PROGENICS PHARMACEUTICALS INC Form S-3/A October 24, 2003 As filed with the Securities and Exchange Commission on October 24, 2003

Registration No. 333-107010

### SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# Amendment No. 2 to FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

### PROGENICS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 2834 (Primary Standard Industrial Classification Code Number) 13-3379479 (I.R.S. Employer Identification No.)

777 Old Saw Mill River Road
Tarrytown, New York 10591
(914) 789-2800
(Address, including zip code, and telephone number, including area code, of registrant□s principal executive offices)

Paul J. Maddon, M.D., Ph.D. Chairman of the Board and Chief Executive Officer Progenics Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591 (914) 789-2800

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Progenics Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591 (914) 789-2800 Hal J. Leibowitz, Esq. Hale and Dorr LLP

60 State Street Boston, Massachusetts 02109 (617) 526-6000

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

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

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

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

effective registration statement for the same offering.

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

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

#### **CALCULATION OF REGISTRATION FEE**

Amount to be Registered <sup>(1)</sup>	Proposed Maximum Offering Price Per Share <sup>(2)</sup>	Proposed Maximum Aggregate Offering Price <sup>(1)</sup>	Amount of Registration Fee
750,000	#20.2F	#1F 262 F00	\$1,235
		Amount to be Registered <sup>(1)</sup> Maximum Offering Price Per Share <sup>(2)</sup>	Amount to be Registered <sup>(1)</sup> Maximum Offering Maximum Amount to be Registered <sup>(2)</sup> Share <sup>(2)</sup> Offering Price <sup>(1)</sup>

<sup>(1)</sup> The Registration Statement as originally filed on July 14, 2003 covered the sale of 2,750,000 shares, for which a registration fee of \$3,658 was paid. This Amendment No. 2 covers an additional 750,000 shares, resulting in an additional registration fee as shown in the table.

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

<sup>(2)</sup> Estimated solely for the purpose of calculating the registration fee. Based on the average of the high and low sales price for the Common Stock on October 17, 2003.

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

#### **SUBJECT TO COMPLETION, DATED OCTOBER 24, 2003**

# PROSPECTUS SUPPLEMENT (To Preliminary Prospectus Dated October 24, 2003)

2,750,000 Shares

# Common Stock per share

We are selling 2,750,000 shares of our common stock. We have granted the underwriters an option to purchase up to 412,500 additional shares of common stock to cover over-allotments.

Our common stock is quoted on the Nasdaq National Market under the symbol [PGNX.] The last reported sale price of our common stock on the Nasdaq National Market on October 23, 2003 was \$19.30 per share.

Investing in our common stock involves risks. See  $\square$ Risk Factors $\square$  beginning on page 6 of this prospectus supplement and page 1 of the related prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the related prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total	
Public offering price	\$	<u> </u>	
Underwriting discount	\$	\$	
Proceeds to Progenics (before expenses)	\$	\$	
The underwriters expect to deliver the shares t	o purchasers	on or about	

### Citigroup CIBC World Markets Lazard

# Legg Mason Wood Walker Incorporated

Punk, Ziegel & Company

, 2003

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You should rely only on the information contained in or incorporated by reference in this prospectus supplement and the related prospectus. We have not authorized anyone to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information contained in this prospectus supplement is accurate as of any date other than the date on the front of this prospectus supplement.

This prospectus supplement is part of a registration statement that we have filed with the Securities and Exchange Commission utilizing a [shelf] registration process. Under this shelf registration process, we are offering to sell our common stock using this prospectus supplement and the related prospectus. In this prospectus supplement, we provide you with specific information about the shares of common stock that we are selling in this offering. Both this prospectus supplement and the related prospectus include important information about us, our common stock being offered and other information you should know before investing. This prospectus supplement also adds, updates and changes information contained in the prospectus. You should read both the prospectus supplement and the related prospectus as well as additional information described under [Where You Can Find More Information] on page 4 of the prospectus before investing in shares of our common stock.

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#### **SUMMARY**

After you read the following summary, you should read and consider carefully the more detailed information and financial statements and related notes that we include in and incorporate by reference into this prospectus supplement and the related prospectus. If you invest in our common stock, you are assuming a high degree of risk. See  $\square$ Risk Factors. $\square$ 

#### Progenics Pharmaceuticals, Inc.

We are a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our principal programs are directed toward symptom management and supportive care, human immunodeficiency virus, or HIV, infection and cancer. We have four product candidates in clinical development and several others in preclinical development.

Our product candidate in the area of symptom management and supportive care is methylnaltrexone, or MNTX, a compound in pivotal phase 3 clinical testing. MNTX is designed to treat the debilitating side effects of narcotic-based pain relievers, which are referred to as opioid analgesics, without interfering with pain relief. We are conducting a broad clinical development program for MNTX in a number of settings. The first three indications that we are pursuing are:

	treatment of constipation in patients with advanced medical illness who are receiving opioids;
	treatment of patients with post-operative ileus, a paralysis of the gastrointestinal tract that frequently occurs after abdominal and other major surgeries; and
sched	treatment of opioid side effects in patients with chronic pain, including those suffering from headaches, joint pain, lower-back pain, sickle-cell disease, muscle pain and other disorders. recently completed phase 2b clinical trial, MNTX induced a more regular laxation, or bowel movement, ule in opioid-treated patients with advanced medical illness. In addition, we observed a significant dependent laxation response and no evidence of breakthrough pain.

In December 2002, we began a phase 3 clinical trial of MNTX in patients with advanced medical illness, and we intend to start a second phase 3 clinical trial of MNTX for this indication later this year. Pending successful completion of these two trials and receipt of regulatory approval, we believe MNTX may be our first product candidate to be approved for marketing, which may occur as early as 2005. We are seeking a strategic collaboration with a large pharmaceutical company to support our development and commercialization efforts for MNTX. While we are engaged in discussions with several potential collaborators, these discussions are at an early stage and may not be successful.

In the area of HIV infection, we are developing viral-entry inhibitors, which are molecules designed to inhibit the virus ability to enter certain types of immune system cells. We are conducting a multi-dose phase 2 clinical trial with our lead HIV product candidate, PRO 542, a genetically engineered molecule designed to selectively target and neutralize HIV. We are also in preclinical development with PRO 140, a monoclonal antibody designed to target the HIV co-receptor CCR5. Receptors and co-receptors are structures on the surface of a cell to which a virus must bind in order to infect the cell.

In addition, we are developing immunotherapies for prostate cancer, including monoclonal antibodies directed against prostate-specific membrane antigen, or PSMA, a protein found on the surface of prostate cancer cells. We are also developing vaccines designed to stimulate an immune response to PSMA. Our PSMA programs are being conducted through PSMA Development Company LLC, our joint venture with Cytogen Corporation. We are also studying a cancer vaccine, GMK, in phase 3 clinical trials for the treatment of malignant melanoma.

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The following table summarizes the current status of our principal development programs and product candidates:

Program/Product Candidates	Indication/Use	Status
Symptom Management and Supportive Care		
MNTX	Treatment of constipation in patients with advanced medical illness who are receiving opioids	Phase 3
	Treatment of patients with post-operative ileus	Phase 2
	Treatment of opioid side effects in patients with chronic pain	Phase 1 expected to begin in 2003
HIV		
PRO 542	HIV therapy	Phase 2
PRO 140	HIV therapy	Phase 1 expected to begin in 2004
CD4 attachment inhibitors	iiiv merupy	Research
and gp41 fusion inhibitors	HIV therapy	
ProVax	HIV vaccine	Research
<b>Prostate Cancer</b> PSMA (1):		
Recombinant protein vaccine	Immunotherapy for prostate cancer	Phase 1
Viral-vector vaccine	Immunotherapy for prostate cancer	Phase 1 expected to begin in 2004
Monoclonal antibody	Immunotherapy for prostate cancer	Phase 1 expected to begin in 2004
Other		
GMK vaccine	Immunotherapy for melanoma	Phase 3
DHA	Treatment of stroke	Preclinical
Hepatitis C therapeutic	Therapy for hepatitis C virus infection	Research

<sup>(1)</sup> Programs conducted through PSMA Development Company LLC, our joint venture with Cytogen Corporation. None of our product candidates have received U.S. Food and Drug Administration, or FDA, approval, and we have not yet received any revenue from the sale of any of our product candidates. We must receive marketing approval from the FDA before we can commercialize any of our product candidates.

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#### **Business Strategy**

Our strategy is to in-license, develop and out-license innovative products for symptom management and supportive care and for the treatment and prevention of viral infections and cancer. Key elements of our strategy include:

Developing products until they are ready for significant collaborations;
 Building a large and diversified pipeline to mitigate clinical and technical risks; and
 In-licensing or acquiring additional product candidates and technologies.

#### **Our Corporate Information**

Progenics was incorporated in December 1986. Our principal executive offices are located at 777 Old Saw Mill River Road, Tarrytown, New York 10591, and our telephone number is (914) 789-2800. Our website is www.progenics.com. We do not intend for the information contained on our website to be incorporated into this prospectus supplement or the related prospectus.

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#### THE OFFERING

Common stock offered 2,750,000 shares Common stock to be outstanding after this offering 15,682,874 shares

Use of proceeds

To fund clinical trials of product candidates, expansion of manufacturing facilities, research and development, in-licensing of technology and establishment of research and development collaborations, as well as for working capital and general corporate

purposes.

Nasdaq National Market symbol **PGNX** This offering involves a high degree of risk. Risk factors See ⊓Risk Factors.⊓

The foregoing information is based on the number of shares of our common stock outstanding as of June 30, 2003. This number does not take into account as of that date:

4,590,594 shares of our common stock reserved for issuance pursuant to outstanding stock options at a weighted average exercise price of \$11.57 per share; and

2,005,081 shares of our common stock reserved for future awards under our stock plans. On July 1, 2003, we granted to employees and directors options to purchase an additional 724,500 shares of our common stock at an exercise price of \$15.06 per share.

Unless otherwise indicated, all information in this prospectus supplement assumes no exercise of the 

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#### **SUMMARY FINANCIAL INFORMATION**

(in thousands, except per share data)

	Years Ended December 31,			Six Months Ended June 30,					
		2000		2001	2002		2002		2003
<b>Statement of Operations Data:</b> Revenues:							(unau	dite	ed)
Contract research and development from joint venture Other contract research and development Research grants Product sales	\$	7,941 1,836 45	\$	199 4,916 3,725 43	\$ 5,298 194 4,544 49	\$	2,084 194 2,727 19	\$	1,903 2,166 87
Total revenues		9,822		8,883	10,085		5,024		4,156
Expenses: Research and development General and administrative Loss in Joint Venture Depreciation and amortization		13,075 5,042 945 709		14,501 6,499 2,225 707	23,761 6,484 2,886 1,049		10,433 3,009 1,108 449		11,972 3,927 1,966 613
Total expenses		19,771		23,932	 34,180		14,999		18,478
Operating loss		(9,949)		(15,049)	(24,095)		(9,975)		(14,322)
Other income (expenses): Interest income Interest expense Payment from collaborator Payment from insurance settlement		4,127 (95)		3,348 (49) 9,852	1,708 (2) 1,600		1,019		382 (6)
Total other income		4,032		13,151	 3,306		2,619		376
Net loss	\$	(5,917)	\$	(1,898)	\$ (20,789)	\$	(7,356)	\$	(13,946)
Per share amounts of net loss (basic and diluted)	\$	(0.49)	\$	(0.15)	\$ (1.66)	\$	(0.59)	\$	(1.09)
Weighted average number of common shares outstanding (basic and diluted)		12,138		12,376	12,551		12,495		12,800

June	30,	2003	

Actual	As Adjusted (1)
(unai	ıdited)

#### **Balance Sheet Data:**

Cash, cash equivalents and marketable securities

\$ 29,795 \$ 78,936

Working capital	28,056	77,197
Total assets	34,841	83,982
Total liabilities	2,451	2,451
Total stockholders∏ equity	32,390	81,531

<sup>(1)</sup> Gives effect to the sale of 2,750,000 shares of our common stock in this offering, assuming a public offering price of \$19.30 per share, and our receipt of the net proceeds after deducting the estimated underwriting discount and offering expenses. See <code>[Use of Proceeds[] and []Capitalization.[]</code>

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#### RISK FACTORS

An investment in our common stock is speculative in nature and involves a high degree of risk. In addition to the other information contained in and incorporated by reference into this prospectus supplement and the related prospectus, you should carefully consider the following risk factors in evaluating our company and its business and prospects.

#### Our product development programs are inherently risky.

We are subject to the risks of failure inherent in the development of product candidates based on new technologies. These risks include, but are not limited to, the possibility that:

	the technologies we use will not be effective;
	our product candidates will be unsafe or otherwise fail to receive the necessary regulatory approvals;
	our product candidates will be hard to manufacture on a large scale or will not be economical to market; or
effect and o Trime theraj involv succe	we do not successfully overcome technological challenges presented by our products. INTX product candidate is based on a novel method of action, which has not yet been proven to be safe or ive. Additionally, some of our HIV product candidates are designed to be effective by blocking viral entry, are GMK product candidate is designed to be a therapeutic cancer vaccine. To our knowledge, other than ris Fuzeon product, no drug designed to treat HIV infection by blocking viral entry and no cancer be be seen approved for marketing in the U.S. Our other research and development programs to similarly novel approaches to human therapeutics. Consequently, there is little precedent for the seful commercialization of products based on our technologies. We may not be able to develop successfully four products.

### If we cannot advance our products beyond the early stages of product development or demonstrate clinical efficacy, we will never commercialize a product.

Many of our products are at an early stage of development. The successful commercialization of our products will require significant further research, development, testing and regulatory approvals and additional investment. If we cannot advance our products beyond the early stages of product development or demonstrate clinical efficacy and safety, we will never commercialize a product. There are a number of technological challenges that we must overcome to complete most of our development efforts. Our products in the research or preclinical development stage may not yield results that would permit or justify clinical testing. Furthermore, products that advance to clinical testing may not be commercialized.

#### A setback in our clinical development programs could adversely affect us.

We have several ongoing late-stage clinical trials. We have an ongoing phase 3 clinical trial for MNTX and expect to commence an additional phase 3 clinical trial of MNTX in 2003. It is likely that we will need to successfully complete both of these trials in order to obtain FDA approval to market MNTX. We have also commenced a phase 2 clinical trial of MNTX for another indication and plan to commence an additional phase 1 trial involving MNTX before the end of 2003. If the results of any of these trials are not satisfactory, or if we encounter clinical trial supply issues, our MNTX development program would be adversely affected, resulting in delays in the commencement of planned trials and our regulatory filing. The need to conduct additional clinical trials or significant revisions to our clinical development plan would lead to delays in our filing for and obtaining the regulatory approvals necessary to market MNTX. Since MNTX is our most clinically advanced product, a setback of this nature would have a material adverse effect on our business.

