Stock, Series C Convertible Preferred Stock and Series D Convertible Preferred Stock earn dividends of 6%, 8%, 8% and 6% per annum, respectively, each payable semi-annually on each April 15 and October 15 while outstanding, and which, at our option, may be paid in cash or in shares of our common stock. On April 15, 2003, October 15, 2003 and April 15, 2004 we paid dividends to the holders of our Series A Convertible Preferred Stock and Series B Convertible Preferred Stock on October 15, 2003 and April 15, 2004 with paid dividends to the holders of our Series C Convertible Preferred Stock, and on April 15, 2004 we paid dividends to the holders of our Series D Convertible Preferred Stock, in each case in shares of common stock, with fractional shares paid in cash.

### Recent Sales of Unregistered Securities

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We issued unregistered securities in the following transactions during the fiscal quarter ended March 31, 2004:

- o On January 22, 2004 we issued (i) 24,600 shares of our Series D Stock and related warrants to purchase 24,600 shares of our common stock pursuant to an exemption from registration under Regulation D of the Securities Act for \$615,000 in the aggregate and (ii) 175,400 shares of our Series D Stock and related warrants to purchase 175,400 shares of our common stock pursuant to an exemption from registration under Regulation S of the Securities Act for \$4,385,000 in the aggregate. A complete description of the designations, preferences, voting powers, qualifications, special or relative rights and privileges of the Series D Stock is contained in our Series D Convertible Preferred Stock Certificate of Designation and a complete description of the terms of the warrants

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are contained in our form of Common Stock Warrant, both filed as exhibits to our current report on Form 8-K dated January 22, 2004.

- o On February 24, 2004 we issued 13,550 shares of common stock from the exercise of options by Craig B. Thompson, having received \$6,328 for their exercise.
- o On March 30, 2004 we issued 300 shares of common stock from the exercise of options by Regina Durlak, having received \$765 for their exercise.

### Securities Authorized for Issuance under Equity Compensation Plans

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The following table provides information as of March 31, 2004, regarding compensation plans (including individual compensation arrangements) under which our equity securities are authorized for issuance.

	Number of securities remaining available for future issuance under equity
Number of	

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Plan category (in thousands)	securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights(1) (b)	compensation plans (excluding securities reflected in column(a)) (c)
Equity compensation plans approved by security holders(2)	962,574	\$ 8.63	340,250
Equity compensation plans not approved by security holders(3)	2,987,710	\$ 7.70	
<b>Total</b>	<b>3,950,284</b>	<b>\$ 7.93</b>	<b>340,250</b>

(1) As adjusted for reverse stock splits that occurred on each of July 24, 1998 and January 25, 1999.

(2) This category consists solely of options.

(3) This category consists solely of warrants.

Series C Convertible Preferred Stock Private Placements -

On June 6, 2003, we filed a Series C Convertible Preferred Stock Certificate of Designation ("Series C Certificate of Designation") with the Secretary of State of the State of Delaware, designating 160,000 shares of our 5,000,000 authorized shares of preferred stock as Series C Convertible Preferred Stock, \$0.01 par value, with a stated value of \$25.00 per share ("Series C Preferred Stock"). Dividends on the Series C Preferred Stock accrue at a rate of 8% on the \$25.00 stated value per share and are payable semi-annually on April 15 and October 15 of each year while the shares are outstanding. We have the option to pay the dividend either in cash or in equivalent shares of common stock. If common stock is to be used to pay the dividend, such common stock is to be valued at the 10-day volume-weighted average price immediately prior to the date of payment.

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Each share of Series C Preferred Stock is convertible by the holder at any time into shares of our common stock at a conversion rate determined by dividing the \$25.00 stated value, plus any accrued and unpaid dividends (the "Liquidation Price"), by a \$4.42 conversion price (the "Conversion Price"), subject to antidilution adjustment. We may at any time after the first anniversary of the date of issuance require that any or all outstanding shares of Series C Preferred Stock be converted into shares of our common stock, provided that the shares of common stock into which the Series C Preferred Stock is convertible is registered pursuant to an effective registration statement. The number of shares of common stock will be determined by (i) dividing the Liquidation Price by the Conversion Price, provided that the closing bid price for our common stock exceeds \$9.00 for 20 consecutive trading days within 180 days prior to notice of conversion, or (ii) if the requirements of (i) above are not met, the number of shares of common stock is determined by dividing 110% of the Liquidation Price by the Conversion Price. The Conversion Price is subject

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to antidilution adjustments, as set forth in the Series C Certificate of Designation.

We may, upon 30 days' notice, redeem any or all outstanding shares of the Series C Preferred Stock by payment of the Liquidation Price to the holder of such shares, provided that the holder does not convert the Series C Preferred Stock into shares of common stock during the 30-day period. The Series C Preferred Stock has a preference in liquidation equal to \$25.00 per share, plus any accrued and unpaid dividends. Each issued and outstanding share of Series C Preferred Stock is entitled to 5.6561 votes with respect to any and all matters presented to our stockholders for their action or consideration. Except as provided by law or by the provisions establishing any other series of preferred stock, holders of our Series A Convertible Preferred Stock, Series B Convertible Preferred Stock, Series C Preferred Stock and Series D Preferred Stock vote together with the holders of our common stock as a single class.

From June 6, 2003 through June 9, 2003, we issued an aggregate of 125,352 shares of our Series C Preferred Stock in private placements to certain accredited and non-U.S. investors in reliance on Regulation D and Regulation S, respectively, under the Securities Act of 1933, as amended (the "Securities Act"). The gross proceeds of the offering were \$3,133,800 as of June 18, 2003. The securities were sold pursuant to exemptions from registration under the Securities Act and we intend to register the shares under the Securities Act.

Subject to adjustment for dilution, each share of Series C Preferred Stock is convertible into 5.6561 shares of common stock.

### Series D Convertible Preferred Stock Private Placements -----

On January 15, 2004, we filed a Series D Convertible Preferred Stock Certificate of Designation ("Series D Certificate of Designation") with the Secretary of State of the State of Delaware, designating 200,000 shares of our 5,000,000 authorized shares of preferred stock as Series D Convertible Preferred Stock, \$0.01 par value, with a stated value of \$25.00 per share ("Series D Preferred Stock"). Dividends on the Series D Preferred Stock accrue at a rate of 6% on the \$25.00 stated value per share and are payable semi-annually on April 15 and October 15 of each year while the shares are outstanding. We have the option to pay the dividend either in cash or in equivalent shares of common stock. If common stock is to be used to pay the

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dividend, such common stock is to be valued at the 10-day volume-weighted average price immediately prior to the date of payment.

