IMMTECH INTERNATIONAL INC
Form 10-K
June 14, 2005

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

FORM 10-K

|X| ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the fiscal year ended March 31, 2005.

|__| 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
(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 |X| 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. |X|

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act).

Yes |X| No |_|

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 June 10, 2005, was $148,005,516.

As of June 10, 2005, the total number of shares of the registrant's common stock outstanding was 11,409,178 shares.

Documents incorporated by reference. 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 extending its proprietary aromatic cation technology platform to the treatment of cancer, diabetes and other diseases. We have advanced clinical programs that include new treatments for malaria, Pneumocystis pneumonia ("PCP") and African sleeping sickness (trypanosomiasis), and drug development programs for fungal infections and tuberculosis. We hold worldwide patents and patent applications, and licenses and rights to license technology, primarily from a scientific consortium that has granted us a worldwide license and exclusive rights to

commercialize products from, and

license rights to, the technology. The 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 and commercialize a pipeline of new oral drugs to treat infectious diseases and other disorders utilizing a proprietary library of aromatic cation compounds. 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 to treat acute infectious diseases have been brought to market during this period. New drugs are needed to overcome the health risks from multi-drug resistant pathogens and to address the increasing number of new pathogens that are causing disease. We are developing a new paradigm focused on reducing the time and cost to develop drugs aimed at solving global health issues.

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) preclinical and human clinical trials and (iii) manufacture of pharmaceutical drugs.

We are working with our scientific and foundation partners to (i) complete the clinical programs for malaria, Pneumocystis pneumonia and African sleeping sickness, (ii) advance new drug candidates into the clinic and (iii) validate the broad application of our technology platform and illustrate its low toxicity and oral deliverability (See "Products and Programs" below). We believe we can build a sustainable and profitable business by selling drugs in niche markets in certain developing countries as we target treatments for multi-billion dollar markets such as fungal infections, tuberculosis, cancer and diabetes. The United States Food and Drug Administration ("FDA") has granted "fast-track" designation to our first oral drug candidate, DB289, to treat African sleeping sickness. Fast-track designation may allow for accelerated FDA review of DB289 to treat African sleeping sickness. However, there is no guarantee that fast-track designation will result in faster product development or impact the likelihood or timing of product approval.

For the fiscal year ended March 31, 2005, we had revenues of approximately $5.9 million and a net loss of approximately $13.4 million which included non-cash compensation expenses of approximately $5.2 million related to the vesting of common stock options and extensions of warrants during the year. Our management believes we have sufficient capital for operations through our next fiscal year. There is no guarantee, however, that we will not need additional

funds before then or that sufficient funds will be available after April 2006 to fund continuing 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 two Phase III pivotal human clinical trials and one Phase II clinical trial of DB289 either in progress or planned within this calendar year and several more laboratory development programs in progress testing the safety and effectiveness of other compounds in animal models for various indications, including TB and fungal diseases. We are able to coordinate the development of simultaneous treatment programs using DB289 by building on the results of our Phase II safety and efficacy trials to initiate a Phase III study in African sleeping sickness, a Phase IIb study in malaria and a Phase III study in PCP. The dosage and treatment regimen for indications vary in each trial; however, our safety data from Phase I and Phase II trials of DB289 for treatment of African sleeping sickness, malaria and PCP have allowed us to expedite development of the aromatic cation technology platform for clinical use.

Malaria

Malaria is the second most common infectious disease in the world and is a significant problem for over 2.6 billion people exposed to this mosquito-borne disease. Each year an estimated 300 to 500 million new clinical cases of malaria occur globally that result in 1.5 to 2.0 million deaths. It is estimated by the WHO that over a million children infected with malaria die in Africa every year; one child every 30 seconds. The Global Fund to Fight AIDS, Tuberculosis and Malaria, and The Medicines for Malaria Venture ("MMV"), both foundations

supported by The Bill and Melinda Gates Foundation ("The Gates Foundation"), are supporting the development of new oral drugs and combination therapies for the safe and effective treatment of patients with common and drug-resistant forms of malaria.

On November 26, 2003, we entered into a Testing Agreement with MMV 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 human clinical trials, and drug development activities of DB289 alone and in combination with other anti-malarial drugs, with the goal of obtaining FDA or equivalent 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 the treatment of malaria. MMV has agreed pursuant to the terms of the Testing Agreement to pay to obtain regulatory approvals for DB289 from at least one internationally accepted regulatory agency 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.