We also have two ongoing pivotal phase 3 clinical trials for GMK. In May 2000, our collaborating research cooperative group in one of these trials, ECOG, recommended to clinical investigators participating in the trial that they discontinue administering GMK. ECOG\[ \]s decision was based on an early analysis of data which, according to ECOG, showed that the relapse-free and overall survival rates for patients receiving the GMK vaccine were lower than for patients receiving high-dose alpha-interferon. As a result of the

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actions of ECOG, that trial did not complete patient dosing as contemplated by the initial trial protocol. We are continuing to follow-up with patients who were enrolled in that trial. However, we cannot predict how long this will take or what the results will show, and we do not expect to know the results much before the first half of 2004 or later. If the results of either of the GMK trials are not satisfactory, we may need to conduct additional clinical trials or abandon our GMK program.

Additionally, if the results of our early stage studies with PRO 542, PRO 140 or our PSMA vaccine and antibody candidates are not satisfactory, we would need to reconfigure our clinical trial programs to conduct additional trials or abandon the program involved.

#### Our clinical trials could take longer to complete than we expect.

Although for planning purposes we forecast the commencement and completion of clinical trials, and have included many of those forecasts in this prospectus supplement, the actual timing of these events can vary dramatically. Delays can be caused by regulatory or patent issues, interim or final results of on-going clinical trials, scheduling conflicts with participating clinicians and clinical institutions and the rate of patient accruals. Clinical trials involving our product candidates may not commence or be completed as forecasted.

Moreover, we have limited experience in conducting clinical trials, and we rely on others to conduct, supervise or monitor some or all aspects of some of our clinical trials. In addition, certain clinical trials for our products may be conducted by government-sponsored agencies and consequently will be dependent on governmental participation and funding. We will have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own.

As a result of these and other factors, our clinical trials may not commence or be completed as we expect or may not be conducted successfully, in which event investors confidence in our ability to develop products may be impaired and our stock price may decline.

#### If testing does not yield successful results, our products will not be approved.

To achieve the results we need to obtain regulatory approval, we or our collaborators must demonstrate a product safety and efficacy in humans through extensive preclinical and clinical testing. Numerous events may arise during, or as a result of, the testing process, including the following:

_	the results of preclinical studies may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials;
	potential products may not have the desired efficacy or may have undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved;
	results attained in early human clinical trials may not be indicative of results that are obtained in later clinical trials;
_	after reviewing test results, we or our collaborators may abandon projects which we might previously have believed to be promising, some of which may be described in this prospectus supplement; and
_ 1	we, our collaborators or regulators may suspend or terminate clinical trials, if we or they believe that the participating subjects or patients are being exposed to unacceptable health risks.
	testing is very expensive and can take many years. Our failure to adequately demonstrate the safety and

#### Even if we get our products approved, they might not be accepted in the marketplace.

which could adversely affect our operating results and credibility.

The commercial success of our products will depend upon their acceptance by the medical community and third party payors as clinically useful, cost effective and safe. Even if our products obtain regulatory approval, they may not achieve market acceptance. If any of our products do not achieve market acceptance, we will likely lose

our entire investment in that product.

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#### Marketplace acceptance will depend in part on competition in our industry, which is intense.

The extent to which any of our products achieve market acceptance will depend on competitive factors. Competition in our industry is intense, and it is accentuated by the rapid pace of technological development. There are products currently in the market that will compete with the products that we are developing, including chemotherapy drugs and AIDS drugs. Many of our competitors have substantially greater research and development capabilities and experience and greater manufacturing, marketing, financial and managerial resources than we do. These competitors may develop products that are superior to those we are developing and render our products or technologies non-competitive or obsolete. If our product candidates receive marketing approval but cannot compete effectively in the marketplace, our operating results and financial position would suffer.

#### A competitor developing an opioid antagonist may reach the market ahead of us.

We are aware that Adolor Corporation, in partnership with Glaxo Group Limited, or Glaxo, a subsidiary of GlaxoSmithKline plc, is developing an opioid antagonist, alvimopan, for post-operative ileus and chronic opioid bowel dysfunction, which are currently in phase 3 clinical development, as well as for acute opioid-induced bowel dysfunction, which is currently in phase 2 trials. Alvimopan is further along in the clinical development process than MNTX. If alvimopan reaches the market before MNTX, it could achieve a significant competitive advantage relative to MNTX. In any event, the considerable marketing and sales capabilities of Glaxo may impair our ability to penetrate the market.

# If we lose our current or future collaborative partners, or if they do not apply adequate resources to our collaborations, our product development and operating results may suffer.

Our business strategy includes entering into collaborations with corporate partners, primarily pharmaceutical and other biotechnology companies, for one or more of the research, development, manufacturing, marketing and other commercialization activities relating to our product candidates. If we lose our current or future collaborative partners, or if they do not apply adequate resources to our collaborations, our product development and operating results may suffer.

The amount and timing of resources dedicated by our current or future collaborators to their collaborations with us is not within our control. If any collaborator breaches or terminates its agreements with us, or fails to conduct its collaborative activities in a timely manner, the commercialization of our product candidates could be slowed down or blocked completely. Our collaborative partners may change their strategic focus or pursue alternative technologies or develop alternative products, either on their own or in collaboration with others, as a means for developing treatments for the diseases targeted by these collaborative programs. Our revenues and earnings also will be affected by the effectiveness of our corporate partners in marketing any successfully developed products.

Our current or future collaborations may not be successful, and we may not receive any funding from them. Disputes may arise between us and our collaborators as to a variety of matters, including financial or other obligations under our contracts, the most promising scientific or regulatory route to pursue or our respective ownership of intellectual property rights. These disputes may be both expensive and time-consuming and may result in delays in the development and commercialization of product candidates.

We have experienced delays in reaching agreement with our PSMA joint venture partner, Cytogen, regarding strategic and operational matters relating to the joint venture. While we and Cytogen have established a process for reaching agreement on these matters, we might not succeed in a timely fashion, which could result in delays in advancing our PSMA programs. We describe the current state of our agreements with Cytogen regarding the joint venture in  $\square$ Management $\square$ s Discussion and Analysis of Financial Condition and Results of Operations. $\square$ 

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# If we are unable to negotiate additional collaborative agreements, our cash burn rate could increase and our rate of product development could decrease.

We intend to continue to pursue new collaborative agreements in the future. For instance, we are currently in discussions with potential strategic collaborators for MNTX. However, we may not be successful in negotiating additional collaborative arrangements. If we do not enter into new collaborative arrangements, we would have to devote more of our resources to clinical product development and product-launch activities, and our cash burn rate would increase or we would need to take steps to reduce our rate of product development.

# If we do not remedy our current failure to achieve milestones or satisfy certain conditions regarding some of our product candidates, we may not maintain our rights under our licenses relating to these product candidates.

We are required to make substantial cash payments, achieve specified milestones and satisfy other conditions, including filing for and obtaining product approvals and introducing products, to maintain our rights under our licenses, including our licenses from UR Labs, Inc., Sloan-Kettering Institute for Cancer Research and Columbia University. We may not be able to maintain our rights under these licenses. Under our license agreements relating to GMK and our HIV product candidates, including PRO 542, we are required, among other things, to have filed for marketing approval for a drug by 2000 and to commence commercialization of the drug by 2002 (for GMK) and to have filed for marketing approval by 2001 (for the HIV products). We have not achieved these milestones and are unlikely to achieve them soon. If we can establish that our failure to achieve these milestones was as a result of technical issues beyond our control or delays in clinical studies that could not have been reasonably avoided, we may be entitled under these license agreements to a revision of these milestone dates. Although we believe that we satisfy one or more of these conditions, we may become involved in disputes with our licensors as to our continued right to a license. If we do not comply with our obligations under our license agreements, the licensors may terminate them. Termination of any of our licenses could result in our losing our rights to, and therefore being unable to commercialize, any related product.

#### We have a history of operating losses, and we may never be profitable.

We have incurred substantial losses since our inception. As of June 30, 2003 we had an accumulated deficit of approximately \$60.3 million. We have derived no significant revenues from product sales or royalties, and we do not expect to achieve significant product sales or royalty revenue for a number of years, if ever. We expect to incur additional operating losses in the future, which could increase significantly as we expand development and clinical trial efforts.

Our ability to achieve long-term profitability is dependent in part on obtaining regulatory approvals for products and entering into agreements for commercialization of our products. However, our operations may not be profitable even if any of our products under development are commercialized.

#### We are likely to need additional financing, but our access to capital funding is uncertain.

Our current and anticipated development projects require substantial capital. We are likely to need substantial additional funds to conduct product development activities. We believe that the anticipated net proceeds from this offering, together with revenue from currently approved government grants and contracts and revenue from the services agreement with our joint venture with Cytogen, should be sufficient to fund our operations at least through the first half of 2005. We cannot predict with any certainty when we will need additional funds or how much we will need. Our need for future funding will depend on numerous factors, many of which are outside our control. See [Management]s Discussion and Analysis of Financial Condition and Results of Operations] as well as Note 1 of Notes to the Consolidated Financial Statements in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2003, which is incorporated by reference into this prospectus supplement.

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Our access to capital funding is uncertain. We do not have committed external sources of funding for most of our drug discovery and development projects, and we may not be able to obtain additional funds on acceptable terms, if at all. If adequate funds are not available, we may be required to:

	delay, reduce the scope of or eliminate one or more of our programs;
	obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves; or
	license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available.
If we r	raise additional funds by issuing equity securities, our current stockholders will be diluted, and new
invest	ors could have rights superior to our existing stockholders.

### We have limited manufacturing capabilities, which could adversely impact our ability to commercialize products.

We have limited manufacturing capabilities, which may result in increased costs of production or delay product development or commercialization. In order to commercialize our product candidates successfully, we or our collaborators must be able to manufacture products in commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. The manufacture of our product candidates can be complex, difficult to accomplish even in small quantities, difficult to scale-up when large-scale production is required and subject to delays, inefficiencies and poor or low yields of quality products. The cost of manufacturing some of our products may make them prohibitively expensive. If supplies of any of our product candidates or related materials become unavailable to us on a timely basis or at all or are contaminated or otherwise lost, our clinical trials could be seriously delayed, since these materials are time-consuming to manufacture and cannot be readily obtained from third-party sources.

We have constructed two pilot-scale manufacturing facilities, one for the production of vaccines and one for the production of recombinant proteins. We believe that, for these types of product candidates, these facilities will be sufficient to meet our initial needs for clinical trials. However, these facilities may be insufficient for late-stage clinical trials for these types of product candidates, and would be insufficient for commercial-scale manufacturing requirements. We may be required to expand further our manufacturing staff and facilities, obtain new facilities or contract with corporate collaborators or other third parties to assist with production.

In the event that we decide to establish a commercial-scale manufacturing facility, we will require substantial additional funds and will be required to hire and train significant numbers of employees and comply with applicable regulations, which are extensive. We may not be able to build a manufacturing facility that both meets regulatory requirements and is sufficient for our clinical trials or commercial-scale manufacturing.

We have entered into arrangements with third parties for the manufacture of some of our products. Our third-party sourcing strategy may not result in a cost-effective means for manufacturing products. In employing third-party manufacturers, we will not control many aspects of the manufacturing process, including their compliance with current Good Manufacturing Practices and other regulatory requirements. We may not be able to obtain adequate supplies from third-party manufacturers in a timely fashion for development or commercialization purposes, and commercial quantities of products may not be available from contract manufacturers at acceptable costs.

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# Manufacturing PRO 542 in amounts sufficient to support large-scale clinical trials has proven particularly difficult, which could delay clinical development.

PRO 542 is a recombinant protein, which generally involves more complex production methods than small-molecule drugs. We are pursuing alternative, potentially redundant manufacturing strategies, including expanding our internal manufacturing through mammalian cell-line fermentation, a standard recombinant manufacturing process, and more sophisticated methods, such as transgenics. Nevertheless, manufacturing PRO 542 is challenging, and these challenges could increase the cost of production, delay product development or commercialization or otherwise adversely impact our ability to commercialize PRO 542.

# We are subject to extensive regulation, which can be costly and time consuming and can subject us to unanticipated fines and delays.

We and our products are subject to comprehensive regulation by the FDA in the U.S. and by comparable authorities in other countries. These national agencies and other federal, state and local entities regulate, among other things, the preclinical and clinical testing, safety, approval, manufacture, labeling, marketing, export, storage, record keeping, advertising and promotion of pharmaceutical products. If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be subject to forced removal of a product from the market, product seizure, civil and criminal penalties and other adverse consequences.

# We do not yet have, and may never obtain, the regulatory approvals we need to successfully market our products.

None of our products have been approved by applicable regulatory authorities for commercialization. The process of obtaining FDA and other required regulatory approvals, including foreign approvals, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. We have had only limited experience in filing and pursuing applications necessary to gain regulatory approvals. The FDA may not approve any of our products under development.

Even if we obtain regulatory approval to market a product:

we might not obtain labeling claims necessary to make the product commercially viable;
we may be required to undertake post-marketing trials to verify the product□s efficacy or safety;
identification of side effects after the product is on the market or the occurrence of manufacturing problems could result in subsequent withdrawal of approval, reformulation of the product, additional preclinical testing or clinical trials, changes in labeling of the product or the need for additional marketing applications; and
we will be subject to ongoing FDA obligations and continued regulatory review. fail to receive regulatory approvals for our products, or we lose previously received approvals, our financial is would be adversely affected.

# We are dependent on our patents and proprietary rights. The validity, enforceability and commercial value of these rights are highly uncertain.

Our success is dependent in part on obtaining, maintaining and enforcing patent and other proprietary rights. The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves many complex legal and technical issues. There is no clear policy involving the breadth of claims allowed, or the degree of protection afforded, under patents in this area. Accordingly, the patent applications owned by or licensed to us may not result in patents being issued. Furthermore, issued patents may not give us an advantage over competitors with similar technology.

We own or have licenses to several issued patents. However, the issuance of a patent is not conclusive as to its validity or enforceability. The validity or enforceability of a patent after its issuance by the patent office can be

challenged in litigation. Our patents may be successfully challenged. Moreover, we may incur substantial costs in litigation to uphold the validity of patents or to prevent infringement. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to us. Moreover, third parties may avoid our patents through design innovation.

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Generally, we have the right to defend and enforce patents licensed by us, either in the first instance or if the licensor chooses not to do so. In addition, our license agreement with UR Labs regarding MNTX gives us the right to prosecute and maintain the licensed patents. We bear the cost of engaging in some or all of these activities with respect to our license agreements with Sloan Kettering for GMK, Columbia for our HIV product candidates subject to the Columbia license and UR Labs for MNTX. With most of our other license agreements, the licensor bears the cost of engaging in all of these activities, although we may share in those costs under specified circumstances. Historically, our costs of defending patent rights, both our own and those we license, have not been material.

We also rely on unpatented technology, trade secrets and confidential information. Third parties may independently develop substantially equivalent information and techniques or otherwise gain access to our technology or disclose our technology, and we may be unable to effectively protect our rights in unpatented technology, trade secrets and confidential information. We require each of our employees, consultants and advisors to execute a confidentiality agreement at the commencement of an employment or consulting relationship with us. However, these agreements may not provide effective protection in the event of unauthorized use or disclosure of this confidential information.