Each share of Series D Preferred Stock is convertible by the holder at any time into shares of our common stock at a conversion rate determined by dividing the \$25.00 stated value, plus any accrued and unpaid dividends (the "Liquidation Price"), by a \$9.00 conversion price (the "Conversion Price"), subject to antidilution adjustment. We may at any time after January 1, 2005 require that any or all outstanding shares of Series D Preferred Stock be converted into shares of our common stock, provided that the shares of common stock into which the Series D Preferred Stock is convertible is registered pursuant to an effective registration statement. The number of shares of common stock will be determined by (i) dividing the Liquidation Price by the Conversion Price, provided that the closing bid price for our common stock exceeds \$18.00 for 20 consecutive trading days within 180 days prior to notice of conversion, or (ii) if the requirements of (i) above are not met, the number of shares of

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common stock is determined by dividing 110% of the Liquidation Price by the Conversion Price. The Conversion Price is subject to antidilution adjustments, as set forth in the Series D Certificate of Designation.

The Series D Preferred Stock has a preference in liquidation equal to \$25.00 per share, plus any accrued and unpaid dividends. Each issued and outstanding share of Series D Preferred Stock is entitled to 2.7778 votes with respect to any and all matters presented to our stockholders for their action or consideration. Except as provided by law or by the provisions establishing any other series of preferred stock, holders of our Series A Convertible Preferred Stock, Series B Convertible Preferred Stock, Series C Convertible Preferred Stock and Series D Convertible Preferred Stock vote together with the holders of our common stock as a single class.

On January 15, 2004, we issued an aggregate of 200,000 shares of our Series D Preferred Stock in a private placement to certain accredited and non-U.S. investors in reliance on Regulation D and Regulation S, respectively, under the Securities Act of 1933, as amended (the "Securities Act"). The gross proceeds of the offering were \$5,000,000. The securities were sold pursuant to exemptions from registration under the Securities Act and we intend to register the shares under the Securities Act.

Subject to adjustment for dilution, each share of Series D Preferred Stock is convertible into 2.7778 shares of common stock.

In January 2004, in connection with the Series D Convertible Preferred Stock private placement offering, we issued warrants to purchase 200,000 shares of our common stock at an exercise price of \$16.00 per share of common stock. The warrants expire on the fifth anniversary of their date of issuance. The warrant exercise period commenced immediately upon issuance of the warrant. At any time after the first anniversary of the date of issuance and if our common stock closing price is above 200% of the exercise price for 20 consecutive trading days, we may, upon 20 days notice, redeem any unexercised portion of any warrants for a redemption fee equal to \$.10 per share of common stock underlying the warrants. During the 20-day notice period, the warrant holder may exercise all or a portion of the warrants by tendering the appropriate exercise price.

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### Conversion of Preferred Stock to Common Stock.

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Series A. On May 10, 2004, holders of Series A Convertible Preferred Stock ("Series A Stock") converted 400 shares of Series A Stock and accrued dividends into 2,264 shares of common stock, respectively.

Series C. On February 3, 2004, February 6, 2004, February 23, 2004, February 24, 2004, April 15, 2004, April 16, 2004, and May 10, 2004, holders of Series C Convertible Preferred Stock ("Series C Stock") converted 5,200 shares, 2,800 shares, 1,768 shares, 1,000 shares, 3,768 shares, 884 shares and 400 shares of Series C stock and accrued dividends into 29,627 shares, 15,953 shares, 10,095 shares, 5,711 shares, 21,311 shares, 5,000 shares, and 2,264 shares of common stock, respectively.

### Amendment to Restated Certificate of Incorporation

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On November 4, 2003, our Board of Directors authorized an amendment to our Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 30 million to 100 million. This amendment was approved by our shareholders at the Company's annual meeting held on January 7, 2004. Additionally, the shareholders approved additional amendments to our Restated Certificate of Incorporation which provide for indemnification of our officers and directors to the maximum extent of Delaware law and to generally update our Restated Certificate of Incorporation as permitted by Delaware law.

Our shareholders also authorized up to a two-for-one stock split of our common stock that our Board of Directors has so far deferred to act upon. The Board of Directors has determined that a stock split is not in our best interest at this time but reserves the right to implement the stock split as approved at such time as it deems prudent, if at all.

### ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth certain selected financial data that was derived from our financial statements (dollars in thousands except per share data):

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	Year ended March 31		
	2004	2003	2002
Statement of Operations:			
REVENUES	\$ 2,416	\$ 1,609	\$ 3,522
EXPENSES:			
Research and development	3,293	2,570	(3)3,958
General and administrative	(6)11,989	(5)3,732	2,928
Equity in loss of joint venture	-----	-----	-----
Total expenses	15,282	6,302	6,886
LOSS FROM OPERATIONS	(12,866)	(4,693)	(3,364)
OTHER INCOME (EXPENSE):			
Interest income	20	14	41
Loss on sales of investment securities - net	-----	-----	-----
Other income (expense) - net	20	14	41
NET LOSS	(12,866)	(4,679)	(3,323)

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CONVERTIBLE PREFERRED STOCK DIVIDENDS AND CONVERTIBLE PREFERRED STOCK DEEMED DIVIDENDS (4)	(3,526)	(452)	(938) (4)
REDEEMABLE PREFERRED STOCK CONVERSION, PREMIUM AMORTIZATION AND DIVIDENDS	-----	-----	-----
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>(16,372)</u>	<u>\$ (5,131)</u>	<u>\$ (4,261)</u>

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	Year ended March 31		
	2004	2003	2002
BASIC AND DILUTED NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS:	-----	-----	-----
Net loss	(1.43)	(0.71)	(0.55)
Convertible preferred stock dividends and convertible preferred stock premium deemed dividends	<u>(0.39)</u>	<u>(0.07)</u>	<u>(0.16)</u>
BASIC AND DILUTED NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$ (1.82)</u>	<u>\$ (0.78)</u>	<u>\$ (0.71)</u>
WEIGHTED AVERAGE SHARES USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE	8,977,817	6,565,495	6,011,416

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March 31,

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	2004	2003	2002
Balance Sheet Data:			
Cash and cash equivalents	6,745	112	2,038
Restricted funds on deposit	2,155	2,740	602
Investment securities available for sale			
Working capital (deficiency)	6,136	(115)	1,567
Total assets	12,586	6,610	2,876
Convertible preferred stock	9,522	5,138	4,032
Deficit accumulated during development stage	(58,539)	(42,167)	(37,036)
Stockholders' equity	9,748	3,192	1,736

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- (1) Includes \$6,113 of research and development costs related to the acquisition of rights to technology and dications which were acquired through the issuance of 611,250 shares of common stock.
  - (2) Includes \$1,288 of costs related to the issuance of warrants to purchase 300,000 shares of common stock as compensation for financial consulting services.
  - (3) Includes \$1,159 credit to (reduction in) research and development costs for the settlement of certain disputed costs previously expensed during the year ended March 31, 2000.
  - (4) See Note 7 to Notes to Financial Statements for a discussion on the convertible preferred stock dividends.
  - (5) Includes \$758 of costs related to the issuance of 150,000 shares of common stock to Cheung Ming Tak to act as our non-exclusive agent to develop and qualify potential strategic partners for the purpose of testing and/or the commercialization of Company products in the PRC; \$188 of costs related to the issuance of 40,000 shares of common stock to The Gabriele Group, L.L.C., for assistance with respect to management consulting, strategic planning, public relations and promotions and includes \$89 of costs related to the issuance of 8,333 shares of common stock and the vesting of 29,165 warrants to Fulcrum Holdings of Australia, Inc. ("Fulcrum").
  - (6) Includes non-cash charges of (i) \$2,744 of costs related to the issuance of warrants to purchase 600,000 shares of common stock issued to China Harvest International Ltd as payment for services to assist in obtaining regulatory approval to conduct clinical trials in China, (ii) \$63 for the issuance of 10,000 shares of common stock issued to Mr. David Tat Koon Shu for consulting services in China, (iii) \$1,400 for the issuance of 100,000 shares of common stock issued to Fulcrum for assisting with listing our securities on a recognized stock exchange and for consulting services, (iv) \$2,780 for the vested portion of 91,667 shares of common stock and the vested portion of warrants to purchase 320,835 shares of common stock issued to Fulcrum during the fiscal year based on agreements signed March 21, 2003, and (v) \$247 for the attainment of certain milestones with respect to the