During the twelve months ended March 31, 2005, the Company received for its efforts related to the Testing Agreement with MMV and UNC approximately $2.4 million. The Company recognized revenues and expenses of approximately $2.3 million during the twelve month period ended March 31, 2005 related to activities within the scope of the Testing Agreement.

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, synthesize and optimize a new series of aromatic cationic compounds in order to identify a second generation drug for treating advanced cases of malaria. Immtech is a third party beneficiary of the Discovery Agreement and, pursuant to the terms of the Consortium Agreement (defined below), has a worldwide license and exclusive right to commercialize the discoveries resulting therefrom.

Clinical Trials Using DB289 for Malaria Treatment

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. For purposes of this study, patients were considered to be "cured" if patients remained free of malaria parasites at 28 days after the start of treatment. All 32 patients 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 monitored for 28 days after the start of treatment to ensure that the malaria parasite had been eliminated.

Out of the 32 patients in the Phase IIa malaria trial, nine were infected with Plasmodium vivax and 23 were infected with Plasmodium falciparum (the most deadly form of malaria

contracted by humans). 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 96% (22 of 23 patients) eliminated the original malaria parasite (and were considered to be cured). Blood samples taken from two of the patients on the 28th day after the start of the treatment program contained malaria parasites but, after more extensive testing of the genetics of the parasites, an independent third party concluded that one of the

two failed patients had cleared the original malaria parasite but had been infected with a new malaria infection. Nine P. vivax patients were treated with DB289 for five days followed by oral Primaquine (a drug 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 after the start 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.

In May 2005, we commenced enrollment in a Phase IIb clinical trial of DB289 for the treatment of uncomplicated P. falciparum malaria. This study is being conducted in Thailand and we have targeted to enroll approximately 120 patients. The study is designed to compare the effectiveness of various three-day dose regimens of DB289 given alone (as mono-therapy) and in combination with artesunate (a drug for treating malaria that is derived from the artemisia plant). For comparison purposes, a separate control group will receive a combination of the drugs artesunate and mefloquin which is a standard treatment for malaria in Thailand. All patients will be treated and then monitored for 28 days.

The patients who participate in the malaria trial will be randomly assigned to groups, each of which will be treated for three days using different dose regimens of DB289; patients will receive either 200 mg of DB289 once per day, either alone or in combination with artesunate, or 100 mg of DB289 twice per day. The patients' blood samples will be evaluated for parasites in the prescreening process to establish a baseline and checked at regular times for the three days of therapy, and then periodically until the 28th day of the study. For purposes of this study, patients will be considered "cured" if the malaria parasites are eliminated 7 days after the start of therapy and do not recur within 28 days after the start of treatment. A separate control group will receive a standard combination therapy regimen and the results from that group will be compared to the patients treated with DB289.

Clinical Trial	Trial Design	End Points	Sites/Size
DB289 alone and in combination with artesunate for the treatment of malaria	o Phase IIb o DB289 alone and in combination with artesunate o Randomized open label o Oral dosing for 3 days	o Parasite clearance o Potential drug interactions between DB289 and artesunate o Safety o Rate of clinical improvement o Comparison to control group	Thailand - approximately 120 patients

A related Phase I study conducted in late 2004 in Paris, France evaluated the potential for increased dosing of DB289 for a shortened time period of three days. In this study we analyzed the pharmacokinetics of DB289 in 54 healthy volunteers (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). We enrolled people from African, Asian and Caucasian populations to evaluate the differences between once per day and twice per day dosing, with

doses ranging from 200 mg to 600 mg per day for three days. The data from this trial indicated that DB289 dosed at 200 mg once per day reached blood levels that are expected to have a therapeutic effect in treating malaria in three days. This shortened treatment period (3 days vs. 5 days) and once daily dosing is expected to increase compliance with a prescribed treatment regimen by malaria patients.

Pneumocystis pneumonia

Pneumocystis pneumonia ("PCP") is a fungus that overgrows the air sacs in the lungs of those whose immune system has been suppressed, causing a potentially life-threatening pneumonia. PCP was previously know as Pneumocystis carinii pneumonia and is now called Pneumocystis jiroveci pneumonia. PCP is one of the most common opportunistic infections in HIV/AIDS patients. Other populations susceptible to PCP include patients on chemotherapy, those undergoing transplant surgery, elderly patients and infants. An estimated 40 million adults and children are afflicted with PCP worldwide.