#### If we infringe third-party patents, we may need to alter or terminate a product development program.

There may be patent rights belonging to others that require us to alter our products, pay licensing fees or cease certain activities. If our products conflict with patent rights of others, they could bring legal actions against us claiming damages and seeking to enjoin manufacturing and marketing of the affected products. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected products. We may not prevail in any action brought against us, and any license required under any patent that we infringe may not be available on acceptable terms or at all. For example, we have filed a number of U.S. and foreign patent applications, one of which is owned jointly with the Aaron Diamond AIDS Research Center, relating to the discovery of the HIV co-receptor CCR5. We are aware that other groups have claimed discoveries similar to those covered by our patent applications. We do not expect to know for several years the relative strength of our patent position as compared to these other groups. We are aware of other intellectual property rights held by third parties that relate to products or technologies we are developing. For example, we are aware of other groups investigating PSMA or related compounds that have patents or patent applications in this area. If asserted against us, these rights could adversely affect our ability to commercialize some of our products.

The research, development and commercialization of a biopharmaceutical often involve alternative development and optimization routes, which are presented at various stages in the development process. The preferred routes cannot be predicted at the outset of a research and development program because they will depend on subsequent discoveries and test results. There are numerous third-party patents in our field, and we may need to obtain a license to a patent in order to pursue the preferred development route of one or more of our products. The need to obtain a license would decrease the ultimate profitability of the applicable product. If we cannot negotiate a license, we might have to pursue a less desirable development route or terminate the program altogether.

## We are dependent on third parties for a variety of functions; these arrangements may not provide us with the benefits we expect.

We rely in part on third parties to perform a variety of functions. We are party to several agreements which place substantial responsibility on third parties for portions of the development of our products. We also in-license technology from medical and academic institutions in order to minimize investments in early research, and we enter into collaborative arrangements with certain of these entities with respect to clinical trials of product candidates. We may not be able to maintain any of these relationships or establish new ones on beneficial terms. Furthermore, we may not be able to enter new arrangements without undue delays or expenditures, and these arrangements may not allow us to compete successfully.

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# We lack sales and marketing experience, which will make us dependent on third parties for their expertise in this area.

We have no experience in sales, marketing or distribution. If we receive required regulatory approvals, we expect to market and sell our products, including MNTX, principally through distribution, co-marketing, co-promotion or licensing arrangements with third parties. We may also consider contracting with a third party professional pharmaceutical detailing and sales organization to perform the marketing function for our products. We currently do not have a marketing partner for MNTX. To the extent that we enter into distribution, co-marketing, co-promotion, detailing or licensing arrangements for the marketing and sale of our products, any revenues we receive will depend primarily on the efforts of these third parties. We will not control the amount and timing of marketing resources these third parties devote to our products. In addition, if we market products directly, significant additional expenditures and management resources would be required to develop an internal sales force. We may not be able to establish a successful sales force should we choose to do so.

#### If we lose key management and scientific personnel on whom we depend, our business could suffer.

We are dependent upon our key management and scientific personnel. In particular, the loss of Dr. Maddon, our Chairman, Chief Executive Officer and Chief Science Officer, or Mr. Prentki, our President, could cause our management and operations to suffer. We have an employment agreement with Mr. Prentki, the initial term of which runs through March 2004, subject to automatic annual extensions unless either party provides six months prior notice of termination. Dr. Maddon semployment agreement expired in December 2002, and we are currently negotiating a new employment agreement with him. Employment agreements do not, however, assure the continued employment of an employee. We maintain key-man life insurance on Dr. Maddon in the amount of \$2.5 million.

Competition for qualified employees among companies in the biopharmaceutical industry is intense. Our future success depends upon our ability to attract, retain and motivate highly skilled employees. In order to commercialize our products successfully, we may be required to expand substantially our personnel, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development and marketing. We may not be successful in hiring or retaining qualified personnel.

# If we are unable to obtain sufficient quantities of the raw and bulk materials needed to make our products, our product development and commercialization could be slowed or stopped.

We currently obtain supplies of critical raw materials used in production of MNTX and GMK from single sources. In particular, we rely on single-source third-party manufacturers for the supply of both bulk and finished form MNTX. However, we do not have long- term contracts with any of these suppliers. In addition, commercialization of GMK requires an adjuvant, QS-21, available only from Antigenics, Inc. We have entered into a license and supply agreement with a subsidiary of Antigenics pursuant to which they agreed to supply us with all of our QS-21 requirements for use in certain ganglioside-based cancer vaccines, including GMK. Our existing arrangements may not result in the supply of sufficient quantities of MNTX or QS-21 needed to accomplish our clinical development programs, and we may not have the right or capability to manufacture sufficient quantities of these products to meet our needs if our suppliers are unable or unwilling to do so. Any delay or disruption in the availability of raw materials would slow or stop product development and commercialization of the relevant product.

### A substantial portion of our funding comes from federal government grants and research contracts. We cannot rely on these grants or contracts as a continuing source of funds.

A substantial portion of our revenues to date has been derived from federal government grants and research contracts. In addition to previous years wards, in 2002 we were awarded, in the aggregate, approximately \$5.6 million in National Institutes of Health grants and research contracts. We cannot rely on grants or additional contracts as a continuing source of funds. The government obligation to make payments under grants is subject to appropriation by the U.S. Congress for funding in each year. Moreover, it is possible that Congress or the government agencies that administer these government research programs will decide to scale back these programs or terminate them. Consequently, the government may not award grants or research contracts to us in the future, and any amounts that we derive from grants or contracts may be less than those received to date.

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# If health care reform measures are enacted, our operating results and our ability to commercialize products could be adversely affected.

In recent years, there have been numerous proposals to change the health care system in the U.S. and in foreign jurisdictions. Some of these proposals have included measures that would limit or eliminate payments for medical procedures and treatments or subject the pricing of pharmaceuticals to government control. In some foreign countries, particularly countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In addition, as a result of the trend towards managed health care in the U.S., as well as legislative proposals to reduce government insurance programs, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drug products. Consequently, significant uncertainty exists as to the reimbursement status of newly approved health care products.

If we or any of our collaborators succeeds in bringing one or more of our products to market, third-party payors may establish and maintain price levels insufficient for us to realize an appropriate return on our investment in product development. Significant changes in the health care system in the United States or elsewhere, including changes resulting from adverse trends in third-party reimbursement programs, could have a material adverse effect on our operating results and our ability to raise capital and commercialize products.

# We are exposed to product liability claims, and in the future we may not be able to obtain insurance against these claims at a reasonable cost or at all.

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We may not be able to avoid product liability exposure. If a product liability claim is successfully brought against us, our financial position may be adversely affected.

Product liability insurance for the biopharmaceutical industry is generally expensive, when available at all. We have obtained product liability insurance in the amount of \$5.0 million per occurrence, subject to a deductible and a \$5.0 million aggregate limitation. In addition, where local statutory requirements exceed the limits of our existing insurance or where local policies of insurance are required, we maintain additional clinical trial liability insurance to meet these requirements. Our present insurance coverage may not be adequate to cover claims brought against us. In addition, some of our license and other agreements require us to obtain product liability insurance. Adequate insurance coverage may not be available to us at a reasonable cost in the future.

We handle hazardous materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business. If we are involved in a hazardous waste spill or other accident we could be liable for damages, penalties or other forms of censure.

Our research and development work and manufacturing processes involve the use of hazardous, controlled and radioactive materials. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials. Despite precautionary procedures that we implement for handling and disposing of these materials, we cannot eliminate the risk of accidental contamination or injury. In the event of a hazardous waste spill or other accident, we could be liable for damages, penalties or other forms of censure.

In addition, we may be required to incur significant costs to comply with environmental laws and regulations in the future or we may be materially and adversely affected by current or future environmental laws or regulations.

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Our stock price has a history of volatility. You should consider an investment in our stock as risky and invest only if you can withstand a significant loss.

Our stock price has a history of significant volatility. Between January 1, 2001 and June 30, 2003, our stock price has ranged from \$30.00 to \$3.82 per share. At times, our stock price has been volatile even in the absence of significant news or developments relating to us. Moreover, the stocks of biotechnology companies and the stock market generally have been subject to dramatic price swings in recent years. Factors that may have a significant impact on the market price of our common stock include:

	the results of preclinical studies and clinical trials involving our products or those of our competitors;
	announcements of technological innovations or new commercial products by us, our collaborators or our competitors;
	developments in our relationships with collaborative partners;
	developments in patent or other proprietary rights;
	governmental regulation;
	changes in reimbursement policies;
	health care legislation;
	public concern as to the safety and efficacy of products developed by us, our collaborators or our competitors;
	fluctuations in our operating results; and
	general market conditions.  this offering, our principal stockholders will still be able to exert significant influence over ers submitted to stockholders for approval.
appro togetl appro	laddon and stockholders affiliated with Tudor Investment Corporation together beneficially own or control eximately 35% of our outstanding shares of common stock. These persons, should they choose to act her, could exert significant influence in determining the outcome of corporate actions requiring stockholder eval and otherwise control our business. This could have the effect of delaying or preventing a change in ol of us and, consequently, could adversely affect the market price of our common stock.
diffic	takeover provisions may make the removal of our Board of Directors or management more cult and discourage hostile bids for control of our company that may be beneficial to our cholders.
prefe	Board of Directors is authorized, without further stockholder action, to issue from time to time shares of rred stock in one or more designated series or classes. The issuance of preferred stock, as well as provisions tain of our stock options that provide for acceleration of exercisability upon a change of control, and Section nd other provisions of the Delaware General Corporation Law could:
	make the takeover of Progenics or the removal of our Board of Directors or management more difficult;
	discourage hostile bids for control of Progenics in which stockholders may receive a premium for their shares of common stock; and
	otherwise dilute the rights of holders of our common stock and depress the market price of our common

If there are substantial sales of common stock, the market price of our common stock could decline.

Sales of substantial numbers of shares of common stock could cause a decline in the market price of our stock. Some of our stockholders are entitled to require us to register their shares of common stock for offer or sale to the public. We have filed Form S-8 registration statements registering shares issuable pursuant to our equity compensation plans. Any sales by existing stockholders or holders of options may have an adverse effect on our ability to raise capital and may adversely affect the market price of our common stock.

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#### FORWARD-LOOKING STATEMENTS

This prospectus supplement and the related prospectus and the documents we have filed with the SEC that are incorporated by reference into this prospectus supplement and the related prospectus contain forward-looking statements that involve risks and uncertainties. Any statements contained, or incorporated by reference, in this prospectus supplement and the related prospectus that are not statements of historical fact may be forward-looking statements. When we use the words ∏anticipates,∏ ∏plans,∏ ∏expects∏ and similar expressions, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. These factors include, among others, the uncertainties associated with product development, the risk that clinical trials will not commence or proceed as planned, the risks and uncertainties associated with dependence upon the actions of our corporate, academic and other collaborators and of government regulatory agencies, the risk that our licenses to intellectual property may be terminated because of our failure to have satisfied performance milestones, the risk that products that appear promising in early clinical trials do not demonstrate efficacy in larger scale clinical trials, the risk that we may not be able to manufacture commercial quantities of our products, the uncertainty of future profitability and other factors set forth more fully in this prospectus supplement and the related prospectus, including those described under the caption | Risk Factors.□

We do not have a policy of updating or revising forward-looking statements, and we assume no obligation to update any forward-looking statements contained in, or incorporated by reference into, this prospectus supplement and the related prospectus as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

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#### COMMON STOCK MARKET DATA

Our common stock is quoted on the Nasdaq National Market under the symbol <code>[PGNX.]</code> The following table sets forth for the periods indicated the high and low bid price per share of our common stock, as reported on the Nasdaq National Market. These prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

	1	High	Low		
2001 First Quarter Second Quarter Third Quarter Fourth Quarter	\$	30.00 22.74 23.25 19.55	\$ 10.00 10.31 10.37 12.96		
2002 First Quarter Second Quarter Third Quarter Fourth Quarter	\$	18.47 17.10 12.13 8.20	\$ 11.33 9.08 3.85 4.95		
2003 First Quarter Second Quarter Third Quarter Fourth Quarter (through October 23, 2003)	\$	7.75 15.80 20.35 20.84	\$ 3.82 4.38 13.08 16.75		

On October 23, 2003, the last reported sale price for our common stock on the Nasdaq National Market was \$19.30 per share. We had approximately 143 holders of record of our common stock as of October 22, 2003.

#### DIVIDEND POLICY

We have paid \$0 in dividends since our inception and presently anticipate that any earnings we record in the future will be retained for development of our business. Therefore, we do not expect to pay dividends on our common stock in the foreseeable future.

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#### **USE OF PROCEEDS**

We estimate that the net proceeds from the sale of the shares of common stock we are offering, assuming a public offering price of \$19.30 per share and after deducting the estimated underwriting discount and expenses payable by us, will be approximately \$49.1 million. If the underwriters  $\square$  over-allotment option is exercised in full, we estimate that the net proceeds from the sale of the shares of common stock we are offering will be approximately \$56.6 million.