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vesting of warrants to purchase 20,000 shares of common stock issued to Pilot Capital Group, LLC (f/k/a The Gabriele Group, LLC) based upon agreements signed July 31, 2002.

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### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### Overview

We are a pharmaceutical company focused on the development and commercialization of oral drugs to treat infectious diseases and neoplastic and metabolic disorders. We have development programs that include fungal infections, malaria, tuberculosis, diabetes, Pneumocystis carinii pneumonia and tropical diseases, including African sleeping sickness (trypanosomiasis) and leishmaniasis. We hold worldwide patents, patent applications, and licenses to worldwide patents, patent applications and technologies from a scientific consortium and exclusive rights to commercialize products from patents and licenses that are integral to our business.

We intend to continue to work with our scientific and foundation partners to (i) validate our technology platform and (ii) demonstrate dications' low toxicity, broad application and oral deliverability. We believe we will be permitted to sell drugs in niche markets in certain African nations as we further develop drugs to target multi-billion dollar markets such as antifungal, TB, cancer and diabetes treatments. Because we demonstrated to the United States Food and Drug Administration ("FDA") DB289's potential to provide improvement over currently available alternative therapies for African sleeping sickness, the FDA granted "fast-track" designation to DB289 for treatment of African sleeping sickness. Fast-track designation may allow for accelerated FDA review of DB289 for treatment of African sleeping sickness, however, there is no guarantee that fast-track designation will result in faster product development or increase the speed or likelihood of obtaining product approval.

Since our formation in October 1984, we have engaged in research and development programs, expanding our network of scientists and scientific advisors, licensing technology agreements and advancing the commercialization of the dication technology platform. To minimize shareholders' dilution, we use foundation and government grants, the expertise and resources of strategic partners and third parties in a number of areas, including (i) laboratory research, (ii) pre-clinical and human clinical trials and (iii) manufacture of pharmaceutical drugs. We have licensing and exclusive commercialization rights to a dicationic anti-infective pharmaceutical platform and are developing drugs intended for commercial use based on that platform. Dication pharmaceutical drugs (structural class defined by molecules with positive charges on each end held together by a linker) work by blocking life-sustaining enzymes from binding to the key sites in the "minor groove" of an organism's DNA, thereby killing the infectious organisms that cause fungal, parasitic, bacterial and viral diseases. The key site on an organism's DNA is an area where enzymes interact with the infectious organism's DNA as part of their normal life cycle. Structurally, dications are chemical molecules that have two positively charged ends held together by a chemical linker. The composition of the dications, with positive charges on both ends (shaped like molecular barbells) allows dications to bind (similar to a band-aid) to the negatively charged key sites of an infectious microorganism's DNA. The bound dications block the life-sustaining enzymes from attaching to the DNA's key sites, thereby killing the infectious organism.

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With the exception of certain research funding agreements and certain grants, we have not generated any revenue from operations. For the period from inception (October 15, 1984) to March 31, 2004, we incurred cumulative net losses of approximately \$55,993,000. We have incurred additional losses since such date and we expect to incur additional operating losses for the foreseeable future. We expect that our cash sources for at least the next year will be limited to:

- o payments from The University of North Carolina at Chapel Hill, charitable foundations and other research collaborators under arrangements that may be entered into in the future; and
- o research grants, such as Small Business Technology Transfer Program ("STTR") grants and Small Business Innovation Research ("SBIR") grants;
- o borrowing funds or the issuance of securities.

The timing and amounts of grant and payment revenues, if any, will likely fluctuate sharply and depend upon the achievement of specified milestones, and results of operations for any period may be unrelated to the results of operations for any other period.

#### Critical Accounting Policies and Estimates

Our significant accounting policies are described in Note 1 to the Notes to the Consolidated Financial Statements. These financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an ongoing basis, we evaluate our estimates, including those related to the fair value of our preferred and common stock and related options and warrants, the recognition of revenues and costs related to our research contracts, and the useful lives or impairment of our property and equipment. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis of judgments regarding the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Grants to perform research are our primary source of revenue and are generally granted to support research and development activities for specific projects or drug candidates. Revenue related to grants to perform research and development is recognized as earned based on the performance requirements of the specific grant. Upfront cash payments from research and development grants are reported as deferred revenue until such time as the research and development activities covered by the grant are performed.

We use the intrinsic-value method of accounting for stock based awards granted to employees in accordance with Accounting Principles Board Opinion No. 25 and its related interpretations. We record stock based compensation expense for non-employees at the fair value of the options or warrants granted in accordance with Statement of Financial Accounting

Standards No. 123 ("SFAS 123") and Emerging Issues Task Force No. 96-18 ("EITF 96-18"). The fair value of options granted to non-employees is estimated using a Black-Scholes option valuation model. The model considers a number of factors, including the market price and volatility of our common stock at the date of measurement. We measure the compensation expense for options and warrants granted to non-employees as the underlying options vest. The compensation expense related to all grants is being amortized using the graded vesting method, in accordance with SFAS 123, EITF 96-18 and FASB Interpretation No. 28, over the vesting period of each respective stock option.

We believe that the accounting policies affecting these estimates are our critical accounting policies.

#### Research and Development Expenses

All research and development costs are expensed as incurred. Research and development expenses include, but are not limited to, payroll and personnel expenses, lab supplies, preclinical studies, raw materials to manufacture clinical trial drugs, manufacturing costs, sponsored research at other labs, consulting, and research-related overhead. Accrued liabilities for raw materials to manufacture clinical trial drugs, manufacturing costs, and sponsored research reimbursement fees are included in accrued liabilities and included in research and development expenses. Specific information pertaining to each of our major research and development projects follows. This information includes to the extent ascertainable project status, costs incurred for the relevant fiscal years (including costs to date), nature, timing and estimated costs of project completion, anticipated completion dates, and the period in which material net cash inflows from projects is expected to commence, if at all.

All of our research and development projects contain high levels of risk. Even if development is completed on schedule, there is no guarantee that any of our products will be licensed for sale. Human trials conducted in foreign and developing countries have additional risks, including governmental and local militia uprisings that may interrupt or displace our work. We are unable to quantify the impact to our operations, financial position or liquidity if we are unable to complete on schedule, or at all, any of our product commercialization programs.