In 2002, we received approval from the FDA and the Ministry of Health in Peru to commence a pilot Phase II clinical trial of DB289 to treat Pneumocystis pneumonia. All patients had acquired immune deficiency syndrome ("AIDS") and had failed standard therapy for PCP prior to enrollment in the trial. Two dosing regimens were studied in this trial; the first 8 patients received 50 mg of DB289 twice per day for 21 days; subsequently 27 patients received 100 mg of DB289 twice per day for 21 days.

Preliminary results demonstrated that the clinical signs and symptoms of PCP improved in all patients treated with DB289 and DB289 was well tolerated, with no significant adverse events reported, other than one determined by the principal investigator to not be related to the administration of DB289. No patient was given further treatment for PCP during the trial, which included a 3 week follow-up period after completing the 21 day DB289 treatment. Patients treated with the higher dosage regimen generally showed faster symptom improvement and required a shorter time to achieve a steady state of drug concentration in the blood. Based on these results, the higher dosage regimen will be used in the upcoming Phase III trial described below.

Within the next several months, we plan to initiate a pivotal Phase III clinical trial program using DB289 to treat PCP in North and South America, including the United States. Designed as a comparative trial against the current standard of care, trimethoprim-sulfamethoxazole, the program's objectives are to show that DB289 has similar efficacy and tolerability. Our current clinical trial protocol for testing of DB289 for the treatment of PCP is set forth below:

Clinical Trial	Trial Design / Phase	End Points	Sites/Size
o DB289 for the treatment of PCP	o Phase III pivotal o Oral dosing of DB289 for 14 days o Twice daily dosages of 100 mg of DB289 o Randomized and double-blind	o Efficacy of clinical cure o Safety and tolerability o Improvement in clinical symptoms o Comparison to current standard of care	o North and South America, including U.S. and Peru o Approximately 270 patients

If we meet the designated end points in our Phase III pivotal trial, we plan to submit a New Drug Application, or NDA, to the FDA (or similar applications with regulatory agencies in foreign countries) for approval of DB289 to treat PCP. If and when marketing approval is received, we expect to sell DB289 for the treatment of PCP both in the United States and other countries.

African Sleeping Sickness (Human trypanosomiasis)

African sleeping sickness is a parasitic disease that is spread by tsetse flies in sub-Sahara Africa. Doctors Without Borders estimates that the geographical range in sub-Sahara Africa where human African sleeping sickness occurs encompasses 36 countries, where more than 60 million people are at risk of contracting the disease. WHO estimates that there are 300,000 to 500,000 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-Sahara region of Africa which includes the countries of Angola, Sudan, Uganda and the Democratic Republic of the Congo ("DRC"). Existing treatments for African sleeping sickness can be highly toxic and cannot be administered orally. African sleeping sickness is fatal if left untreated.

Our clinical trials of DB289 to treat African sleeping sickness are being conducted under an Investigational New Drug ("IND") application with the FDA. On April 23, 2004, the FDA granted "Fast-Track" drug development designation to use DB289 to treat human African sleeping sickness. We believe our studies have demonstrated DB289's potential to safely and effectively treat this life-threatening disease for which no other oral treatment exists, without the serious side-effects associated with alternative (non-orally deliverable) therapies. We believe 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. There is no guarantee, however, that fast-track designation will result in faster product development or impact the likelihood and timing of product approval.

We believe our studies demonstrate that DB289 can be used to treat human African sleeping sickness without the serious side-effects associated with pentamidine, the primary treatment currently in use in Africa. Pentamidine is the current standard therapy for treatment of African sleeping sickness which is generally administered by intramuscular injection by medical personnel in hospital or clinic facilities. The oral administration 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 therapies is limited.

In September 2002, we completed an open-label, non-controlled Phase IIa study of DB289 in the DRC to treat 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). Clearance of the parasite at the end of treatment testing was the primary endpoint for this study. Patients evaluated at three and six months after treatment remained parasite free with two relapses detected. Follow-up testing for this trial was completed in March 2005, with a cure rate of 76% at 24 months after treatment, the secondary

endpoint for the study. Based upon the promising early 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 phase of a multi-phase, multi-site Phase II/III randomized human clinical trial to treat African sleeping sickness with DB289, initially designed to enroll 350 people. The first phase of the study included the testing of 81 patients who were administered twice daily dosing of 100 mg of DB289 for five days. Half the patients in this phase of the study received DB289 and half the patients received pentamidine intramuscular injections (standard first line therapy). The clinical trial was conducted in two sites in Maluku and Vanga in the DRC. Patient monitoring included EKG monitoring, blood sampling to check clinical chemistry and hematology parameters and various other clinical measurements and tests, including the clearance of parasites from blood, lymph nodes and cerebrospinal fluid ("CSF", a fluid that surrounds the brain and spinal cord). In February 2004 treatment of the first 81 patients was completed. The results from the initial 81 patients continued to show DB289 to be well tolerated with a favorable safety profile. At the Vanga site 5 patients treated with DB289 for 5 days did not clear the parasite from their lymph nodes and received additional treatment. The patients have completed the 12 month follow-up testing without any recurrence of the disease, while 1 of the 41 patients treated with pentamidine has experienced a relapse of the disease.