We are offering our common stock at this time to take advantage of what we believe are favorable market conditions to increase our cash reserves in order to fund our operations. We expect to use the net proceeds from this offering:

to fund expansion of our manufacturing facilities;  to fund research and development; and for working capital and general corporate purposes. We have not identified precisely the amounts we plan to spend on each of the uses of proceeds listed above, nor have we determined the timing of these expenditures. The amounts actually expended for each purpose may vary significantly depending upon numerous factors, including:  the results of our research and development and product testing; our potential relationships with in-licensors and collaborators; changes in the focus and direction of our research and development programs; potential acquisitions; the cost of filing, prosecuting, defending and enforcing patent claims; the regulatory approval process; and manufacturing, marketing and other costs associated with commercialization of our products. We may also use a portion of the proceeds from this offering to in-license technology, establish research and development collaborations or acquire technology or companies in complementary fields. Although in the ordinary course of our business we engage in discussions regarding these types of transactions, we are not currently a party to any definitive agreement or letter of intent regarding any of these transactions.		to fund clinical trials of product candidates;
for working capital and general corporate purposes.  We have not identified precisely the amounts we plan to spend on each of the uses of proceeds listed above, nor have we determined the timing of these expenditures. The amounts actually expended for each purpose may vary significantly depending upon numerous factors, including:  the results of our research and development and product testing;  our potential relationships with in-licensors and collaborators;  changes in the focus and direction of our research and development programs;  potential acquisitions;  the cost of filing, prosecuting, defending and enforcing patent claims;  manufacturing, marketing and other costs associated with commercialization of our products.  We may also use a portion of the proceeds from this offering to in-license technology, establish research and development collaborations or acquire technology or companies in complementary fields. Although in the ordinary course of our business we engage in discussions regarding these types of transactions, we are not		to fund expansion of our manufacturing facilities;
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<ul> <li>our potential relationships with in-licensors and collaborators;</li> <li>changes in the focus and direction of our research and development programs;</li> <li>potential acquisitions;</li> <li>the cost of filing, prosecuting, defending and enforcing patent claims;</li> <li>the regulatory approval process; and</li> <li>manufacturing, marketing and other costs associated with commercialization of our products.</li> <li>We may also use a portion of the proceeds from this offering to in-license technology, establish research and development collaborations or acquire technology or companies in complementary fields. Although in the ordinary course of our business we engage in discussions regarding these types of transactions, we are not</li> </ul>	have	ave not identified precisely the amounts we plan to spend on each of the uses of proceeds listed above, nor we determined the timing of these expenditures. The amounts actually expended for each purpose may vary
changes in the focus and direction of our research and development programs;  potential acquisitions;  the cost of filing, prosecuting, defending and enforcing patent claims;  the regulatory approval process; and  manufacturing, marketing and other costs associated with commercialization of our products.  We may also use a portion of the proceeds from this offering to in-license technology, establish research and development collaborations or acquire technology or companies in complementary fields. Although in the ordinary course of our business we engage in discussions regarding these types of transactions, we are not		the results of our research and development and product testing;
<ul> <li>potential acquisitions;</li> <li>the cost of filing, prosecuting, defending and enforcing patent claims;</li> <li>the regulatory approval process; and</li> <li>manufacturing, marketing and other costs associated with commercialization of our products.</li> <li>We may also use a portion of the proceeds from this offering to in-license technology, establish research and development collaborations or acquire technology or companies in complementary fields. Although in the ordinary course of our business we engage in discussions regarding these types of transactions, we are not</li> </ul>		our potential relationships with in-licensors and collaborators;
<ul> <li>the cost of filing, prosecuting, defending and enforcing patent claims;</li> <li>the regulatory approval process; and</li> <li>manufacturing, marketing and other costs associated with commercialization of our products.</li> <li>We may also use a portion of the proceeds from this offering to in-license technology, establish research and development collaborations or acquire technology or companies in complementary fields. Although in the ordinary course of our business we engage in discussions regarding these types of transactions, we are not</li> </ul>		changes in the focus and direction of our research and development programs;
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We may also use a portion of the proceeds from this offering to in-license technology, establish research and development collaborations or acquire technology or companies in complementary fields. Although in the ordinary course of our business we engage in discussions regarding these types of transactions, we are not		the regulatory approval process; and
	devel ordin	pay also use a portion of the proceeds from this offering to in-license technology, establish research and opment collaborations or acquire technology or companies in complementary fields. Although in the ary course of our business we engage in discussions regarding these types of transactions, we are not

Pending our use of the net proceeds from this offering as described above, we intend to invest the net proceeds in short-term interest bearing, investment grade securities.

We believe that the net proceeds from this offering, together with revenue from currently approved government grants and contracts and revenue from the services agreement with our joint venture with Cytogen, should be sufficient to fund our operations at least through the first half of 2005. However, this is a forward-looking statement based on our current operating plan and the assumptions on which it relies. We may change our plans and our assumptions may turn out to be incorrect, in which event we could use up our assets before such time. We anticipate that we will seek any required additional funds from external sources, such as future offerings of equity or debt securities or agreements with corporate partners and collaborators. We may not be able to negotiate such arrangements or obtain additional funds on acceptable terms, if at all.

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#### **CAPITALIZATION**

(in thousands, except share and per share data)

The following table shows:

our actual capitalization at June 30, 2003; and

our capitalization at June 30, 2003, as adjusted to reflect our sale of 2,750,000 shares of common stock in
this offering, assuming a public offering price of \$19.30 per share and the receipt of the net proceeds

therefrom after deducting the estimated underwriting discount and offering expenses. See ∏Use of

Proceeds.□

	June 30, 2003				
		Actual	A	As Adjusted	
Cash, cash equivalents and marketable securities	\$	29,795	\$	78,936	
Stockholders equity:  Preferred stock, \$.001 par value; 20,000,000 shares authorized; no shares issued or outstanding  Common stock, \$.0013 par value; 40,000,000 shares authorized; 12,932,874 shares issued and outstanding, actual; and 15,682,874 shares issued					
and outstanding, as adjusted Additional paid-in capital Accumulated deficit Accumulated other comprehensive income		17 92,578 (60,253) 48		20 141,716 (60,253) 48	
Total stockholders□ equity		32,390		81,531	
Total capitalization	\$	32,390	\$	81,531	

The number of shares of our common stock in the actual and as adjusted columns in the table above excludes:

- ☐ 4,590,594 shares of our common stock issuable upon exercise of outstanding options at a weighted average exercise price of \$11.57 per share as of June 30, 2003; and
- 2,005,081 shares of our common stock available for future issuance under our stock option plans as of June 30, 2003.

On July 1, 2003, we granted to employees and directors options to purchase an additional 724,500 shares of our common stock at an exercise price of \$15.06 per share.

This table should be read in conjunction with our financial statements and the related notes, which are incorporated by reference into this prospectus supplement and the related prospectus.

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#### **DILUTION**

Our net tangible book value as of June 30, 2003 was \$32,390,014 or \$2.50 per share. Net tangible book value is total tangible assets less total liabilities. Net tangible book value per share is determined by dividing our net tangible book value by the number of shares of our common stock outstanding. Without taking into account any changes in our net tangible book value after June 30, 2003, other than to give effect to the proposed sale of the 2,750,000 shares of our common stock offered by this prospectus supplement at an assumed public offering price of \$19.30 per share, our net tangible book value at June 30, 2003 would have been \$81,530,514 or \$5.20 per share. This represents an immediate increase in net tangible book value of \$2.70 per share to our existing stockholders and an immediate dilution in net tangible book value of \$14.10 per share to new investors. The following table illustrates this per share dilution:

Assumed public offering price per share Net tangible book value per share as of June 30, 2003 Increase in net tangible book value per share attributable to this offering	\$ 2.50 2.70	\$ 19.30
Net tangible book value per share as of June 30, 2003 after giving effect to this offering		5.20
Dilution per share to new investors in this offering		\$ 14.10

The foregoing table assumes no exercise of outstanding options. See [Capitalization.] The exercise of options could result in further dilution to new investors.

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#### SELECTED FINANCIAL DATA

(in thousands, except per share data)

The selected financial data presented below as of December 31, 2001 and 2002 and for each of the three years in the period ended December 31, 2002 are derived from our financial statements, which are incorporated by reference in this prospectus supplement and which have been audited by PricewaterhouseCoopers LLP. The selected financial data presented below as of December 31, 1998, 1999 and 2000 and for each of the two years in the period ended December 31, 1999 are derived from our audited financial statements that are not included in this prospectus supplement. The selected financial data presented below as of June 30, 2003 and for the six months ended June 30, 2002 and 2003 have been derived from our unaudited financial statements which are incorporated by reference in this prospectus supplement and, in our opinion, reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of our financial position and results of operations. Operating results for the six months ended June 30, 2003 are not necessarily indicative of results that may be expected for any other interim period or for the year ending December 31, 2003. The data set forth below should be read in conjunction with \[ \] Management\[ \] S Discussion and Analysis of Financial Condition and Results of Operations\[ \] and the financial statements and related notes included elsewhere or incorporated by reference in this prospectus supplement.

		Years Ended December 31,											Six Months Ended June 30,				
		1998		1999		2000		2001		2002		2002	2003				
Statement of Operations Data: Revenues: Contract research and development from joint venture	\$		\$		\$		\$	199	\$	5,298	\$	2,084	\$	1,903			
Other contract research and development Research grants		11,135 1,251		14,867 1,106		7,941 1,836		4,916 3,725		194 4,544		194 2,727		2,166			
Product sales		180	_	40		45	_	43		49		19		87			
Total revenues		12,566	_	16,013		9,822		8,883	_	10,085		5,024		4,156			
Expenses: Research and development General and administrative Loss in Joint Venture Depreciation and		8,296 3,841	l	11,227 3,866 2,047		13,075 5,042 945		14,501 6,499 2,225		23,761 6,484 2,886		10,433 3,009 1,108		11,972 3,927 1,966			
amortization  Total expenses		388 12,525	_	697 17,837	_	709 19,771	_	707 23,932	_	1,049 34,180		14,999		613 18,478			
Operating income (loss)	_	41	_	(1,824)		(9,949)		(15,049)		(24,095)		(9,975)		(14,322)			
Other income (expenses): Interest income Interest expense Payment from collaborator Payment from insurance		1,455 (43)		1,440 (112)		4,127 (95)		3,348 (49) 9,852		1,708 (2)		1,019 		382 (6)			
settlement			_		_					1,600		1,600					
Total other income		1,412		1,328		4,032	_	13,151		3,306	_	2,619		376			
Net income (loss)	\$	1,453	\$	(496)	\$	(5,917)	\$	(1,898)	\$	(20,789)	\$	(7,356)	\$	(13,946)			

Cir. Months

Per share amounts on net income (loss): Basic	\$ 0.16	\$ (0.05)	\$	(0.49)	\$ (0.15)	\$ (1.66)	\$ (0.59)	\$ (1.09)
Diluted	\$ 0.14	\$ (0.05)	\$	(0.49)	\$ (0.15)	\$ (1.66)	\$ (0.59)	\$ (1.09)
Weighted average number of common shares outstanding: Basic Diluted	9,068 10,727	9,728 9,728		12,138 12,138	12,376 12,376	12,551 12,551	12,495 12,495	12,800 12,800
			9	S-21				

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#### December 31,

	1998	1999	2000	2001	2002	J	une 30, 2003	
Balance Sheet Data: Cash, cash equivalents and marketable securities Working capital Total assets Total liabilities Total stockholders equity	\$ 24,650 25,137 27,900 1,821 26,079	\$ 67,617 53,053 71,261 3,440 67,821	\$ 60,424 48,808 67,013 2,259 64,754	\$ 61,877 40,650 67,481 3,136 64,345	\$ 42,374 36,209 48,118 2,971 45,147	\$	29,795 28,056 34,841 2,451 32,390	

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# MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### Overview

We are a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. We commenced principal operations in late 1988 and since that time have been engaged primarily in research and development efforts, development of our manufacturing capabilities, establishment of corporate collaborations and raising capital. In order to commercialize the principal products that we have under development, we will need to address a number of technological challenges and comply with comprehensive regulatory requirements. Accordingly, we cannot predict the amount of funds that we will require, or the length of time that will pass, before we receive revenues from sales of any of our products.

To date, our product sales have consisted solely of limited revenues from the sale of research reagents. We expect that sales of research reagents in the future will not significantly increase over current levels. Our other sources of revenues through June 30, 2003 have been payments received under our current and former collaboration agreements and from PSMA Development Company LLC, our joint venture with Cytogen Corporation, research grants and contracts related to our cancer and HIV programs and interest income.

To date, a majority of our expenditures have been for research and development activities. We expect that our research and development expenses will increase significantly as our programs progress and we make filings for related regulatory approvals. With the exception of the years ended December 31, 1997 and 1998, we have had recurring losses and had, at June 30, 2003, an accumulated deficit of approximately \$60.3 million. We will require additional funds to complete the development of our products, to fund the cost of clinical trials, and to fund operating losses that we expect to continue for the foreseeable future. We do not expect our products under development to be commercialized in the near future.

We have a 50% interest in PSMA Development Company LLC. We were required to fund the first \$3.0 million of the joint venture s research and development costs. We recorded these amounts as capital contributions to the joint venture. During the fourth quarter of 2001, we surpassed the \$3.0 million threshold, at which time we began recognizing revenue for services and costs being provided to and paid by the joint venture. The level of future revenues from the joint venture will depend upon the extent of research and development services requested by the joint venture and the future financial position of the joint venture.

We provide services to the joint venture under a services agreement. From April 1, 2002 through June 30, 2003, we performed services for the joint venture under a month-to-month extension of the services agreement. In July 2003, we and Cytogen agreed to an updated work plan governing the activities of the joint venture for the remainder of 2003, including the execution of various third-party contracts. In addition, we and Cytogen agreed to a budget for 2003 and our respective capital contributions for the year. We and Cytogen also agreed to an amended services agreement pursuant to which the members of the joint venture will provide research and development services for the remainder of 2003. The joint venture work plan, budget and other operational and financial matters relating to periods after 2003 will require the agreement of the members of the joint venture. If we do not agree on terms for future periods, our revenues could be adversely affected.

# **Results of Operations**

#### Six Months Ended June 30, 2003 and 2002

**Revenues.** Our revenues consist of contract research and development revenue from the joint venture, revenue from other contract research and development, research grants and product sales. Contract research and development revenue from joint venture decreased to \$1,903,000 for the six months ended June 30, 2003 from \$2,084,000 for the six months ended June 30, 2002. In 2003, contract research and development revenue consisted primarily of reimbursement of labor costs expended by us on behalf of the joint venture. All other costs are paid directly by the joint venture. In 2002, contract research and development revenue included reimbursement of all of the joint venture sexpenses, which we paid. Therefore, although our

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revenue remained relatively stable, our research and development work for the joint venture actually increased.

Revenues from other contract research and development decreased to \$0 for the six months ended June 30, 2003 from \$194,000 for the six months ended June 30, 2002. The decrease resulted from the expiration of two collaboration agreements in the first quarter of 2002.

Revenues from research grants decreased to \$2,166,000 for the six months ended June 30, 2003 from \$2,727,000 for the six months ended June 30, 2002. The decrease resulted from the funding of a fewer number of grants during the 2003 period.

Revenues from product sales increased to \$87,000 for the six months ended June 30, 2003 from \$19,000 for the six months ended June 30, 2002. We received more orders for research reagents during the 2003 period.

**Expenses.** Our research and development expenses include scientific labor, supplies, facility costs, clinical trial costs, patent costs and product manufacturing costs. Research and development expenses increased to \$11,972,000 for the six months ended June 30, 2003 from \$10,433,000 for the six months ended June 30, 2002. The increase was principally due to (i) an increase of \$1,113,000 related to increased headcount in 2003 in our research and development, manufacturing and medical departments, (ii) an increase of \$186,000 in manufacturing supplies, particularly for MNTX, (iii) an increase of \$175,000 in clinical trial activity and related costs, and (iv) an increase of \$63,000 in spending on our HIV research programs.

In late 2001, we in-licensed MNTX, an investigational drug in late-stage clinical development designed to reverse certain side effects of opiod pain medications. MNTX has entered phase 3 clinical trials and has become our lead product candidate. A major portion of our spending has been and will continue to be concentrated on this product candidate.

Our general and administrative expenses include executive and administrative labor, professional fees, office rent and supplies. General and administrative expenses increased to \$3,927,000 for the six months ended June 30, 2003 from \$3,009,000 for the six months ended June 30, 2002. The increase was principally due to an increase of \$484,000 in additional professional fees specifically related to intellectual property filings and prosecutions, \$243,000 related to an increase in headcount and an increase of \$191,000 in the cost of insurance.