#### Malaria

We expensed research and development costs for our Malaria program for the fiscal years ended March 31, 2002, March 31, 2003 and March 31, 2004 of approximately \$0, \$45,000, and \$250,000 respectively. Since our inception through May 2004, approximately \$318,000 has been expensed on research and development for the malaria project.

#### Pneumocystis carinii pneumonia ("PCP")

We expensed research and development costs for the PCP program for the fiscal years ended March 31, 2002, March 31, 2003, and March 31, 2004 of approximately \$30,000, \$194,000 and \$241,000, respectively. Since our inception through May 2004, approximately \$471,000 has been expensed on the PCP program.

#### Trypanosomiasis

Research and development costs expensed by the Company for our trypanosomiasis program for the fiscal years ended March 31, 2002, March 31,

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2003, and March 31, 2004 have been approximately \$2,530,000, \$1,228,000 and \$2,018,000, respectively. Since

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our inception through May 2004, approximately \$6,637,000 has been expensed on the trypanosomiasis program.

### Antifungal Program & Tuberculosis ("TB")

Each of the antifungal and TB studies is estimated to cost between \$25-40 million dollars (including manufacturing and formulation of their respective drugs). The Company is unable to calculate when initial drug sales for the antifungal and TB treatments may commence because of the early stage of development.

We expensed research and development costs for the antifungal program for the fiscal years ended March 31, 2002, March 31, 2003, and March 31, 2004 of approximately \$0, \$1,000 and \$32,000, respectively. Since our inception through May 2004, approximately \$367,000 has been expensed on the antifungal program.

We expensed research and development costs for the TB program for the fiscal years ended March 31, 2002, March 31, 2003 and March 31, 2004 of approximately \$50,000, \$10,000 and \$24,000 respectively. Since our inception through May 2004, approximately \$104,000 has been expensed.

### Pharmaceutical Cancer Program

We expensed research and development costs for the pharmaceutical cancer program for the fiscal years ended March 31, 2002, March 31, 2003, and March 31, 2004 of approximately \$0, \$0 and \$0, respectively. Since our inception through May 2004, approximately \$24,000 has been expensed on the pharmaceutical cancer program.

### Liquidity and Capital Resources

From our inception through March 31, 2004, we have financed our operations with:

- o proceeds from various private placements of debt and equity securities, an initial public offering and other cash contributed from stockholders, which in the aggregate raised approximately \$39,258,000;
- o payments from research agreements, foundation grants and SBIR grants and STTR program grants of approximately \$11,259,000; and
- o the use of stock, options and warrants in lieu of cash compensation.

On January 22, 2004, we sold in private placements pursuant to Regulation D and Regulation S of the Securities Act of 1933, as amended ("Securities Act") (i) 200,000 shares of our Series D Convertible Preferred Stock, \$0.01 par value ("Series D Stock") at a stated value of \$25.00 per share and (ii) warrants to purchase 200,000 shares of our common stock with a \$16.00 per share exercise price, for the aggregate consideration of \$5,000,000 before issuance cost. The net proceeds were approximately \$4,571,000. Each share of Series D Stock, among other things, (i) earns a 6% dividend payable, at our discretion, in cash or common stock, (ii) has

a \$25.00 (plus accrued but unpaid dividends) liquidation preference pari passu with our other outstanding preferred stock, (iii) is convertible into 2.7778 shares of common stock and (iv) may be converted to common stock by us any time after January 1, 2005. The related warrants expire five years from the date of grant.

From June 6, 2003 through June 9, 2003, we issued an aggregate of 125,352 shares of our Series C Preferred Stock in private placements to certain accredited and non-U.S. investors in reliance on Regulation D and Regulation S, respectively, under the Securities Act. The securities were sold pursuant to exemptions from registration under the Securities Act and were subsequently registered on Form S-3 (Registration Statement No. 333-108278). The gross proceeds of the offering were \$3,133,800 and the net proceeds were approximately \$2,845,000.

On September 25, 2002 and October 28, 2002, we issued an aggregate of 76,725 shares of our Series B Convertible Preferred Stock and 191,812 related warrants in private placements to certain accredited and non-U.S. investors in reliance on Regulation D and Regulation S, respectively, under the Securities Act. The warrants have an exercise period of five years from the date of issuance and an exercise price of 6.125 per share. The securities were sold pursuant to exemptions from registration under the Securities Act and were subsequently registered on Form S-3 (Registration Statement No. 333-101197). The gross proceeds of the offering were \$1,918,125 and the net proceeds were approximately \$1,859,000.

On February 14, 2002 and February 22, 2002, we issued an aggregate of 160,100 shares of our Series A Convertible Preferred Stock and 400,250 related warrants in private placements to certain accredited and non-U.S. investors in reliance on Regulation D and Regulation S, respectively, under the Securities Act. In connection with this offering, we issued in the aggregate 60,000 shares of common stock and 760,000 warrants to purchase shares of common stock to consultants assisting in the private placements. The warrants have an exercise period of five years from the date of issuance and exercise prices of (i) \$6.00 per share for 500,000 warrants, (ii) \$9.00 per share for 130,000 warrants and (iii) \$12.00 per share for 130,000 warrants. The \$9.00 and \$12.00 warrants will not vest, and therefore will not be exercisable, unless our common stock meets or exceeds the respective exercise price for 20 consecutive trading days prior to January 31, 2003. The gross proceeds of the offering were \$4,003,000 and the net proceeds were \$3,849,000.

On December 8, 2000, we completed a private placement offering that raised net proceeds of approximately \$4,306,000 of additional net equity capital through the issuance of 584,250 shares of common stock.

On April 26, 1999, we issued 1,150,000 shares of common stock through an initial public stock offering ("IPO"), resulting in net proceeds of approximately \$9,173,000. The underwriters received warrants to purchase 100,000 additional shares of common stock at \$16.00 per share. Those warrants were due to expire on April 25, 2004. All warrants other than warrants to purchase 21,400 shares expired. The warrant to purchase 21,400 shares was pursuant to an agreement with the holder. We used \$110,000 of the net proceeds of the IPO to repay amounts due to the State of Illinois and Northwestern University. Substantially all of the remaining net proceeds of the IPO were used to fund our research and development efforts, including clinical and pre-clinical studies. Any net proceeds not applied to our research and development efforts were used

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for working capital and general corporate purposes, including hiring additional employees.

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Our cash resources have been used to finance research and development, including sponsored research, capital expenditures, expenses associated with the efforts of the Scientific Consortium and general and administrative expenses. Over the next several years, we expect to incur substantial additional research and development costs, including costs related to early-stage research in pre-clinical and clinical trials, increased administrative expenses to support research and development operations and increased capital expenditures for expanded research capacity, various equipment needs and facility improvements or relocation.