Based on this information, the 30 patients in the second phase of the trial were administered DB289 for 10 days (twice daily at 100 mg per dose); twice the duration of the prior treatment regimen. All 30 patients cleared the African sleeping sickness parasite at the end of the treatment period and those returning for testing at the 3-month follow-up, which is the primary endpoint for the trial, remained disease free. No untoward adverse events were reported. Medical investigators will continue to monitor the patients at 6, 12, 18 and 24 month follow-up evaluations to check for any recurrence of the disease. No additional patients are to be enrolled in this trial.

For the Phase III pivotal study we plan to open additional clinical sites, two in the DRC, one in Angola and one or two in south Sudan where we intend collectively with the two original sites to enroll 250 patients. We expect that this study will provide the appropriate efficacy and safety data required to support regulatory approval to use DB289 to treat stage 1 African sleeping sickness.

The Phase III pivotal clinical trial design for using DB289 to treat human African sleeping sickness has been established under a Special Protocol Assessment with the FDA, which means the clinical trial protocol has been reviewed and agreed to by the FDA prior to the

start of the trial. In addition, in light of the potential benefit of using DB289 to treat African sleeping sickness, the FDA has approved the inclusion of pregnant women, nursing mothers and children into our Phase III clinical trial. The trial design is set forth below:

Clinical Trial	Trial Design / Phase	End Points	Sites/Size
o DB289 to	o Phase III pivotal	o Clearance of parasite	o Democratic

treat human trypanosomiasis	o Oral dosing for 10 days (100 mg twice a day) o Randomized comparison to pentamidine	from blood, lymph nodes and CSF after treatment and 12 and 24 months post-treatment o Safety and tolerability of DB289 compared to pentamidine	Republic of the Congo, Angola and Sudan o Approximately 250 patients, including pregnant women, nursing mothers and adolescents 12 and older

We plan to submit a New Drug Application, or NDA, to the FDA (or similar applications with regulatory agencies in foreign countries) for approval of DB289 to treat African sleeping sickness and to apply for an Accelerated Approval of our NDA (or similar accelerated approval under the foreign regulatory programs), if we meet the designated end points in our Phase III pivotal trial. The FDA has indicated that it would consider a NDA for DB289 to treat African sleeping sickness upon submission of safety and efficacy data at the 12 month end point. Typically, if approval is based upon Accelerated Approval or a similar accelerated approval program, continued testing through the 24 month post-treatment program is required to validate the surrogate endpoints used in the trial. Additional studies, including a clinical Phase IV trial may also be required. The clinical data and the parasitological cure rate at the follow-up testing at 12 months post-treatment will be submitted to the FDA in support of Accelerated Approval and the data from the 24 month post-treatment testing will be the primary endpoint in support of final approval. 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 as a WHO Recommended Drug, and be included on their Essential Medicines List. We believe inclusion of DB289 as a WHO Recommended Drug and inclusion on the Essential Medicines List will enable us to sell DB289 to treat African sleeping sickness, while continuing to perform any required post-approval studies. The WHO generally accepts marketing approvals from drug regulatory agencies in the United States, UK, European Union and Japan as well as other countries with established regulatory agencies.. In addition to becoming a WHO Recommended drug and/or inclusion on the WHO Essential Medicines List, the distribution of pharmaceutical drugs in sub-Sahara Africa requires individual approval from each country where the drugs are sold. Once approved, we intend to approach certain governmental and charitable agencies to offer to sell DB289 for distribution in the sub-Sahara nations. We anticipate six to nine 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.

Funding for African sleeping sickness research and clinical trials

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-Sahara Africa. The research group led by UNC includes Immtech and, in addition to UNC, five other universities and research centers around the world that collectively

employ scientists and physicians considered to be the foremost experts in one or both of these diseases.

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 agreed to pay to us up to $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. 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 to treat African sleeping sickness.

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 DB289 to treat African sleeping sickness into the pivotal multi-phase, multi-site 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. Under the Clinical Research Agreement, approximately $1.0 million of the additional grant was paid to us in June 2003 and approximately $1.4 million on March 14, 2005 (approximately $1.4 million of the of the $3.0 million March 14, 2005 payment described below was attributable to our services under the additional grant).