Loss in joint venture increased to \$1,966,000 for the six months ended June 30, 2003 from \$1,108,000 for the six months ended June 30, 2002. The increase was due to an increase in the headcount assigned to the joint venture PSMA project and the related cost of supplies. Additionally, the joint venture commenced clinical trials with one product candidate and incurred contract manufacturing expenses beginning in 2003.

Depreciation and amortization expense increased to \$613,000 for the six months ended June 30, 2003 from \$449,000 for the six months ended June 30, 2002 as we purchased new capital equipment and incurred expenses for leasehold improvements to support our growth.

Interest income decreased to \$382,000 for the six months ended June 30, 2003 from \$1,019,000 for the six months ended June 30, 2002 as cash available for investment decreased and was subject to lower interest rates in 2003.

Our net loss increased to \$13,946,000 for the six months ended June 30, 2003 from \$7,356,000 for the six months ended June 30, 2002.

### Years Ended December 31, 2002 and 2001

**Revenues.** We recognized \$5,298,000 and \$199,000 of revenue for research and development services performed for our joint venture during 2002 and 2001, respectively.

Other contract research and development revenues declined to \$194,000 in 2002 from \$4,916,000 in 2001 primarily due to a decrease in funding received from Bristol-Myers Squibb Company, after we and Bristol-Myers Squibb mutually terminated our collaboration agreement in May 2001. We received \$3,673,000 from Bristol-Myers Squibb in 2001 under the agreement and \$0 in 2002. Revenues from contract

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research and development performed for other collaborators decreased to \$194,000 in 2002 from \$1,243,000 in 2001 as our commitments for such work were completed.

Revenues from research grants increased to \$4,544,000 in 2002 from \$3,725,000 in 2001. The increase resulted from the funding of a greater number of grants in 2002. Sales of research reagents increased to \$49,000 in 2002 from \$43,000 in 2001 resulting from increased orders for such reagents during 2002.

**Expenses.** Research and development expenses increased to \$23,761,000 in 2002 from \$14,501,000 in 2001. The increase was principally due to (i) an increase of \$4,033,000 in spending on the joint venture □s PSMA project and our HIV research program, (ii) an increase of \$2,537,000 in manufacturing supplies (particularly for MNTX), (iii) an increase of \$2,292,000 related to an increase in headcount from 50 in 2001 to 70 in 2002 in the research and development, manufacturing and medical departments, and (iv) additional rent of \$303,000 for new laboratory space as we expanded our programs to include MNTX.

General and administrative expenses remained relatively unchanged at \$6,484,000 in 2002 and \$6,499,000 in 2001. The minimal decrease was principally due to a decrease of \$180,000 in professional fees offset by an increase of \$371,000 in operating expenses such as rent.

Loss in joint venture increased to \$2,886,000 in 2002 from \$2,225,000 in 2001. The increase was primarily due to the growth and acceleration of the joint venture selection development programs to develop in vivo immunotherapies for prostate cancer and the costs of licensing transactions. The increase in the joint venture loss was due to an increase in the headcount assigned to the PSMA project and the related cost of supplies. Additionally, prior to reaching the \$3.0 million threshold, we recognized 100% of the joint venture is research and development losses; that percentage was reduced to 50% subsequent to reaching that threshold in December 2001.

Depreciation and amortization increased to \$1,049,000 in 2002 from \$707,000 in 2001 as we purchased capital assets and made leasehold improvements in 2002 to accommodate expansion.

Interest income decreased to \$1,708,000 in 2002 from \$3,348,000 in 2001 as cash available for investing decreased and interest rates declined year over year.

During 2002, we received a \$1,600,000 payment from an insurance settlement related to a heat excursion in our storage facility. During 2001, we received a non-recurring payment of \$9,852,000 from Bristol-Myers Squibb in connection with the termination of our collaboration with Bristol-Myers Squibb. As a result of the termination of the collaboration, we will receive no additional payments from Bristol-Myers Squibb.

Our net loss increased to \$20,789,000 in 2002 from a net loss of \$1,898,000 in 2001.

### Years Ended December 31, 2001 and 2000

**Revenues.** We recognized \$199,000 of revenue for research and development services performed for our PSMA joint venture during 2001 and \$0 in 2000. We were required to fund the first \$3.0 million of the joint venture search and development costs. We recorded these amounts as capital contributions to the joint venture. That \$3.0 million threshold was reached in the fourth quarter of 2001. Other contract research and development revenue declined to \$4,916,000 in 2001 from \$7,941,000 in 2000. In 2001, research and development revenue included funding received from Bristol-Myers Squibb after we and Bristol-Myers Squibb mutually terminated our collaboration agreement in May 2001. We received \$3,673,000 from Bristol-Myers Squibb in 2001 under the agreement and \$6,213,000 in 2000.

**Expenses.** Research and development expenses increased to \$14,501,000 in 2001 from \$13,075,000 in 2000. The increase was principally due to increases of \$774,000 related to increased headcount, \$342,000 for additional rent for new laboratory space as we expanded our research and development programs to include MNTX in October 2001 and \$148,000 for related laboratory supplies.

General and administrative expenses increased to \$6,499,000 in 2001 from \$5,042,000 in 2000. The increase was principally due to \$795,000 related to increased headcount, an increase of \$243,000 in legal expenses related to our intellectual property filings and prosecutions and \$103,000 of additional rent for new office space to accommodate growth.

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Loss in joint venture increased to \$2,225,000 in 2001 from \$945,000 in 2000. The increase was primarily due to the growth and acceleration of the joint venture development programs to develop in vivo immunotherapies for prostate cancer and the costs of licensing transactions.

Interest income decreased to \$3,348,000 in 2001 from \$4,127,000 in 2000 as cash available for investing remained relatively constant and interest rates decreased year over year.

Interest expense decreased to \$49,000 in 2001 from \$95,000 in 2000. The decrease was principally due to the recognition of interest expense as we discounted future capital contributions to the joint venture that decreased in 2001 and reduced capital lease obligations in 2001. We also received a non-recurring payment of approximately \$9,852,000 from Bristol-Myers Squibb in connection with the termination of our collaboration with Bristol-Myers Squibb. As a result of the termination of the collaboration, we will receive no additional payments from Bristol-Myers Squibb.

Our net loss decreased to \$1,898,000 in 2001 from a net loss of \$5,917,000 in 2000.

### **Liquidity and Capital Resources**

We have funded our operations since inception primarily through two public offerings of common stock, private placements of equity securities, payments received under collaboration agreements, funding under government research grants and contracts, interest on investments, a line of credit that was repaid and terminated, and the proceeds from the exercise of outstanding options and warrants.

At June 30, 2003, we had cash, cash equivalents and marketable securities totaling approximately \$29.8 million compared with approximately \$42.4 million at December 31, 2002. The net cash used in operations for the six months ended June 30, 2003 was \$12.4 million compared with \$6.6 million of net cash used in operations for the same period in 2002. The increase in net cash used in operations for the six months ended June 30, 2003 resulted primarily from higher net losses resulting from increased research and development activity in connection with MNTX and PSMA and increased contributions to the joint venture.

The net cash provided by investing activities for the six months ended June 30, 2003 was \$16.7 million compared with \$5.2 million of net cash provided by investing activities for the same period in 2002. The net cash provided by investing activities for the six months ended June 30, 2003 resulted primarily from the net sale of \$19.4 million of marketable securities offset by the purchase of a \$2.0 million certificate of deposit and the purchase of \$676,000 of fixed assets including capital equipment and leasehold improvements as we acquired and built out additional research and development space. We expect to spend an additional \$250,000 during the balance of 2003 in connection with the installation of a new bioreactor.

Net cash provided by financing activities for the six months ended June 30, 2003 was \$1,021,000 as compared with \$859,000 of net cash provided by financing activities for the same period in 2002. The net cash provided by financing activities for both periods reflects the exercise of stock options under our employee stock option plans and the sale of common stock under our employee stock purchase plans. We incurred approximately \$165,000 of costs during the second quarter of 2003 associated with the filing of a registration statement contemplating the sale from time to time of shares of our common stock. These costs will be offset against any proceeds when and if an offering is completed.

We are required to make capital contributions to fund 50% of the current and future spending on the PSMA projects under the terms of the joint venture. This amount was \$2.3 million during the six months ended June 30, 2003. The level of commitment by Progenics and Cytogen to fund the joint venture is based on a budget requiring approval by both parties. The current budget is intended to be sufficient to fund research and development projects for 2003. The budget must also consider the ability of the members to fund the joint venture.

In September 2003, we were awarded a contract by the National Institutes of Health, or NIH, an agency of the Department of Health and Human Services, to develop an HIV vaccine. The contract provides for up to \$28.6 million in funding to us over five years. Funding under this contract is subject to compliance with its terms, and the payment of fees is subject to achievement of specified milestones. We anticipate that these funds will be used principally in connection with our ProVax HIV vaccine program.

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We provide services to the joint venture under a services agreement. For the six months ended June 30, 2003, we performed services for the joint venture under a month-to-month extension of the services agreement and a work plan and budget approved by the members. For the six months ended June 30, 2003, we recognized approximately \$1,903,000 of contract research and development revenue for services performed on behalf of the joint venture. The level of future revenues from the joint venture will be dependent upon the extent of research and development services requested by the joint venture, the future financial position of the joint venture and the extension, if any, and terms of an amended services agreement or of any new services agreement.

In July 2003, we and Cytogen: (i) agreed to an updated work plan governing the activities of the joint venture for the remainder of 2003, including the execution of various third-party contracts; (ii) agreed to a budget for the joint venture operations for 2003 and related capital contributions of the parties; and (iii) agreed to an amended services agreement pursuant to which the members will provide research and development services for the remainder of 2003. The joint venture work plan, budget, and other operational and financial matters relating to periods after 2003 will require the agreement of the members of the joint venture.

Our total expenses for research and development from inception through June 30, 2003 have been approximately \$106.8 million. We currently have major research and development programs investigating symptom management and supportive care, human immunodeficiency virus-related diseases and cancer, for which we are or have licensed technology and collaborated with other pharmaceutical and biotechnology companies as well as academic institutions. In addition, we are conducting several smaller research projects in the areas of virology and cancer. For various reasons, many of which are outside of our control, including the early stage of our programs, the timing and results of our clinical trials and our dependence on third parties, we cannot estimate the total remaining costs to be incurred and timing to complete our research and development programs. However, we expect to increase our spending on MNTX to approximately \$15.0 million in 2003 for purchases of clinical supplies and the conduct of clinical trials. We expect that our spending on other programs will remain relatively constant in 2003. For the years ended December 31, 2000, 2001 and 2002, research and development costs incurred were as follows:

	2000		2001	2002	
		(in	thousand	s)	
Cancer MNTX HIV Other programs	\$ 5,710 6,924 441	\$	4,230 9,768 503	\$	6,987 7,017 7,277 2,480
Total	\$ 13,075	\$	14,501	\$	23,761

We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity.

We believe that our existing capital resources together with revenue from currently approved government grants and contracts and revenue from the services agreement with the joint venture should be sufficient to fund operations for at least the next 12 months. During the next 12 months, we expect to expend substantial funds to conduct research and development activities, preclinical studies, clinical trials and other related general and administrative activities. Our expenditures for these activities will include required payments under operating leases and licensing, collaboration and service agreements as noted in the table below.

For periods beyond 12 months, we may seek additional financing to fund operations through the offering being made by this prospectus supplement and the related prospectus as well as other offerings of equity or debt securities or agreements with corporate partners and collaborators with respect to the development of our technologies. We also plan to seek funding from additional grants and government contracts. We cannot assure you, however, that we will be able to obtain additional funds on acceptable terms, if at all. We will require substantial funds to conduct research and development activities, preclinical studies, clinical trials and other general and administrative activities. Our expenditures for these activities

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will include required payments under operating leases and licensing, collaboration and service agreements as noted in the table below.

Our cash requirements may vary materially from those now planned because of results of research and development and product testing, changes in existing relationships with, or new relationships with, licensees, licensors or other collaborators, changes in the focus and direction of our research and development programs, competitive and technological advances, the cost of filing, prosecuting, defending and enforcing patent claims, the regulatory approval process, manufacturing and marketing and other costs associated with the commercialization of products following receipt of regulatory approvals and other factors.

Other than currently approved grants and research contracts, we have no committed external sources of capital and, as discussed above, expect no significant product revenues for a number of years, as it will take at least that much time, if ever, to bring our products to the commercial marketing stage.

The above are forward-looking statements based on our current operating plan and the assumptions on which it relies. There could be changes that would consume our assets earlier than planned.

The following table summarizes our contractual obligations as of June 30, 2003 for future operating lease payments and license and milestone payments for license and corporate collaboration agreements:

			Pay	yments d	ue b	y period	
				(in tho	usan	ıds)	Creater
	Total	ss than ne year		1 to 3 years		4 to 5 years	Greater than 5 years
Operating leases License and collaboration agreements (1)	\$ 1,600 25,500	\$ 800 6,400	\$	800 3,200	\$	5,000	\$ 10,900

<sup>(1)</sup> Assumes attainment of milestones covered under each agreement. The timing of the achievement of the related milestones is highly uncertain, and accordingly the actual timing of payments, if any, is likely to vary, perhaps significantly, relative to the timing contemplated by this table. Certain of these agreements require us to pay annually minimum royalties or maintenance fees in a maximum aggregate amount of \$500,000, which are not included in this table. This table also does not reflect the payment obligations of our joint venture with Cytogen.

Subsequent to June 30, 2003, we executed a lease for approximately 33,800 square feet of additional laboratory, manufacturing and office space in Tarrytown, New York. The base monthly rent for the lease will be approximately \$74,000 from commencement until August 31, 2007 and approximately \$79,000 from September 1, 2007 until December 31, 2009. In addition, we are negotiating to lease additional space which, together with the newly executed lease, would provide us with approximately 49,000 square feet.

### **Critical Accounting Policies**

### Revenue Recognition

We recognize revenue from contract research and development as we perform services, provided a contractual agreement exists, the contract price is fixed or determinable, and our collection of the resulting receivable is probable. In situations where we receive payment in advance of the performance of services, these amounts are deferred and recognized as revenue as we perform the related services. Non-refundable fees, including payments we receive for services, up-front licensing fees and milestone payments are recognized as revenue based on the percentage of costs incurred to date, estimated costs to complete and total expected contract revenue in accordance with EITF Issue No. 91-6, [Revenue Recognition of Long-Term Power Sale Contracts, which is a systematic method that is representative of the revenue earned or obligations fulfilled under those arrangements. However, the revenue we recognize is limited to the amount of non-refundable fees received. Non-refundable fees that we receive in consideration for granting collaborators the right to license product candidates developed by us are recognized as revenue on a straight-line basis over the term of the underlying agreements. With regard to our revenues from non-refundable

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fees, changes in estimates of our costs to complete could have a material impact on the revenues we recognize.