As of March 31, 2004, we had federal net operating loss carryforwards of approximately \$42,840,000, which expire from 2006 through 2024. We also had approximately \$41,092,000 of stated net operating loss carryforwards as of March 31, 2004, which expire from 2009 through 2024, available to offset certain future taxable income for state (primarily Illinois) income tax purposes. Because of "change of ownership" provisions of the Tax Reform Act of 1986, approximately \$920,000 of our net operating loss carryforwards for federal purposes are subject to an annual limitation regarding utilization against taxable income in future periods. As of March 31, 2004, we had federal income tax credit carryforwards of approximately \$750,000, which expire from 2008 through 2024.

We believe our existing resources, but not including proceeds from any grants we may receive, are sufficient to meet our planned expenditures through June 2005, although there can be no assurance that we will not require additional funds. In addition, we anticipate the receipt of approximately an additional \$3.2 million payment (restricted funds) under the Clinical Research Subcontract with the University of North Carolina at Chapel Hill ("UNC") (funded by The Gates Foundation) and approximately an additional \$2.7 million under the agreement with MMV in calendar year 2004. Our working capital requirements will depend upon numerous factors, including the progress of our research and development programs (which may vary as product candidates are added or abandoned), pre-clinical testing and clinical trials, achievement of regulatory milestones, our corporate partners fulfilling their obligations to us, the timing and cost of seeking regulatory approvals, the level of resources that we devote to the development of manufacturing, our ability to maintain existing, and establish new, collaborative arrangements with other companies to provide funding to us to support these activities and other factors. In any event, we will require substantial funds in addition to our existing working capital to develop our product candidates and otherwise to meet our business objectives.

We have, through our purchase of Super Insight Limited, obtained an ownership interest in improved real property on which we intend to construct a pharmaceutical manufacturing facility. We plan to purchase and install a pharmaceutical production line for which we have received estimates of \$8 to \$12 million from several consultants for the initial equipment and installation based on requirements for capacity and quality supplied by us. We are seeking partners both in the PRC and domestically to fund part or all of the capital cost of construction of the pharmaceutical production line.

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### Payments Due under Contractual Obligations

We have future commitments at March 31, 2004 consisting of operating lease obligations as follows:

Year Ending March 31,	Lease Payments
2005	\$153,000
	-----
Total	\$153,000

### Results of Operations

Year Ended March 31, 2004 Compared with Year Ended March 31, 2003

Revenues under collaborative research and development agreements were approximately \$2,416,000 and \$1,609,000 in the years ended March 31, 2004 and 2003, respectively. In 2004, we recognized revenues of approximately \$2,114,000 relating to the clinical research subcontract agreement between us and UNC funded by a grant that UNC received from The Gates Foundation, and approximately \$302,000 relating to the testing agreement with MMV, while in 2003, there were revenues recognized of approximately \$1,389,000 relating to the clinical research subcontract agreement, grant revenues of approximately \$70,000 from SBIR grants from the NIH and revenues of \$150,000 relating to the Confidentiality, Testing and Option Agreement with Neurochem Inc., a Canadian company. Research and development expenses increased from approximately \$2,570,000 in 2003 to approximately \$3,293,000 in 2004. Expenses relating to the clinical research subcontract agreement with UNC increased from approximately \$1,294,000 in 2003 to approximately \$2,099,000 in 2004. The initiation of the MMV testing agreement in 2004 accounted for expenses of approximately \$301,000. Expenses relating to pre-clinical and clinical trial costs primarily for *Pneumocystis carinii* pneumonia decreased from approximately \$442,000 in 2003 to approximately \$198,000 in 2004. The decrease in expenses for *Pneumocystis carinii* pneumonia was primarily due to the payment of start up costs to a contract research organization in South Africa and Peru in 2003 which were not incurred in 2004. Other research and development costs relating primarily to SBIR's and obligations to UNC decreased from approximately \$329,000 in 2003 to approximately \$190,000.

General and administrative expenses were approximately \$11,990,000 in 2004, compared to approximately \$3,732,000 in 2003. The increase in general and administrative expenses was primarily due to non-cash expenses for common stock, stock options and warrant issuance in 2004 of approximately \$7,234,000 as compared to approximately \$1,035,000 in 2003. Non-cash expenses in 2004 included (i) approximately \$2,744,000 for the issuance of a warrant to purchase 600,000 shares of common stock issued to China Harvest International Ltd. as payment for services to assist us in obtaining regulatory approval to conduct clinical trials in China, (ii) approximately \$63,000 for the issuance of 10,000 shares of common stock issued to Mr. David Tat Koon Shu for consulting services in China, (iii) approximately \$1,400,000 for the issuance of 100,000 shares of common stock issued to Fulcrum for assistance with listing our securities on a recognized stock exchange and for consulting services, (iv) approximately

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\$2,780,000 for the vested portion of 91,667 shares of common stock and the vested portion of warrants to purchase 320,835 shares of common stock issued to Fulcrum during the fiscal year based on agreements signed March 21, 2003 and (v)

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approximately \$247,000 for the reaching of certain milestones which resulted in the vesting of a warrant to purchase 20,000 shares of common stock issued to Pilot Capital Group, LLC (f/k/a The Gabriele Group, LLC) based upon agreements signed July 31, 2002. Legal expenses for patents increased from approximately \$215,000 in 2003 to approximately \$481,000 in 2004. Legal fees increased from approximately \$650,000 in 2003 to approximately \$1,610,000 in 2004 primarily due to increased litigation fees. Expenses relating to the start-up and consolidation of Immtech Therapeutics and Immtech Hong Kong into Immtech accounts were approximately \$398,000. Accounting fees increased from approximately \$125,000 in 2003 to approximately \$231,000 in 2004. Additionally, the expensing of a retainer fee to Wyndham increased general and administrative expenses in 2004 by \$160,000.

We incurred a net loss of approximately \$12,846,000 for the year ended March 31, 2004, as compared to a net loss of approximately \$4,679,000 for the year ended March 31, 2003.

In 2004, we also charged deficit accumulated during the development stage of approximately \$3,526,000 of non-cash convertible preferred stock dividends and convertible preferred stock premium deemed dividends.

Year Ended March 31, 2003 Compared with Year Ended March 31, 2002

Revenues under collaborative research and development agreements were approximately \$1,609,000 and \$3,522,000 in the years ended March 31, 2003 and 2002, respectively. In 2003, we recognized revenues of approximately \$1,389,000 relating to a clinical research subcontract agreement with UNC funded by a grant that UNC received from The Gates Foundation, compared to approximately \$2,946,000 in 2002. We also recognized approximately \$70,000 from SBIR grants in 2003, while in 2002 there were grant revenues of approximately \$576,000 through STTR and SBIR programs from the NIH.

Research and development expenses decreased from approximately \$2,570,000 in 2002 to \$3,958,000 in 2003. The decrease in research and development costs is primarily attributable to the decrease in the revenues relating to the clinical research subcontract agreement with UNC and the decrease in the grant revenues from SBIR grants from the NIH.

General and administrative expenses were approximately \$3,732,000 in 2003, compared to approximately \$2,928,000 in 2002. In the year ended 2003, there were general and administrative compensation expenses of approximately \$758,000 related to the issuance of 150,000 shares of common stock to Cheung Ming Tak to act as our non-exclusive agent to develop and qualify potential strategic partners for the purpose of testing and/or commercializing Company products in the PRC.