In the aggregate, we have received The Gates Foundation grant funds under the Clinical Research Subcontract as follows: (a) $4.3 million was paid to us in fiscal year 2001 to fund Phase II clinical trials to test DB289's effectiveness against African sleeping sickness in approximately 30 patients, (b) approximately $1.4 million was paid to us in September 2002 upon the successful completion of our Phase IIa clinical trial, (c) approximately $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, (d) approximately $1.0 million in June 2003 relating to the additional grant for improving drug synthesis and formulation and (e) approximately $3.0 million was paid to us on March 14, 2005 (a portion of which was from the additional acceleration grant described above) 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 extended by mutual agreement or terminated for a material breach by either party. Through March 31, 2005, we have received approximately $11.7 million under sub-contracts with UNC for the development of DB289 to treat African sleeping sickness. We and our research partners are working with our funding sources to develop next steps and to endeavor to secure an increase in funding to advance the development of a treatment for African sleeping sickness.

During the year ended March 31, 2005 the Company received approximately $3.0 million under the clinical research subcontract. Approximately $3.6 million was utilized for clinical and research purposes conducted and expensed during the twelve month period ended March 31, 2005.

Antifungal Program

In collaboration with the Company's scientists, Scientific Consortium scientists have identified several aromatic cationic compounds with the

potential to treat both Candida and Aspergillus infections, which account for a significant percentage of all systemic fungal infections. In vitro studies have identified 5 dications that display broad based antifungal activity against each of Candida, Aspergillus and Cryptococcus fungi. Additional compounds were reactive specifically against Candida fungi and Aspergillus fungi. We are currently formulating larger quantities of our lead compounds for in vivo testing of systemic fungal infection in animal models of Candida and Aspergillus. We believe that the results from these studies will enable us to select in calendar 2005 a compound to advance into preclinical studies required prior to human trials.

The market for an effective antifungal drug was estimated by DataMonitor in 2003 to be approximately $4.0 billion annually and growing 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 a patient 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 rapidly lead to 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.

Tuberculosis Program

Mycobacterium tuberculosis ("TB") is the world's number one killer among infectious diseases, causing 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, or one-third of the world's population, are infected with TB, including 10 to 15 million people in the U.S. The combination of the rapid spread of TB and the appearance of multi-drug resistant ("MDR") strains of the TB organism make TB a major health threat throughout the world. 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 its most threatening disease and an alarming increase in MDR TB cases is also developing in the United States. TB is a difficult infection to treat because the bacteria that cause the disease can "hide" inside white blood cells where they are protected against antibiotic drugs.

WHO and the National Institutes of Health ("NIH") have increased research efforts to discover new drugs to treat TB. Their research is focused on developing oral drugs that are effective against MDR strains of TB and the creation of therapies to shorten the treatment period

required to cure the disease. Their overall target is to reduce the current nine-to eighteen-month treatment period to two to six months.

In collaboration with the NIH laboratories and Dr. Scott G. Franzblau of the University of Illinois at Chicago ("UIC"), we have screened nearly 800 of our dication compounds for potential drug candidates to treat TB. Of the 50 compounds showing favorable activity, 5 dications showed in vitro activity comparable or superior in performance to drugs currently available to treat TB. Prodrug analogs of several lead compounds have been synthesized and will be tested for in vivo activity. Several new compounds with positive in vitro activity will be tested in in vivo models of TB. In addition, animal pharmacologic and toxicity studies will be used to determine dose level and

safety of drug candidates. We believe that the results from these tests will enable us to select in calendar 2005 a compound to advance into preclinical studies required prior to human trials.

Cancer Program

Hundreds of our aromatic cationic compounds have been screened by the National Cancer Institute of the NIH for activity against 64 different cancer cell lines in tissue culture studies. Thirty-eight compounds were identified as having promising activity against certain cancers including lung, breast, prostate or colon cancer and were referred for further evaluation in in vivo models.

Additional studies with aromatic cations have identified several of our compounds that form "stacked dimers" which can interact with specific DNA sequences that control gene expression. These compounds may offer significant potential for the development of a novel class of therapeutics that could be used to treat cancer.

We have previously provided CombinatoRx, Inc. of Boston, Massachusetts, under a confidentiality, material transfer and testing agreement, certain of our aromatic cationic compounds, including DB289 and DB75, for testing for activity against certain cancers. Prior to our supply of compounds to CombinatoRx for testing, CombinatoRx tested various combinations of drugs not normally associated with cancer treatments for effectiveness against cancer and had promising results. Several of our aromatic dication compounds have similar medicinal properties to those used by CombinatoRx in its earlier tests.