In connection with the formation of our equally-owned joint venture, we have funded the first \$3.0 million of research and development costs incurred on behalf of the joint venture. Prior to reaching \$3.0 million of such costs, we recognized reimbursements on a net basis and did not recognize any revenue from the joint venture. Subsequent to having funded \$3.0 million of research and development costs, in the fourth quarter of 2001, both members are required to fund the joint venture to support ongoing research and development efforts conducted by us on behalf of the joint venture. Accordingly, following \$3.0 million of funding, we, acting as a principal, recognize payments for research and development as revenue. We are the primary obligor responsible for providing the service, by conducting research and development, desired by the joint venture, including the acceptability of the research and development services and we have established the amounts we will be reimbursed for the services by selecting the subcontractors and suppliers we employ in conducting the research and development for the joint venture. Changes in those factors may have a significant impact on the revenue that we recognize in the future.

For the year ended December 31, 2002, we recognized approximately \$5,298,000 of contract research and development revenue for services performed on behalf of the joint venture. A portion of these revenues was reimbursement for costs expended to outside parties. Beginning in 2003, all costs to outside parties will be paid directly by the joint venture. The level of future revenues from the joint venture will be dependent upon the extent of research and development services requested by the joint venture and the future financial position of the joint venture. The level of commitment by Progenics and Cytogen to fund the joint venture is based on an annual budget that is approved by both parties. That budget is intended to be sufficient to fund research and development projects for 2003. The budget must also consider the ability of the members to fund the joint venture. During the six month period ended June 30, 2003, each member contributed \$2.3 million to the joint venture.

### Clinical Trial Expenses

Clinical trial expenses, which are included in research and development expenses, represent obligations resulting from our contracts with various clinical research organizations in connection with conducting clinical trials for our product candidates. These costs are expensed based on the expected total number of patients in the trial, the rate at which the patients enter the trial and the period over which the clinical research organizations are expected to provide services. We believe that this method best approximates the efforts expended on a clinical trial with the expenses we record. We adjust our rate of clinical expense recognition if actual results differ from our estimates.

### **Impact of Recently Issued Accounting Standards**

In May 2003, the Financial Accounting Standards Board issued Statement No. 150 (|FAS 150|), Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. FAS 150 specifies that instruments within its scope embody obligations of the issuer and that, therefore, the issuer must classify them as liabilities. FAS 150 requires issuers to classify as liabilities the following three types of freestanding financial instruments: (1) mandatorily redeemable financial instruments; (2) obligations to repurchase the issuer ∫s equity shares by transferring assets; and (3) certain obligations to issue a variable number of shares. FAS 150 defines a ∏freestanding financial instrument∏ as a financial instrument that (1) is entered into separately and apart from any of the entity so other financial instruments or equity transactions or (2) is entered into in conjunction with some other transaction and can be legally detached and exercised on a separate basis. For all financial instruments entered into or modified after May 31, 2003, FAS 150 is effective immediately. For all other instruments of public companies, FAS 150 goes into effect at the beginning of the first interim period beginning after June 15, 2003. For contracts that were created or modified before May 31, 2003 and still exist at the beginning of the first interim period beginning after June 15, 2003, entities should record the transition to FAS 150 by reporting the cumulative effect of a change in an accounting principle. FAS 150 prohibits entities from restating financial statements for earlier years presented. We do not expect the adoption of FAS 150 to have a material impact on our financial statements.

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#### **BUSINESS**

We are a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our principal programs are directed toward symptom management and supportive care, HIV infection and cancer. We have four product candidates in clinical development and several others in preclinical development.

Our product candidate in the area of symptom management and supportive care is MNTX, a compound in pivotal phase 3 clinical testing. A pivotal clinical trial is one that is designed to produce results sufficient to support regulatory approval. MNTX is designed to treat the debilitating side effects of opioid analysesics, without interfering with pain relief. We are conducting a broad clinical development program for MNTX in a number of settings. The first three indications that we are pursuing are:

	treatment of constipation in patients with advanced medical illness who are receiving opioids;
	treatment of patients with post-operative ileus, a paralysis of the gastrointestinal tract that frequently occurs after abdominal and other major surgeries; and
indica	treatment of opioid side effects in patients with chronic pain, including those suffering from headaches, joint pain, lower-back pain, sickle-cell disease, muscle pain and other disorders. of these indications represents a large potential market. We are developing a different dosage form for each tion: subcutaneous for patients with advanced medical illness; intraveneous for patients with post-operative and oral for patients with chronic pain.

In our recently completed phase 2b clinical trial, MNTX induced a more regular laxation schedule in opioid-treated patients with advanced medical illness. In addition, we observed a significant dose-dependent laxation response and no evidence of breakthrough pain.

In December 2002, we began a pivotal phase 3 clinical trial of MNTX in patients with advanced medical illness, and we intend to start a second pivotal phase 3 clinical trial of MNTX for this indication later this year. Pending successful completion of these two clinical trials and receipt of regulatory approval, we believe MNTX may be our first product candidate to be approved for marketing, which may occur as early as 2005. We are seeking to establish a strategic collaboration with a large pharmaceutical company to support our development and commercialization efforts for MNTX. While we are engaged in discussions with several potential collaborators, these discussions are at an early stage and may not be successful.

In the area of HIV infection, we are developing viral-entry inhibitors, which are molecules designed to inhibit the virus ability to enter certain types of immune system cells. We are conducting a multi-dose phase 2 clinical trial with our lead HIV product candidate, PRO 542, a genetically engineered molecule designed to selectively target and neutralize HIV. We are also in preclinical development with PRO 140, a monoclonal antibody designed to target the HIV co-receptor CCR5. Receptors and co-receptors are structures on the surface of a cell to which a virus must bind in order to infect the cell.

In addition, we are developing immunotherapies for prostate cancer, including monoclonal antibodies directed against PSMA, a protein found on the surface of prostate cancer cells. We are also developing vaccines designed to stimulate an immune response to PSMA. Our PSMA programs are being conducted through PSMA Development Company LLC, our joint venture with Cytogen. We are also studying a cancer vaccine, GMK, in phase 3 clinical trials for the treatment of malignant melanoma.

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The following table summarizes the current status of our principal development programs and product candidates:

Program/Product Candidates	Indication/Use	Status	
Symptom Management and Supportive Care MNTX	Treatment of constipation in	Phase 3	
PHVIX	patients with advanced medical illness who are receiving opioids	Thuse 5	
	Treatment of patients with post-operative ileus	Phase 2	
	Treatment of opioid side effects in patients with chronic pain	Phase 1 expected to begin in 2003	
HIV			
PRO 542	HIV therapy	Phase 2	
PRO 140	HIV therapy	Phase 1 expected to begin in 2004	
CD4 attachment inhibitors and gp41 fusion	HIV therapy	Research	
ProVax	HIV vaccine	Research	
<b>Prostate Cancer</b> PSMA(1):			
Recombinant protein vaccine	Immunotherapy for prostate cancer	Phase 1	
Viral-vector vaccine	Immunotherapy for prostate cancer	Phase 1 expected to begin in 2004	
Monoclonal antibody	Immunotherapy for prostate cancer	Phase 1 expected to begin in 2004	
Other			
GMK vaccine	Immunotherapy for melanoma	Phase 3	
DHA	Treatment of stroke	Preclinical	
Hepatitis C therapeutic	Therapy for hepatitis C virus infection	Research	

<sup>(1)</sup> Programs conducted through PSMA Development Company LLC, our joint venture with Cytogen Corporation. None of our product candidates have received FDA approval, and we have not yet received any revenue from the sale of any of our product candidates. We must receive marketing approval from the FDA before we can commercialize any of our product candidates.

### **Symptom Management and Supportive Care**

Narcotic medications such as morphine and codeine, which are referred to as opioids, are the mainstay in controlling severe pain. We estimate that approximately 190 million prescriptions for opioids are written annually in the U.S. Physicians prescribe opioids for patients with advanced medical illness, patients undergoing surgery and patients who experience chronic pain, as well as for other indications.

Opioids relieve pain by interacting with receptors that are located in the brain and spinal cord, which comprise the central nervous system. Opioids also activate receptors outside the central nervous system, resulting, in many cases, in undesirable side effects, including constipation, delayed gastric emptying, nausea and vomiting, itching and urinary retention. Current treatment options for opioid-induced constipation include laxatives and stool softeners, which are only minimally effective. As a result, patients may have to stop opioid therapy and endure pain in order to obtain relief from opioid-induced constipation.

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#### MNTX

MNTX is a selective, peripheral, opioid-receptor antagonist that is designed to reverse certain side effects induced by treatment with opioids. MNTX is a novel derivative of naltrexone, a drug that is prescribed for narcotic and alcohol dependence. MNTX competes with opioid analgesics for binding sites on opioid receptors, but is unable to cross the blood-brain barrier. As a result, MNTX [turns off] the effects of opioid analgesics outside the central nervous system. MNTX binds to local opioid receptors in the gastrointestinal tract and is also absorbed into the bloodstream, potentially relieving opioid-related side effects elsewhere in the body, including skin itch and urinary retention. To date, patients treated with MNTX in addition to opioid pain medications have experienced no decline in pain relief and have experienced a reversal of many of the side effects related to opioids.

We licensed worldwide exclusive rights to MNTX from UR Labs, Inc. in October 2001. UR Labs had licensed MNTX from the University of Chicago, where it was discovered. MNTX has been studied in approximately 400 patients and volunteers in numerous clinical trials. The compound has been shown in clinical trials, to date, to be well tolerated and highly active in blocking opioid-related side effects without interfering with pain relief.

The first indication we are pursuing for MNTX is relief of opioid-induced bowel Advanced Medical Illness. dysfunction in patients with advanced medical illness, including cancer, AIDS and heart disease. At the June 2003 meeting of the American Society of Clinical Oncology, we presented data from a multi-center, 33-patient phase 2b clinical trial of MNTX for the reversal of opioid-induced constipation in patients with advanced medical illness. Patients were randomized to receive one of four doses of MNTX: 20 mg, 12.5 mg, 5 mg and a 1 mg dose, which was intended to function as a placebo dose. Patients received a subcutaneous injection and were treated every-other-day for one week. After the one-week blinded dosing period, patients were eligible to receive open-label doses of MNTX for up to three additional weeks. An analysis of the data showed that MNTX had significant activity at various doses. Median time to laxation was approximately one hour after receiving active doses of MNTX. In contrast, with the 1 mg dose, time to laxation exceeded 48 hours. Laxation within four hours of dosing was reported in approximately 60% of patient doses for the active MNTX dose range and was approximately 10% of the 1 mg dose. Furthermore, the 24-hour laxation response rate for patients receiving active doses averaged 66% on treatment days as opposed to an average of only 4% on nontreatment days. Results from the entire study (double-blinded and open-label portions) showed that 58% of patients receiving active doses of MNTX laxated within four hours, and that patients who were treated in the open label portion of the study experienced drug activity for up to one month. In addition, the median frequency of laxations increased from two per week pre-treatment to four to six bowel movements per week while on treatment at the active doses of MNTX.

There were no serious adverse events reported related to MNTX in the phase 2b clinical trial. The most common side effects were transient flatulence and mild abdominal cramping, which are necessary physiological prerequisites to a bowel movement in patients with significant constipation. As in previous trials, no evidence of opioid withdrawal was observed in the phase 2b trial, and there was no increase in analgesic requirements.

Based upon the preliminary results of the open-label portion of the phase 2b study and the findings of prior clinical trials, we began enrolling patients in a randomized, double-blind, placebo-controlled pivotal phase 3 clinical study in December 2002 to evaluate the ability of single subcutaneous doses of MNTX to induce laxation within four hours. We expect to complete enrollment of a total of approximately 150 patients for this study in early 2004. This clinical trial also includes a three-week open-label phase in which patients receive MNTX as requested. We also plan to initiate a second, randomized, double-blind placebo-controlled pivotal phase 3 clinical trial of MNTX in advanced medical illness testing an every-other-day treatment regime over two weeks.

**Post-operative Ileus.** We are also developing MNTX for the treatment of post-operative ileus. In May 2003, we initiated a multicenter, randomized, double-blind, placebo-controlled phase 2 clinical study of intravenous MNTX in post-operative ileus in 60 individuals who have undergone colectomies, which is the

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removal of all or part of the colon. The goal of the study is to determine whether MNTX treatment can restore bowel function and reduce the severity or duration of ileus compared to placebo. We expect results from this trial in the first half of 2004 and, assuming successful completion of the phase 2 clinical trial, to initiate a phase 3 clinical trial for this indication thereafter.

**Chronic Pain.** We are developing MNTX for the treatment of constipation in people receiving opioids for chronic pain. Many people suffering from chronic pain are ambulatory and are not under constant doctor supervision. We therefore believe an oral formulation of MNTX would be well suited for this population. We expect to initiate in 2003 a phase 1 clinical trial to study the safety and pharmacology of oral MNTX and, assuming successful completion of the phase 1 clinical trial, to initiate phase 2 studies in 2004.

#### HIV

HIV infection causes a slowly progressing deterioration of the immune system resulting in Acquired Immune Deficiency Syndrome, or AIDS. HIV specifically infects cells that have the CD4 receptor on their surface. Cells with the CD4 receptor are critical components of the immune system and include T lymphocytes, monocytes, macrophages and dendritic cells. The devastating effects of HIV are largely due to the multiplication of the virus in these cells, resulting in their dysfunction and destruction.

UNAIDS estimated that, as of the end of 2002, 42 million people worldwide were living with HIV. In high-income countries, 1.6 million people are infected and approximately 75,500 people were newly infected with HIV during 2002. Furthermore, reports from the National AIDS Programs stated that, as of June 2002, approximately 1.2 million people in North and South America were living with HIV.

At present, three classes of products have received marketing approval from the FDA for the treatment of HIV infection and AIDS: reverse transcriptase inhibitors, protease inhibitors and entry inhibitors. Reverse transcriptase and protease inhibitors inhibit two of the viral enzymes required for HIV to replicate once it has entered the cell.

Since the late 1990s, many HIV patients have benefited from combination therapy of protease and reverse transcriptase inhibitors. While combination therapy slows the progression of disease, it is not a cure. HIV\[]\s rapid mutation rate results in the development of viral strains that are resistant to reverse transcriptase and protease inhibitors. Increasingly, after years of this combination therapy, patients begin to develop resistance to these drugs. The potential for resistance is exacerbated by interruptions in dosing which lead to lower drug levels and permit increased viral replication. Interruption in dosing is common in patients on combination therapies, because these drug regimens often require more than a dozen tablets to be taken at specific times each day. An additional problem is that many currently approved drugs produce toxic side effects in many patients, affecting a variety of organs and tissues, including the peripheral nervous system and gastrointestinal tract. These side effects may result in patients interrupting or discontinuing therapy. Our viral-entry inhibitors represent a potential new class of drugs for these patients.

Viral infection occurs when the virus binds to a host cell, enters the cell, and by commandeering the cell sown reproductive machinery, creates thousands of copies of itself within the host cell. This process is called viral replication. Our scientists and their collaborators have made important discoveries in understanding how HIV enters human cells and initiates viral replication.