We incurred a net loss of approximately \$4,679,000 for the year ended March 31, 2003, as compared to a net loss of approximately \$3,323,000 for the year ended March 31, 2003.

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In 2002 and 2003, respectively, we also charged deficit accumulated during the development stage of approximately \$938,000 and \$452,000 of non-cash convertible preferred stock dividends.

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Impact of Inflation

Although it is difficult to predict the impact of inflation on our costs and revenues in connection with our operations, we do not anticipate that inflation will materially impact our costs of operation or the profitability of our products when and if marketed.

Unaudited Selected Quarterly Information

The following table sets forth certain unaudited selected quarterly information (amounts in thousands, except per share amounts):

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	Fiscal Quarter Ended				
	March 31, 2004	December 31, 2003	September 30, 2003	June 30, 2003	March 31, 2003
Statements of Operations Data:					
REVENUES .....	\$ 618	\$ 654	\$ 659	\$ 485	\$ 585
EXPENSES:					
Research and development .....	966	815	905	607	706
General and administrative ..	1,807(7)	2,580(6)	6,596(5)	1,007(4)	673
Total expenses .....	2,773	3,395	7,501	1,614	1,379
LOSS FROM OPERATIONS .....	(2,155)	(2,741)	(6,842)	(1,129)	(794)
OTHER INCOME (EXPENSE):					
Interest income .....	10	6	4	1	1
NET LOSS .....	(2,145)	(2,735)	(6,838)	(1,128)	(793)
CONVERTIBLE PREFERRED STOCK DIVIDENDS AND PREFERRED STOCK PREMIUM DEEMED DIVIDENDS(1) .....					
	(2,107)	(131)	(93)	(1,195)	(89)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS .....	\$ (4,252)	\$ (2,866)	\$ (6,931)	\$ (2,323)	\$ (882)
NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS:					
Net loss .....	\$ (0.22)	\$ (0.30)	\$ (0.79)	\$ (0.14)	\$ (0.11)
Convertible preferred stock dividends and convertible preferred stock premium					

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deemed dividends .....	\$ (0.22)	\$ (0.01)	\$ (0.01)	\$ (0.15)	\$ (0.01)
	-----	-----	-----	-----	-----
BASIC AND DILUTED NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS .....	\$ (0.44)	\$ (0.31)	\$ (0.80)	\$ (0.29)	\$ (0.12)
	=====	=====	=====	=====	=====

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- (1) See Note 7 to Notes to Financial Statements for a discussion on the convertible preferred stock dividends.
- (2) Includes \$758 of costs related to the issuance of 150,000 shares of common stock to Cheung Ming Tak to act as our non-exclusive agent to develop and qualify potential strategic partners for the purpose of testing and/or the commercialization of Company products in the PRC.
- (3) Includes \$188 of costs related to the issuance of 40,000 shares of common stock to The Gabriele Group, L.L.C. for assistance with respect to management consulting, strategic planning, public relations and promotions.
- (4) Includes \$337 of costs related to the issuance of 25,000 common shares and the vesting of 87,500 warrants to Fulcrum under the agreement signed March 21, 2003.
- (5) Includes (i) \$2,744 of costs related to the issuance of warrants to purchase 600,000 shares of common stock issued to China Harvest International Ltd. as payment for services to assist in obtaining regulatory approval to conduct clinical trials in China, (ii) \$63 for the issuance of 10,000 shares of common stock issued to Mr. David Tat Koon Shu for consulting services in China, (iii) \$1,400 for the issuance of 100,000 shares of common stock issued to Fulcrum for assisting with listing our securities on a recognized stock exchange and for consulting services, and (iv) \$1,016 for the issuance of 25,000 common shares and the vesting of 87,500 warrants to Fulcrum under the agreement signed March 21, 2003.
- (6) Includes (i) \$947 of costs related to the issuance of 25,000 common shares and the vesting of 87,500 warrants to Fulcrum under the agreement signed March 21, 2003, and (ii) \$247 for the attainment of certain milestones with respect to the vesting of warrants to purchase 20,000 shares of common stock issued to Pilot Capital Group, LLC (f/k/a The Gabriele Group, LLC) based upon agreements signed July 31, 2002.
- (7) Includes \$480 of costs related to the issuance of 16,667 common shares and the vesting of 58,335 warrants to Fulcrum under the agreement signed March 21, 2003.

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ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The exposure of market risk associated with risk-sensitive instruments is not material, as our operations are conducted primarily in U.S. dollars and we invest primarily in short-term government obligations and other cash equivalents. We intend to develop policies and procedures to manage market

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risk in the future if and when circumstances require.

### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements appear following Item 15 of this report and are incorporated herein by reference.

### ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

### ITEM 9A CONTROLS AND PROCEDURES

#### Disclosures and Procedures

We maintain controls and procedures designed to ensure that we are able to collect the information we are required to disclose in the reports we file with the SEC, and to process, summarize and disclose this information within the time periods specified in the rules of the SEC. Our Chief Executive and Chief Financial Officers are responsible for establishing and maintaining these procedures and, as required by the rules of the SEC, evaluate their effectiveness. Based on their evaluation of our disclosure controls and procedures, which took place as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive and Chief Financial Officers believe that these procedures are effective to ensure that we are able to collect, process and disclose the information we are required to disclose in the reports we file with the SEC within the required time periods.

#### Internal Controls

We maintain a system of internal controls designed to provide reasonable assurance that: transactions are executed in accordance with management's general or specific authorization; transactions are recorded as necessary (i) to permit preparation of financial statements in conformity with generally accepted accounting principles and (ii) to maintain accountability for assets. Access to assets is permitted only in accordance with management's general or specific authorization and the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

Since the date of the most recent evaluation of our internal controls by our Chief Executive and Chief Financial Officers, there have been no significant changes in such controls

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or in other factors that could have significantly affected those controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

### PART III.

### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

#### Information Regarding Directors and Executive Officers

The table below sets forth the names and ages of our directors and executive officers as of June 4, 2004, as well as the positions and offices held

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by such persons. A summary of the background and experience of each of these individuals is set forth after the table. Each director serves for a term of one year and is eligible for reelection at our next annual shareholders' meeting.

Name	Age	Position(s)
T. Stephen Thompson	57	Director, President and Chief Executive Officer
Cecilia Chan	41	Director and Executive Vice President
Gary C. Parks	54	Treasurer, Secretary and Chief Financial Officer
Harvey R. Colten, MD	65	Director
Judy Lau	44	Director
Levi H.K. Lee, MD	63	Director
Eric L. Sorkin	44	Director
Frederick W. Wackerle	65	Director

T. Stephen Thompson, President, Chief Executive Officer and Director and a director of Immtech Hong Kong Ltd. also. Mr. Thompson has served as a Director since November 27, 1991. He joined Immtech in April 1991 from Amersham Corporation, where he was President and Chief Executive Officer. He was responsible for Amersham Corporation's four North American divisions: Life Sciences, Radiopharmaceuticals, Diagnostics and Quality and Safety Products. In addition, he had direct responsibility for the Clinical Reagent (in vitro diagnostic) Division in the United Kingdom. He was employed by Amersham Corporation from 1986 to 1991. Mr. Thompson has 20 years' experience in healthcare, with previous positions as President of a small diagnostic start-up, General Manager of the Infectious Disease and Immunology Business Unit in the Diagnostic Division of Abbott Laboratories from 1981 to 1986, and Group Marketing Manager for the Hyland Division of Baxter International Inc. from 1978 to 1981. Mr. Thompson is a member of the Board of Directors of Matritech, Inc. (NASDAQ: NMPS). Mr. Thompson holds a B.S. from the University of Cincinnati and an MBA from Harvard University.