Other Programs and Trials

Malaria - We are planning a clinical trial designed to study the use of DB289 as a prophylaxis (drug used for prevention) for those traveling to malaria-endemic regions. The market for a malaria prophylaxis includes approximately 125 million international travelers who visit malaria-endemic regions each year. In addition, we are completing preclinical studies required prior to conducting human clinical trials of DB289 for the treatment of malaria in children and pregnant women.

Three other indications - neurological disorders, diabetes and hepatitis C - are therapeutic areas for which we believe our aromatic cation technology platform is appropriate and promising. In addition, recent research indicates that the aromatic cation compounds may be

useful as small molecule drugs that can potentially selectively control gene expression and provide treatment for microbial infections, cancer and disorders of genetic origin.

C. Technology

Aromatic Cation Compounds

Our pharmaceutical program focuses on the development and commercialization of oral drugs to treat fungal, parasitic, bacterial and viral diseases and certain other disorders. Aromatic dications are molecules having two positively charged ends that are held together by a linker; at the atomic level, they look like molecular barbells. Our portfolio of compounds also includes a subclass of aromatic compounds containing a single positive charge (monocations). Certain aromatic monocations have been found to have excellent

activity against specific targeted diseases, most notably viral diseases.

One mechanism of action of many of our compounds involves binding to segments of deoxyribonucleic acid ("DNA"). Aromatic cation drugs bind in the minor groove of DNA and in so doing, interfere with the activity of enzymes needed for microbial growth. The composition of the dications, with positive charges on the ends and linkers of different length, shape, flexibility and curvature, allows binding to specific sites of the DNA or other receptors, interfering with key biochemical processes fundamental to microbe growth and development.

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, and is therefor difficult and costly to administer outside of a hospital setting. In addition, due to its narrow dosage margin between safety and toxicity, it needs to be administered by a person trained in the use and administration of drugs.

Scientists at UNC discovered that much of pentamidine's toxicity was the result of bi-products formed when the drug is metabolized, or breaks down within the body. This discovery led to the design of new compounds which do not metabolize in the same way. Additional modifications to the structures of these compounds improved their binding activity and enhanced the applicability of this new class of antimicrobial agents as new drugs.

Scientific Consortium members have thus far designed and synthesized over 2,300 well-defined aromatic cationic compounds. Many of the compounds have been tested in a wide variety of assays and animal models for activity against various diseases. Consortium scientists at UNC and Georgia State continue to design and synthesize cationic molecules using computer models that help predict structures that will be medicinally efficacious. One or more of the universities within the Scientific Consortium have patents covering the molecular structure of the compounds and, 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 aromatic cations for activity against specific microorganisms (using both laboratory and animal models). Our scientists have many years of experience in making aromatic cation compounds

and have developed proprietary computer models which help our scientists rationally 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 a worldwide license and exclusive right to commercialize such compounds and uses.

DB289

DB289 is an aromatic dication that utilizes prodrug oral delivery technology to deliver (via capsule or tablet pill) the active drug into blood circulation. 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 single dose study evaluated the dosage levels of DB289 for safety and pharmacokinetics. The multi-dose study was designed to evaluate the safety and pharmacokinetics of three dosage levels of DB289 administered twice a day over a period of five 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 of DB289 through the digestive system. The studies showed that DB289 passed easily through the digestive membrane and the drug was present (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 of the volunteers were similar to levels that showed positive activity in animal models in malaria, PCP and African sleeping sickness.

On May 4, 2005, we announced results of a human Phase I trial to compare the current capsule formulation with two new tablet formulations of DB289. The study, conducted in Florida in 42 healthy volunteers, tested the consistency of absorption of DB289 into the blood of each of the three formulations and any differences in absorption between the capsule and tablet formulations. Each volunteer took one 100 mg dose of each formulation, in random order, with successive doses after a seven day interval. The results showed that the pressed tablets of DB289 produced blood concentration levels similar to the capsule formulation and that the tablet formulations yielded more consistent blood levels of the drug. The tablets cost less to manufacture and are expected to be more stable and easier to ship, store and dispense in tropical climates with high temperature and humidity.