In the 1980s, our founders demonstrated that the initial step of HIV infection involves the specific attachment of the virus to the CD4 receptor on the surface of human immune system cells. These researchers also showed that a specific glycoprotein, gp120, located on the surface of the virus, binds with high affinity to the CD4 receptor. Although these researchers demonstrated that binding to CD4 was necessary for HIV attachment, further discoveries have shown that attachment alone is not sufficient to enable the virus to enter the cell and initiate viral replication.

Subsequently, our scientists, in collaboration with researchers at the Aaron Diamond AIDS Research Center, or ADARC, described in an article in *Nature* the discovery of a co-receptor for HIV on the surface

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of human immune system cells. This co-receptor, CCR5, enables fusion of HIV with the cell membrane after binding of the virus to the CD4 receptor. This fusion step results in entry of the viral genetic information into the cell and subsequent viral replication. These scientists further determined that the gp120 binding site on CCR5 is a discrete region at one end of the CCR5 molecule. Further work by other scientists has established the existence of a second co-receptor, CXCR4.

We have a letter agreement with ADARC pursuant to which we have the exclusive right to pursue the commercial development, directly or with a partner, of products related to HIV based on patents jointly owned by ADARC and us. In addition, we previously had an arrangement with ADARC, not subject to a written agreement, pursuant to which ADARC provided services to us, including assistance with tests and studies of some of our leading HIV product candidates.

Based on our pioneering research, we believe we are a leader in the discovery of viral entry inhibitors, a promising new class of HIV therapeutics. For the large number of patients who are failing conventional anti-retroviral or combination therapy, we believe viral entry inhibitors could become the next generation of therapy. Fuzeon, formerly referred to as T-20, is an entry inhibitor developed by Trimeris, Inc. in collaboration with F. Hoffmann-La Roche Ltd that was approved for marketing by the FDA in March 2003. PRO 542, PRO 140 and Fuzeon inhibit different steps in the sequence of events leading to the entry of HIV into target cells, and therefore may act synergistically in their ability to block HIV infection of healthy cells.

Based on our participation in the discoveries of CD4 and CCR5, we are pursuing several approaches in the research and development of products designed to block entry of HIV into human immune system cells. Our PRO 542 product candidate and our viral-entry inhibition programs are based on the CD4 receptor, and our PRO 140 and HIV co-receptor/fusion programs are based on the CCR5 co-receptor.

#### PRO 542

PRO 542 is our proprietary antibody-like product candidate that is designed to neutralize HIV by preventing it from attaching to the CD4 receptor on the surface of immune system cells. In a phase 2 clinical trial of 12 HIV-infected individuals, PRO 542 significantly reduced viral loads by 60% to 80% for up to six weeks after a single dose. We are presently conducting a multi-dose open-label phase 2 clinical study of PRO 542 in patients with advanced disease who are no longer responding to currently available anti-retroviral medications. Patients are receiving three intravenous doses of PRO 542 per week for three weeks. The goal of the study is to determine if repeat dosing can induce sustained viral load reductions in this setting. We are also investigating the safety, pharmacokinetics and immunogenicity of PRO 542 treatment. Sustained reduction in viral load is a primary goal of HIV therapy. We expect to receive the results from this study in early 2004.

In 1999, we completed two dose-escalation phase 1/2 clinical trials of PRO 542 which were designed to measure the safety, pharmacokinetics, immunogenicity, and antiviral activity of PRO 542. Pharmacokinetic studies analyze how the body acts on a drug once the drug is administered and will determine, for example, how long the drug persists in the body. Immunogenicity studies analyze the extent to which a patient immune system mounts a response to the drug, which could impair the drug ability to have its desired therapeutic effect and could, in some cases, have serious health consequences to the patient. Immunogenicity can be a serious problem, particularly for antibody-based drugs.

Our first dose-escalation clinical trial of PRO 542 was conducted in 15 HIV-positive adult patients at Mount Sinai Medical Center in New York City. Findings indicated peak and one-week serum concentrations of PRO 542 compared favorably with preclinical models, approximating drug levels previously shown to neutralize clinical HIV strains *in vitro*. Data from this trial demonstrated that in patients receiving the highest dosage of PRO 542, infectious HIV was reduced to undetectable levels for prolonged periods following treatment. Results from this trial also indicated that administration of a single dose of PRO 542 was able to produce a statistically significant reduction in viral load in patients treated with the highest dose. Viral load is the concentration of virus nucleic acid, or genetic material, in the blood and is a widely used indicator of infection levels. PRO 542 serum concentrations remained above HIV inhibitory levels for greater than one week. In addition, PRO 542 was well tolerated and non-immunogenic in all patients treated.

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We believe that these results support expanded clinical testing of this agent as a potentially non-toxic therapy for HIV infection.

The second dose-escalation phase 1/2 clinical trial was conducted in 18 HIV-positive children at Baylor College of Medicine in Houston, the University of California at San Francisco, and the University of Pennsylvania by the AIDS Clinical Trials Group, a leading cooperative HIV research group supported by the National Institute of Allergy and Infectious Diseases. This trial was the first time PRO 542 was tested on children or in multiple doses. By 28 days after therapy, peak viral load was reduced in all six children treated with multiple doses. Additionally, the drug was well tolerated by all patients tested. During 2000, we initiated, in cooperation with the Pediatric AIDS Clinical Trial Group of the National Institutes of Health, a new phase 2 trial to define the dose and frequency of administration of PRO 542 for HIV-infected children, including those resistant to available antiviral therapies.

We also determined in preclinical *in vitro* testing that the combination of PRO 542 and Fuzeon demonstrated significantly enhanced anti-HIV activity in blocking the entry of HIV into healthy cells. In further preclinical *in vitro* studies, a [triple cocktail] of PRO 542, PRO 140 and Fuzeon, each of which inhibits a different step in the sequence of events leading to the entry of HIV into targeted cells, acted synergistically to block HIV infection of healthy cells. A scientific article regarding this research subsequently appeared in the *Journal of Infectious Diseases*.

During 2002, we achieved two major milestones in our PRO 542 clinical program. We identified a target population of patients who are most likely to benefit from PRO 542, those with advanced disease, and established clinical proof-of-concept that infrequent dosing with PRO 542 yielded prolonged viral-load reduction. In September 2002, we reported final results from a phase 2 clinical trial of PRO 542, which showed that PRO 542 reduced plasma concentrations of HIV in infected individuals who were no longer responding to currently available antiretroviral medications. In these 12 treatment-experienced patients, a single dose of PRO 542 reduced viral concentrations in the blood by 60% to 80% on average. The viral-load reductions were sustained throughout the six-week follow-up period, and no serious side effects were observed. Additional findings from this phase 2 clinical trial of PRO 542, announced in February 2003, indicate that the magnitude of viral load reductions were correlated strongly with viral susceptibility to PRO 542 prior to drug treatment, as measured by the PhenoSense HIV Entry assay from ViroLogic, Inc. We believe that viral-resistance testing may identify patients who will derive the greatest benefit from therapy with HIV entry inhibitors. In addition, patient viruses collected six weeks after treatment initiation showed no evidence of having developed resistance to PRO 542.

During the course of 2002, we devoted concentrated efforts both internally and with third-party collaborators to enhance our ability to supply adequate quantities of PRO 542 for our clinical program through the creation of a high-producing genetically engineered PRO 542 cell line and the expansion of our internal manufacturing capabilities. In March 2003, we entered into an agreement with Gala Design, Inc. to create a high-producing genetically engineered cell line that expresses PRO 542. Additionally, we are preparing to install a 1,000-liter bioreactor that will utilize the new cell line to increase productivity. This facility, which we expect will be operational during 2004, is designed to provide us with an additional source of PRO 542 in support of our clinical program. We believe that the investment in cell-line development provides us with a viable strategic alternative to our reliance on transgenic goats as a source of PRO 542.

Our phase 2 clinical program also includes studies that employ repeated subcutaneous dosing of PRO 542. In these studies, we intend to use the PhenoSense HIV Entry assay to select for those patients harboring the most sensitive viruses to PRO 542 neutralization. In July 2002, we announced an agreement with ViroLogic, to use their proprietary HIV resistance-testing technology, the PhenoSense HIV Entry assay, in the development of PRO 542 and PRO 140, our second experimental viral entry inhibitor.

Additional clinical trials may include treating patients with PRO 542 in combination with Fuzeon. The initiation of these studies will depend on the commercial availability of supplies of Fuzeon for use in clinical trials. In preclinical studies, PRO 542 and Fuzeon were shown to be synergistic in inhibiting HIV, as each drug was designed to block the virus in a different manner before it enters the human immune cells.

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#### PRO 140

PRO 140 is a humanized monoclonal antibody designed to block the ability of HIV to infect cells by inhibiting virus-cell binding. We have designed PRO 140 to target a distinct site on the HIV co-receptor CCR5 without interfering with the normal function of CCR5. We expect to begin phase 1 clinical trials in 2004. The goal of the phase 1 studies will be to determine the safety, pharmacokinetics, immunogenicity and anti-viral activity of PRO 140 in healthy volunteers and HIV-infected individuals.

In May 1999, we announced the development of a panel of proprietary anti-CCR5 monoclonal antibodies created at Progenics and evaluated in collaboration with ADARC. These antibodies are designed to block the ability of HIV to infect cells isolated from healthy individuals by inhibiting virus-cell fusion, an approach not targeted by current HIV therapies. One murine monoclonal antibody, which we have designated PRO 140, inhibited HIV infection at concentrations that had no apparent effect on the normal function of CCR5. We believe that these properties were correlated with PRO 140 $\square$ s ability to bind to a distinct site on CCR5 that does not interfere with the normal receptor function of CCR5. Effective April 1999, we entered into a development and license agreement with Protein Design Labs, Inc., for the development of a humanized version of PRO 140 that retains the antibody  $\square$ s antiviral activity but is more suitable for chronic use in humans.

We subsequently announced in 2000 the findings from a preclinical study carried out in collaboration with ADARC in which PRO 140 potently blocked each of 17 primary HIV isolates that use CCR5 as a fusion co-receptor. These viruses are typical of those associated with person-to-person transmission of HIV and predominate during the early stages of infection, when antiviral therapies have proven to be most effective. PRO 140 was shown in these *in vitro* models to be effective at protecting both primary T-cells and macrophages, immune system cells that provide the major targets for HIV infection *in vivo*. We also announced in 2000 the results of preclinical *in vitro* studies where it was shown that a [triple cocktail] of PRO 542, PRO 140 and Fuzeon], each of which inhibits a different step in the sequence of events leading to the entry of HIV into targeted cells, acted synergistically to potently block HIV infection of healthy cells.

In January 2001, a scientific article in the *Journal of Virology* described how PRO 140 demonstrated potent, broad-spectrum antiviral activity against more than 40 genetically diverse primary HIV viruses isolated directly from infected individuals *in vitro*. In April 2001, we announced that single doses of a murine-based PRO 140 reduced viral burdens to undetectable levels in a well-recognized animal model of HIV infection. In mice treated with PRO 140, initially high HIV concentrations became undetectable for up to nine days after a single dose.

Later in 2001, we also reported that we had identified the molecular basis for the synergistic antiviral activity observed for HIV entry inhibitors PRO 542, PRO 140 and the fusion inhibitor Fuzeon. The multi-step nature of HIV entry into cells attachment, co-receptor binding and fusion may leave the virus susceptible to inhibition by combinations of drugs that act at different stages of the process. In laboratory studies, the drug combinations provided a synergistic activity whereby actions of the first drug (PRO 542 or PRO 140) temporarily immobilizes the virus and holds it in a way that makes it more susceptible to the second drug (PRO 140 or Fuzeon). Preclinical studies also demonstrated that HIV failed to develop resistance to PRO 140 despite 40 weeks of continued exposure to the drug. This period is considerably longer than that required for HIV to develop resistance to other classes of antiviral agents in similar laboratory studies.

Additionally, in December 2001, we further reported that multiple doses of PRO 140 reduced and then maintained viral loads at undetectable levels for the duration of therapy in an animal model of HIV infection. Sustaining undetectably low levels of virus in the blood is a primary goal of HIV therapy.

In February 2002, we announced that we had selected a humanized form of the PRO 140 antibody for clinical testing. Unlike its mouse-based predecessor, humanized PRO 140 is designed to be suitable for repeat dosing in humans. Humanization of the PRO 140 monoclonal antibody was accomplished under our collaborative agreement with Protein Design Labs entered in April 1999. We expect to file an Investigational New Drug Application with the FDA for humanized PRO 140 in early 2004. We plan to use ViroLogic□s

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PhenoSense HIV Entry assay to select for patients harboring the most sensitive viruses to PRO 140 inhibition.

### CD4 attachment inhibitors and gp41 fusion inhibitors

In March 2000, we entered into a research and license agreement with Pharmacopeia, Inc., to develop small molecule HIV therapeutics that block the attachment of the virus to its primary cellular receptor, CD4. This agreement expanded on a collaboration with Pharmacopeia that commenced in September 1997. Under the terms of this agreement, we have provided proprietary CD4 attachment assays and expertise related to the interaction between HIV and CD4, and Pharmacopeia is engaging in a screening program of its internal compound library. In August 2000, we expanded our collaboration with Pharmacopeia to add two additional programs, including one program directed to the HIV envelope glycoprotein gp41. Under the terms of the agreement we are entitled to an exclusive, royalty-bearing license to active compounds identified in these programs.

In November 2001, we were awarded approximately \$600,000 from the National Institutes of Health for the development of novel inhibitors of HIV entry and infection. Entry inhibitors are a new class of HIV drugs that may offer benefits in both safety and efficacy over currently available HIV therapies. The grant supports an ongoing collaboration between Progenics and Pharmacopeia, Inc. to develop orally available small-molecule inhibitors of the HIV envelope glycoprotein gp41, which mediates fusion and entry of HIV into cells of the human immune system. The project combines Pharmacopeia proprietary, high-throughput assays with screening technologies developed at Progenics for identifying fusion inhibitors. Pharmacopeia has utilized these technologies to screen its libraries of several million novel, drug-like compounds, and screening of other libraries is underway for other undisclosed targets. We continue to assess the results of this collaboration as they become available.

#### **ProVax**

We are conducting research on our ProVax vaccine candidate, which we believe may be useful in preventing HIV infection or as a therapeutic treatment for HIV-positive individuals. We are currently performing government-funded research and development of the ProVax vaccine in collaboration with the Weill/Cornell Medical College.

In 2002, we announced the development of vaccine candidates that contain critical surface proteins whose form closely mimics the structures found on the virus. The findings were described in articles in the *Journal of Virology*.

In September 2003, we were awarded a contract by the NIH to develop an HIV vaccine. The contract provides for up to \$28.6 million in funding to us over five years. Funding under this contract is subject to compliance with its terms, and the payment of fees is subject to achievement of specified milestones. We anticipate that these funds will be used principally in connection with our ProVax HIV vaccine program.