Cecilia Chan, Executive Vice President and Director. Ms. Chan has served as Director since November 16, 2001. She has 18 years of experience in making investments and business development. She began working on Immtech's growth strategy in 1998 as a private investor, spearheading Immtech's initial public offering in April 1999. She joined Immtech as

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Vice President in July, 1999 and was elected to our board of directors in November 2001. Ms. Chan is responsible for strategic development, creating joint ventures and licensing agreements, fund raising and directing our uses of capital resources as we advances through milestones and various growth stages. Prior to joining Immtech, Ms. Chan was a Vice President at Dean Witter Realty, Inc. until 1993 and thereafter concentrated her efforts as a private investor until she joined Immtech. During her eight years at Dean Witter, Ms. Chan completed over \$500 million in investments and was vice-president of public partnerships having assets in excess of \$800 million. Since 1993, Ms. Chan has developed and funded investments in the United States and the PRC. She graduated from New York University in 1985 with a Bachelor of Science degree in International Business.

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Judy Lau, Director. Ms. Lau has served as Director since October 31, 2003. Since July 2002 to date, Ms. Lau has served as the Chairperson of Convergent Business Group, a Hong Kong-based investment advisory firm with investments focused in high technology, life sciences, healthcare and environmental engineering projects in the greater China region. From May of 2001 to July of 2002, Ms. Lau served as General Manager of China Overseas Venture Capital Co. Ltd., a venture capital firm. From October of 2000 to April of 2001, Ms. Lau served as Chief Executive Officer of the Good Fellow Group, a Chinese investment firm; and from March of 1999 to September of 2000, Ms. Lau was the Managing Director of America Online HK, an Internet Service Provider and Hong Kong affiliate of Time Warner, Inc. From April of 1998 to February of 1999, Ms. Lau worked as a consultant to Pacific Century Group. Ms. Lau has served in the position of Director of Immtech Hong Kong Ltd. since June, 2003. Ms. Lau was named in 2000, one of the thirty-six most influential Business Women of Hong Kong by Capital Magazine and is a Fellow of the Hong Kong Association for the Advancement of Science and Technology.

Levi Hong Kaye Lee, M.D., Director. Dr. Lee has served as Director since October 31, 2003. Dr. Lee has been in private medical practice, specializing in pediatrics, since 1971. His practice is located in Hong Kong. Dr. Lee received a B.A. in Biochemistry from the University of California, Berkeley, in 1962, and received his M.D. from the University of California, San Francisco, in 1966. Dr. Lee has served in the position of Director of Immtech Hong Kong Ltd. since June, 2003. He was appointed a Diplomat of the American Board of Pediatrics in 1971.

Gary C. Parks, Treasurer, Secretary and Chief Financial Officer. Mr. Parks joined Immtech in January 1994, having previously served at Smallbone, Inc., from 1989 until 1993, where he was Vice President, Finance. Mr. Parks was a Division Controller with International Paper from 1986 to 1989. Prior to that, he was Vice President, Finance, of SerckBaker, Inc., a subsidiary of BTR plc, from 1982 to 1986 and a board member of SerckBaker de Venezuela. Mr. Parks holds a B.A. from Principia College and an MBA from the University of Michigan.

Harvey Colten, MD, Director. Dr. Colten has served as Director since October 30, 2000. He is currently Vice President and Senior Associate Dean for Academic Affairs at Columbia University Health Sciences Division and College of Physicians and Surgeons. Prior to this, he served as Chief Medical Officer at iMetrikus, Inc., a healthcare Internet company focused on improving the communication between the patient, physician and the medical

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industry from 2000 until 2002, and prior to that he was the Dean of the Medical School and Vice President for Medical Affairs at Northwestern University from 1997 to 2000. He previously served as the Harriet B. Spoehrer Professor and Chair of the Department of Pediatrics and Professor of Molecular Microbiology at Washington University School of Medicine, St. Louis, Missouri, whose faculty he joined in 1986. He earned a B.A. at Cornell University in 1959, an MD from Western Reserve University in 1963, and an M.A. (honorary) from Harvard in 1978. Following his clinical training, he was a researcher at the National Institutes of Health from 1965 to 1970. In 1970, he was appointed to the faculty at the Harvard Medical School, where he was named Professor of Pediatrics in 1979 and Chief of the Division of Cell Biology, Pulmonary Medicine, and Director of the Cystic Fibrosis Program at Children's Hospital Medical Center, Boston. He is a member of the Institute of Medicine and was Vice-Chair of its Council. He is a member of the American Society for Clinical Investigation, the Society for Pediatric Research, the Association of American Physicians, the American

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Pediatric Society, the American Association of Immunologists (former secretary and treasurer), and the American Society for Biochemistry and Molecular Biology. He is also a Fellow of the American Association for the Advancement of Science, the American Academy of Allergy and Immunology and the American Academy of Pediatrics. Dr. Colten is a Diplomat of the American Board of Pediatrics, served on the American Board of Allergy and Immunology, was a member of the National Heart, Lung, and Blood Institute Advisory Council, and serves on the Board of Directors of the Oasis Institute and the March of Dimes Scientific Advisory Council, in addition to many other Federal and private health groups that advise on scientific and policy issues. Dr. Colten also served as Vice Chairman of the Board of Directors of Parents as Teachers National Center. He has been on editorial boards and advisory committees of several leading scientific and medical journals, including the New England Journal of Medicine, Journal of Clinical Investigation, Journal of Pediatrics, Journal of Immunology, Annual Review of Immunology, Proceedings of the Association of American Physicians and American Journal of Respiratory Cell and Molecular Biology.

Eric L. Sorokin, Director. Mr. Sorokin has served as Director since January 6, 2000. He is a private investor. Prior to 1994, Mr. Sorokin worked for eleven years at Dean Witter Realty Inc., a wholly owned subsidiary of Morgan Stanley, which grew to hold an investment portfolio of real estate and other assets of over \$3 billion. He became a Managing Director in 1988 and was responsible for the acquisition, structuring and debt placement of various investments including real estate, fund management and asset-backed securities. Mr. Sorokin managed Dean Witter Realty's retail (shopping center) portfolio of over two million square feet, and participated in the development of office, residential, industrial and retail property and in the acquisition of over five million square feet of properties. Since 1994, Mr. Sorokin has developed and funded investments in the United States and the PRC. He is a graduate of Yale University with a Bachelor of Arts degree in Economics.