Prodrug Formulation

One of the most significant accomplishments of our research and development program was the discovery of technology to make aromatic cation drugs orally deliverable. This proprietary technology temporarily masks the positive charges of the aromatic cation, enabling it to effectively move across negatively-charged digestive barriers 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 (and then through the blood-brain barrier, if so desired) had reduced the attractiveness of aromatic cations as effective drug treatments. Our scientists

have patented prodrug synthesis methods allowing for oral delivery and making this entire class of compounds significantly more attractive for commercial development.

D. The Scientific Consortium

The Scientific Consortium responsible for the invention and development of the aromatic cation library of compounds includes scientists from UNC, Georgia State, Duke University and Auburn University.

Consortium Agreement and License

On January 15, 1997, we entered into a Consortium Agreement with UNC and a third party (to which each of Georgia State, Duke University and Auburn University agreed shortly thereafter to become a party). The Consortium Agreement provided that aromatic cations 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 license with the Scientific Consortium with regard to compounds developed on or prior to January 15, 1997 ("current compounds").

Pursuant to the Consortium Agreement, the worldwide license and exclusive right to commercialize (together with related technology and patents) to use, manufacture, have manufactured, promote, sell, distribute or otherwise dispose of any and all products based directly or indirectly on aromatic cations developed by the Scientific Consortium on or prior to January 15, 1997, was transferred by the third party to us. The January 28, 2002, License Agreement grants to us a similar worldwide license and exclusive right to commercialize discoveries covering products based on cationic technology developed by the Scientific Consortium after January 15, 1997 and incorporates the license and exclusive right to commercialize discoveries assigned to us by the Consortium Agreement. The Consortium Agreement provides us with rights to the Scientific Consortium's growing library of aromatic cationic compounds (which currently exceeds 2,300 well-defined cations) 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 aromatic cations, infectious diseases, computer modeling of cationic 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 aromatic cation technology platform. 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, 2005, we reimbursed UNC approximately $441,000 for such patent and patent-related costs, and in the past, we have reimbursed to UNC approximately $1,861,000 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.

E. Our Subsidiaries

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 1.2 million 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.

Subsequently, through a sublicense agreement, we transferred to Immtech HK the rights licensed to us under the Consortium Agreement to develop and license the aromatic cation technology platform in certain Asian countries and to commercialize resulting products. 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.

Immtech Therapeutics Limited

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.

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 $400,000 in cash. Super Insight is a British Virgin Islands company.

Immtech Life Science Limited

Immtech Life Science owns two floors of a building (the "Property") located in the Futian Free Trade Zone, Shenzhen, in the People's Republic of China. We are exploring the possibility of housing a pharmaceutical production facility for the manufacture of products here or at another location within PRC. 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 would 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 Science is a Hong Kong company.

F. Manufacturing

The Scientific Consortium

Scientific Consortium members, specifically the synthetic chemistry laboratories at Georgia State and 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 aromatic cations 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 purposes.

Third Party Sources

In October 2003, we entered into an agreement with Cardinal Health PTS, Inc. ("Cardinal Health") to develop prototype formulations of DB289 to improve oral bioavailability of DB289. Pursuant to a September 2004 agreement, once the formulation was selected, we engaged Cardinal Health to produce commercial quantities of good manufacturing practices ("GMP") grade DB289 tablets with drug product to be produced by a third party. The tablets were used in a Phase I clinical trial that compared the bioavailability of the original capsules to the tablets produced by Cardinal Health. 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. Since February 2004, we have entered into several additional agreements with Cambrex for process optimization, analytical method development and production of scaled-up quantities of GMP grade DB289. 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.

In January 2005, we entered into an agreement with UPM Pharmaceuticals, Inc. ("UPM") for the manufacture, packaging and labeling of GMP grade tablets of DB289 for clinical trials (including the Phase III trials for PCP and African sleeping sickness), as well as continued formula optimization and method validation testing. UPM has previously conducted analytical method validation and stability studies for us, as well as manufacturing supplies for clinical trials. UPM is a leading provider of contract drug development, manufacturing, analytical and regulatory services. UPM provides formulation, cGMP manufacturing, clinical trial materials, analytical testing and related regulatory documentation for pharmaceutical companies.

Our China Facility

See disclosure above under the heading "Immtech Life Science Limited". The Property is located in a mixed-use office park and is suitable for administrative offices and research and development facilities, as well as potentially housing a pharmaceutical production facility capable of producing up to 10 tons of drug product per year. In addition, we have begun the site

selection process to find a location in PRC for a manufacturing plant capable of producing up to 60 tons of GMP quality drug product per year. Depending on a variety of factors, we may elect not to develop the Property or may use the Property as a finishing and packaging facility rather than as a manufacturing plant.

G. Strategy

Our strategy is to develop and commercialize a pipeline of new oral drugs to treat infectious diseases and other disorders utilizing a proprietary library of aromatic cation compounds. 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 the treatment of infectious diseases have been brought to market during this period.

New drugs are needed to overcome the health risks of multi-drug resistant pathogens and the increasing number of new pathogens that are causing disease. We are developing a new paradigm focused on reducing the time and cost to develop drugs aimed at solving global health issues.

Our pipeline of drug development activities includes programs in fungal diseases and tuberculosis. We expect during this calendar year to select a drug candidate for the treatment of fungal infections and for tuberculosis and to begin preclinical safety and pharmacology studies required prior to human trials. In addition, we have evidence that our compounds may be useful in treating bacterial infections, as well as potentially being effective in the treatment of cancer.

Three other indications - neurological disorders, diabetes and hepatitis C - are therapeutic areas for which we believe our aromatic cation technology platform is appropriate and promising. In addition, recent research indicates that the aromatic cation compounds may be useful as small molecule drugs that can potentially selectively control gene expression and provide treatment for microbial infections, cancer and disorders of genetic origin.

We believe we have been successful in developing a drug with a low toxicity profile that is orally available using our aromatic cation platform 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 are advancing our pipeline in both antifungal and TB drugs, and continue to pursue other attractive therapeutic opportunities.

We intend to proceed with the development and commercialization of aromatic cations (which include dications) as drug products pursuant to our agreement with the Scientific Consortium as follows:

- Generate revenues by sales of human drug products to commercial entities, governments, international organizations and foundations expedited through the FDA's Accelerated Approval program and/or other countries' similar programs;
- Generate additional stockholder value by developing our pipeline of drug candidates targeting fungal infections, tuberculosis and other indications;
- Conclude Phase IIb trials of DB289 for the treatment of malaria and

prepare for Phase III pivotal trial;

- Conduct a pilot study of the use of DB289 as a prophylaxis for malaria;

- Utilize the FDA's fast-track designation of DB289 for the treatment of African sleeping sickness to potentially expedite commercial sales through Accelerated Approval of our NDA or any foreign accelerated drug approval procedure;

- Conduct pivotal Phase III human clinical trial of DB289 for the treatment of Pneumocystis pneumonia (PCP);

- Develop, alone or with pharmaceutical, biotechnology or financial partners, drug development programs for the treatment of cancer and diabetes; and

- License our compounds as agents for use in animal health indications.

Our strategy is to commercialize aromatic cations and our prodrug technology and generate revenues first in niche markets by selling drugs for serious or life-threatening diseases where aromatic cations 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 believe our first product candidates demonstrate the power and versatility of the aromatic cation platform and prodrug 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 believe that our collaborations and use of grant funds enable us to minimize stockholder dilution as we advance 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 compounds which the Scientific Consortium members are developing for other indications.

H. Research and Development

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

We estimate that we have spent approximately $1.1 million, $0.9 million and $1.5 million, respectively, in fiscal years ended March 31, 2003, 2004 and 2005, on Company sponsored research and development and approximately $1.5 million, $2.4 million and $5.8 million, respectively, in fiscal years ended March 31, 2003, 2004 and 2005, on research and development sponsored by others. All research and development activity for fiscal years ended March 31, 2003, 2004 and 2005 has been in support of our pharmaceutical commercialization effort.

I. Patents and Licenses

Our pharmaceutical compounds, including DB289 and DB75, 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. Protection of our aromatic cation technology platform includes exclusive licensing rights to 222 aromatic cation patents and patent applications, 138 of which have been issued in the United States and in various global markets as of March 2005. In addition to the 222 aromatic cation 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. 148 of our licensed patents and patent applications, which includes 45 licensed U.S. patents and patent applications, were submitted after June 8, 1995, including patents covering DB289, DB75 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 several months at a minimum. 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 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.

Patents

Patents and patent applications include protection for the chemical substances and uses of pharmaceutical compounds to treat conditions related to diseases including PCP, TB, Cryptosporidium parvum, Giardia lamblia, Leishmania mexicana amazonesis, Trypanosoma

brucei rhodesienes, various fungi, Plasmodium falciparum, Alzheimer's disease, amyloidosis, Type II diabetes, 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 compounds 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 stack in a way to cover a larger section of a DNA binding site.

Patent Licenses

In accordance with the terms of the Consortium Agreement, we have obtained license rights to the patents covering the technology platform for making aromatic cationic pharmaceutical drugs and to treat certain indications with such products. As o