Frederick W. Wackerle, Director. Mr. Wackerle has served as Director since December 17, 2001. He is an author, private investor and President of Fred Wackerle, Inc. He has been an advisor to Chief Executive Officers ("CEOs") and boards and previously was an executive search consultant for 35 years. Mr. Wackerle specialized in advising corporate boards on management succession. In the past ten years, he devoted a significant amount of his time to investing in and advising biotechnology companies on succession planning, and recruited CEO candidates and board members for companies that include Biogen, Inc., ICOS Corp., Amylin

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Pharmaceuticals, Inc., Enzon, Inc., Medtronic Inc. and Ventana Medical Systems. Mr. Wackerle has recently published a book on management succession entitled, "The Right CEO—Straight Talk About Making CEO Selection Decisions" (Jossey-Bass), and is a graduate of Monmouth College, Illinois, where he has been active on their Board of Trustees. He is also a board member of The Rehabilitation Institute of Chicago.

### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and 10% stockholders of a registered class of equity securities to file reports of ownership and reports of changes in ownership of our common stock and other equity securities with the SEC. Directors, executive officers and 10% stockholders are required to furnish us with copies of all Section 16(a) forms they file. Based on a review of the copies of such reports furnished to us, we believe that during fiscal 2003, our directors, executive officers and 10%

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stockholders complied with all Section 16(a) filing requirements applicable to them. Ms. Vivian Lee, the wife of Dr. Lee, one of our independent directors, purchased 2,000 shares and sold 1,000 shares of our common stock in a series of trades on February 5, 2004, resulting in a profit of \$235 to Ms. Lee. Dr. Lee paid \$235 to us as a Section 16 fee.

### Board Committees

The board of directors has an audit committee, a compensation committee and a nominating committee. The function, composition, and number of meetings of each of these committees are described below.

### Audit Committee

The audit committee (a) has sole authority to appoint, replace and compensate our independent auditors and is directly responsible for oversight of their work; (b) approves all audit fees and terms, as well as any permitted non-audit services; (c) meets and discusses directly with our independent auditors their audit work and related matters and (d) oversees and performs such investigations with respect to our internal and external auditing procedures and affairs as the audit committee deems necessary or advisable and as may be required by applicable law.

The members of the audit committee are Directors Sorkin (Chairman), Colten and Lau. Each member of the audit committee is "independent" in accordance with the rules of the SEC and the listing standards of the American Stock Exchange. The board has determined that Mr. Eric Sorkin, the current chairman of the audit committee, qualifies as an "audit committee financial expert" within the meaning of the regulations of the SEC.

### Compensation Committee

The compensation committee (a) annually reviews and determines salaries, bonuses and other forms of compensation paid to our executive officers and management; (b) selects recipients of awards of incentive stock options and non-qualified stock options and establishes the number of shares and other terms applicable to such awards; and (c) construes the provisions of and generally administers the First Amended and Restated Immtech International, Inc. 2000 Stock Incentive Plan.

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The members of the compensation committee are Directors Wackerle (Chairman), Lau and Sorkin.

### Nominating Committee

The nominating committee has authority to review the qualifications of, interview and nominate candidates for election to the board of directors.

The members of the nominating committee are Directors Colten (Chairman), Lee and Wackerle. Each member of the nominating committee is "independent" in accordance with the listing standards of the American Stock Exchange.

### Code of Ethics

We have adopted a "code of ethics", as defined by the SEC, that applies to our Chief Executive Officer, Chief Financial Officer, principal

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accounting officer and persons performing similar functions with Immtech and our subsidiaries. We have filed with the SEC a copy of our Code of Ethics as Exhibit 14.1 to this Annual Report on Form 10-K. We also post the text of our Code of Ethics on our Internet website (www.immtech-international.com).

### ITEM 11. EXECUTIVE COMPENSATION

#### Summary Compensation Table

The following table sets forth certain information regarding the compensation of our Chief Executive Officer, our Executive Vice President and our Chief Financial Officer for the fiscal years ended March 31, 2002, 2003 and 2004. Except as set forth below, no other compensation was paid to these individuals during the years indicated.

	Year	Annual Compensation	Long-Term Compensation Awards
		Salary (\$)	Securities Underlying Options/SARs (#)
	----	-----	-----
T. Stephen Thompson	2004	\$185,000	40,000
President, Chief Executive Officer	2003	\$150,000	75,000
and Director	2002	\$150,000	0
Cecilia Chan	2004	\$148,000	25,000
Executive Vice President and	2003	\$120,000	50,000
Director	2002	\$120,000	0
Gary C. Parks	2004	\$134,375	15,000
Secretary, Treasurer and Chief	2003	\$143,250 (1)	25,000
Financial Officer	2002	\$125,000	10,000

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(1) Includes a bonus of \$18,250.

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#### Stock Option Grants and Exercises During the Fiscal Year Ended March 31, 2004

The following table sets forth information concerning stock option grants made during the fiscal year ended March 31, 2004, to our executive officers named in the "Summary Compensation Table" above. This information is for illustration purposes only and is not intended to predict the future price of our common stock. The actual future value of the options will depend on the market value of the common stock.

#### STOCK OPTION GRANTS IN FISCAL YEAR ENDED MARCH 31, 2004

Individual Grants

-----  
Percent

Potential Realized Annual Percentage Change in Price Appreciation

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Name	Number of Securities Underlying Options/SARs Granted	of Total Options/SARs Granted to Employees (%)	Exercise Price (\$/SH)	Expiration Date	5% (\$)
T. Stephen Thompson	40,000	30.30	21.66	11/5/2013	1,411,274
Cecilia Chan	25,000	18.94	21.66	11/5/2013	882,046
Gary C. Parks	15,000	11.36	21.66	11/5/2013	529,228

The following table sets forth certain summary information concerning exercised and unexercised options and warrants to purchase common stock held by the executive officers named in the "Summary Compensation Table" as of March 31, 2004.

STOCK OPTION AND WARRANT EXERCISES IN FISCAL YEAR ENDED MARCH 31, 2004, AND FISCAL YEAR-END OPTION/WARRANT VALUES

	Shares Acquired on Exercise (#)	Realized Value (\$)	Number of Unexercised Options/Warrants at Fiscal Year End (#)		Ex
			Exercisable	Unexercisable	
T. Stephen Thompson	0	0	87,653	75,414	1
Cecilia Chan	0	0	253,355	48,957	3
Gary C. Parks	0	0	37,628	27,567	

- 
- (1) Based on the March 31, 2004, value of \$18.52 per share, minus the average per share exercise price of \$3.27 multiplied by the number of shares underlying the options and warrants.
  - (2) Based on the March 31, 2004, value of \$18.52 per share, minus the average per share exercise price of \$2.55 multiplied by the number of shares underlying the options.
  - (3) Based on the March 31, 2004, value of \$18.52 per share, minus the average per share exercise price of \$6.14 multiplied by the number of shares underlying the options and warrants.
  - (4) Based on the March 31, 2004, value of \$18.52 per share, minus the average per share exercise price of \$2.55 multiplied by the number of shares underlying the options.