#### **Prostate Cancer**

Cancer is a category of diseases, each of which is characterized by aberrations in cell growth and differentiation. The establishment and spread of a tumor is a function of its growth characteristics and its ability to suppress or evade the body normal defenses, including surveillance and the elimination of cancer cells by the immune system. Eradication of malignant cells that can metastasize, or spread, to vital organs, leading to death, is central to the effective treatment of cancer.

Despite recent advances in treatment, therapies for many types of cancer suffer from serious limitations. The principal therapies for cancer have historically been surgery, radiation and chemotherapy. A significant drawback to conventional anti-cancer therapy is that both occult, or hidden, and residual disease is difficult or impossible to eliminate fully, which can lead to relapse.

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Prostate cancer is the most common form of cancer affecting U.S. males and is the second leading cause of cancer deaths in men each year. The American Cancer Society estimates that 28,900 men will die from prostate cancer and 220,900 new cases will be diagnosed in 2003 in the U.S.

Conventional therapies for prostate cancer include radical prostectomy, in which the prostate gland is surgically removed, radiation and hormone therapies and chemotherapy. Surgery and radiation therapy may result in urinary incontinence and impotence. Hormone therapy and chemotherapy are generally not intended to be curative and are not actively used to treat localized, early-stage prostate cancer.

#### **PSMA**

Through PSMA Development Company LLC, our joint venture with Cytogen Corporation, we are engaged in a research and development program relating to vaccine and antibody immunotherapeutics based on PSMA. PSMA is a protein that is abundantly expressed on the surface of prostate cancer cells as well as cells in the newly formed blood vessels of most other solid tumors. We believe that PSMA has applications in immunotherapeutics for prostate cancer and potentially for other types of cancer.

In December 2002, the joint venture initiated a phase 1 clinical trial with its therapeutic recombinant protein vaccine, which is designed to stimulate a patient immune response system to recognize and destroy prostate cancer cells. The vaccine combines the PSMA cancer antigen with an immune stimulant to induce an immune response against prostate cancer cells. The genetically engineered PSMA vaccine generated potent immune responses in preclinical animal testing. The clinical trial is designed to evaluate the safety and immune-stimulating properties of the vaccine in patients with either newly diagnosed or recurrent prostate cancer.

The joint venture is also pursuing, in collaboration with AlphaVax Human Vaccines, Inc., a vaccine program that utilizes viral vectors designed to deliver the PSMA gene to immune system cells in order to generate potent and specific immune responses to prostate cancer cells. In preclinical studies, this viral-vector prostate cancer vaccine generated a potent dual response against PSMA, yielding a response by both antibodies and killer T cells, the two principal mechanisms used by the immune system to eliminate abnormal cells. The joint venture is completing preclinical development activities on the PSMA viral-vector vaccine in anticipation of initiating phase 1 clinical trials in the first half of 2004.

The joint venture has also developed novel human monoclonal antibodies which bind to PSMA. These antibodies, produced in collaboration with Abgenix, Inc., were developed to recognize the three-dimensional physical structure of the protein and possess a high affinity and specificity for PSMA. We expect that the joint venture will begin phase 1 clinical trials with one of these antibodies in 2004.

In November 2002, the joint venture reported that fully human monoclonal antibodies substantially reduced tumor growth in an animal model of human prostate cancer. These antibodies demonstrated the ability to selectively deliver a lethal payload to cells that expressed PSMA on their surface. The joint venture is in the process of selecting the optimal toxin and radioactive payloads in parallel with producing clinical-grade antibodies. We expect the joint venture to begin phase 1 clinical studies with a conjugated antibody in 2005.

#### **Other Product Candidates and Research Programs**

# **GMK Vaccine**

GMK is a proprietary therapeutic vaccine that is designed to prevent recurrence of melanoma in patients who are at risk of relapse after surgery. We are currently conducting two phase 3 clinical trials of GMK. GMK is composed of the ganglioside GM2 joined to the carrier protein keyhole limpet hemocyanin, or KLH, and combined with the adjuvant QS-21. QS-21 is a compound in the Stimulon family of adjuvants developed and owned by Aquila Biopharmaceuticals, Inc., a wholly owned subsidiary of Antigenics, Inc. GMK is designed to stimulate the immune system to produce specific antibodies to the ganglioside antigens. These antibodies have been shown *in vitro* to recognize and destroy cancer cells. Based

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on the *in vitro* results and the clinical trial results described below, we believe that vaccination of cancer patients with ganglioside conjugate vaccines may delay or prevent recurrence of cancer and prolong overall survival.

Melanoma is a highly lethal cancer of the skin cells that produce the pigment melanin. In early stages, melanoma is limited to the skin, but in later stages it can spread to the lungs, liver, brain and other organs. The National Cancer Institute, or NCI, estimated that in 2000 there were 550,860 melanoma patients in the U.S. The American Cancer Society estimates that there will be 54,200 new cases of melanoma diagnosed in the U.S. during 2003. Melanoma accounts for 4% of skin cancer cases, but 79% of skin cancer deaths. Melanoma has one of the fastest growing incidence rates of any cancer in the U.S. Increased exposure to the ultraviolet rays of the sun may be an important factor contributing to the increase in new cases of melanoma.

GMK is being developed for the treatment of patients with Stage II or Stage III melanoma. The American Cancer Society estimates that the 5-year relative survival rate of Stage II melanoma patients is between 65% and 70% and that the 5-year survival rate for Stage III melanoma patients is approximately 45%.

GMK entered a pivotal phase 3 clinical trial in the United States in August 1996. GMK was administered in this study on an out-patient basis by 12 subcutaneous injections over a two-year period. This clinical trial compares GMK with high-dose alpha-interferon in Stage IIb (advanced Stage II) and Stage III melanoma patients who have undergone surgery but are at high risk for recurrence. This randomized trial has been conducted nationally by the Eastern Cooperative Oncology Group, or ECOG, in conjunction with the Southwest Oncology Group, or SWOG, and other major cancer centers, cooperative cancer research groups, hospitals and clinics. ECOG and SWOG are leading cooperative cancer research groups supported by the NCI and are comprised of several hundred participating hospitals and clinics, primarily in the United States. The primary endpoint of the U.S. trial is a comparison of the recurrence of melanoma in patients receiving GMK versus patients receiving high-dose alpha-interferon, the conventional treatment for high-risk melanoma patients. Additionally, the study is designed to compare quality of life and overall survival of patients in both groups.

In May 2000, as a result of an unplanned early analysis of a subset of the 880 patients enrolled in the trial, ECOG recommended to clinical investigators participating in the trial that they discontinue administering GMK. ECOG\[]\s decision was based on its early analysis of data from the subset group which, according to ECOG, showed that the relapse-free and overall survival rates for patients receiving the GMK vaccine were lower than for patients receiving high-dose alpha-interferon.

As a result of the actions of ECOG, the trial did not complete patient dosing as contemplated by the initial trial protocol. Despite ECOG[]s action, we extended our clinical trial to allow those patients who so elected, with the advice of their treating physicians, to complete the full dosing protocol. We continue to monitor all patients in the trial until its scheduled completion as contemplated by the initial protocol. This action has been taken with the knowledge of the FDA and the various institutional review boards at the clinical sites affected. We refer to []extending[] the trial in this manner as an []extension study.[] ECOG is assisting us in continued patient follow-up and data compilation. We are planning to meet with the FDA in 2004 to finalize the method of analysis for this study. Given recent FDA actions on similar product candidates, we are considering amending our statistical plan for this study to compare median 5.5-year survival between the two treatment groups. We anticipate reaching median 5.5-year survival in late 2003 and would plan to perform the final analysis in 2004.

While all patients received at least a portion of the planned dosing, only about one-half of the patients received the full number of doses of GMK. We believe that the likely potential outcomes of the ECOG trial as supplemented by the extension study are as follows: if the data are good, the data could support a filing with the FDA for marketing approval; if the data are not good or inconclusive, they would not support a marketing approval and further studies would be required.

In May 2001, we initiated a large international phase 3 clinical trial of the GMK vaccine to prevent the relapse of malignant melanoma. The study is being conducted with the European Organization for Research

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and Treatment of Cancer, or EORTC, Europe\s leading cancer cooperative group. The EORTC phase 3 trial expects to enroll 1,300 patients who are at intermediate risk for recurrence of the disease. The study is recruiting patients from Europe and Australia. EORTC will randomize patients after surgery to receive either GMK or the current standard of care, which is no treatment but close monitoring. Patients on the vaccine arm of the study will receive 14 doses of GMK over three years, with an estimated two years of additional follow-up. We do not expect final data from this trial until 2009. The primary endpoint of this trial is to compare the recurrence of melanoma in patients receiving GMK with patients receiving observation and no treatment. The study will also compare overall survival of patients in both groups. Patient accrual for this study has proceeded more slowly than anticipated due to regulatory delays. At present we expect to enroll all 1,300 patients by mid-2005.

#### **DHA**

We licensed from Sloan-Kettering Institute for Cancer Research patent rights and technology relating to a derivative of vitamin C called dehydroascorbic acid, or DHA. We have obtained exclusive worldwide rights to use DHA for the treatment of diseases involving oxidative damage to tissue, including tissues of the central nervous system. In preclinical studies conducted in an animal model, DHA demonstrated significant dose-dependent decreases in brain damage, neurological deficits, and death caused by stroke when administered as long as three hours after a stroke. While we continue with limited preclinical research and activities in conjunction with our academic collaborators, we are also examining strategic alternatives regarding the DHA program, including out-licensing.

### Hepatitis C Therapeutic

We recently reported our discovery of the first liver-specific receptor for the hepatitis C virus, which is a major cause of liver disease. This receptor may provide a new target for hepatitis C therapy. We are performing additional research based on this discovery.

### **Business Strategy**

Our strategy is to in-license, develop and out-license innovative products for symptom management and supportive care and the treatment and prevention of cancer and viral infections. Key elements of our strategy include:

- Develop Products Until They Are Ready For Significant Collaborations. Our strategy is to retain worldwide commercialization rights to our product candidates until we have established clinical proof of concept. We believe that by using our internal development capabilities to advance our product candidates into late-stage clinical trials, we will be able to enter development and commercialization collaborations that will maximize financial returns to us. We seek to establish collaborations that would reduce our spending on large, late-stage trials and increase the likelihood of a successful commercial introduction. We are engaged in discussions with several pharmaceutical companies concerning a strategic collaboration regarding MNTX.
- Build a Large and Diversified Pipeline to Mitigate Clinical and Technical Risk. We are developing a large and diverse product pipeline consisting of product candidates in multiple therapeutic areas and various stages of development. We currently have 13 programs in various stages of research and development, including four product candidates in clinical studies and four others completing preclinical development, as well as several other research projects. We believe that this strategy will mitigate some of the risks associated with drug development and increase our probability of developing a commercial product.
- In-license or Acquire Additional Product Candidates and Technologies. We are actively seeking promising product candidates and technologies around which to build development programs. Our in-licensing strategy has generated our clinical development programs for MNTX, novel HIV therapeutics and cancer immunotherapies. For example, we identified MNTX and, after licensing the compound, quickly commenced and completed a phase 2 trial and initiated a phase 3 trial.

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Additionally, we have entered into license agreements with leading research institutions, such as Sloan-Kettering and Columbia University, under which we obtained rights to use certain technologies in our cancer and HIV programs. We believe we can complement our existing pipeline by selectively accessing new drug programs through similar license agreements.

### **Corporate Collaborations**

### PSMA Development Company LLC

In June 1999, we and Cytogen Corporation formed a joint venture in the form of a limited liability company for the purposes of conducting research, development, manufacturing and marketing of products related to PSMA. All patents and know-how owned by us or Cytogen and used or useful in the development of PSMA-based antibody or vaccine immunotherapeutics have been licensed to the joint venture. The principal intellectual property licensed initially are several patents and patent applications owned by Sloan-Kettering that relate to PSMA. We and Cytogen must also offer to license to the joint venture patents, patent applications and technical information used or useful in the joint venture sield to which we or Cytogen acquire licensable rights. By the terms of the joint venture, Cytogen is principally responsible for product marketing, and we have co-promotion rights. To date, we have been principally responsible for preclinical and clinical development.

Each member of the joint venture currently owns 50% of the joint venture. Each member made an initial capital contribution of \$100,000. In general, each member has equal representation on the joint venture  $\square$ s management committee, equal voting rights and equal rights to profits and losses of the joint venture. Pursuant to the joint venture agreement, a member  $\square$ s voting and ownership interest will be diluted if it fails to make required capital contributions. Under specified circumstances, a change in control of one of the members will result in that member  $\square$ s loss of voting, management and marketing rights.

In general, the amount of funds that we and Cytogen must pay to fund the operations of the joint venture is based on a budget that is required to be approved by both parties and updated periodically. We are required to fund that portion of the budget equal to our percentage interest in the joint venture. We were required to fund the initial cost of research up to \$3.0 million. During the fourth quarter of 2001, we had surpassed the \$3.0 million in funding for research costs, and funding obligations were thereafter shared equally by Cytogen and us.

Under the joint venture agreement, we were required to pay to the joint venture \$2.0 million in supplemental capital contributions, which was used by the joint venture to pay a \$2.0 million non-refundable licensing fee to Cytogen.

We provide research and development services to the joint venture and are compensated for our services based on agreed upon terms which approximate our cost. All inventions made by us in connection with our research and development services to the joint venture are required to be assigned to the joint venture for its use and benefit.

The joint venture agreements generally terminate upon the last to expire of the patents licensed by the members to the joint venture or upon a breach by either member that is not cured within 60 days of written notice. Of the patents and patent applications that are the subject of the joint venture, the issued patents expire on dates ranging from 2014 and 2016. Patent term extensions and pending patent applications may extend the period of patent protection and thus the term of the joint venture agreements, when and if such patent applications are allowed and issued.

In July 2003, we and Cytogen:

agreed to an updated work plan governing the activities of the joint venture for the remainder of 2003, including the execution of various third-party contracts;
agreed to a budget for the joint venture $\square$ s operations for 2003 and related capital contributions of the parties; and
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agreed to an amended services agreement pursuant to which the members will provide research, development and related services for the remainder of 2003.

The joint venture work plan, budget and other operational and financial matters relating to periods after 2003 will require the further agreement of us and Cytogen.

### ViroLogic, Inc.

In May 2002 we entered into a fee-for-service agreement with ViroLogic, Inc. under which ViroLogic has agreed to perform clinical laboratory tests using ViroLogic s HIV resistance-testing technology on samples we provide. Services under the contract are performed upon our submission of a work order setting forth an agreed-upon scope of clinical laboratory tests and services to be performed by ViroLogic, as well as a fee schedule. We are not obligated to submit any work orders and can terminate any work order with or without cause upon 30 days written notice, with the obligation to pay for work performed under the work order. As of June 30, 2003, we have paid to ViroLogic \$46,000 under this agreement.

#### Licenses

We are a party to license agreements under which we have obtained rights to use specified technologies. Set forth below is a summary of each of these licenses.

### Sloan-Kettering

We are party to a license agreement with Sloan-Kettering under which we obtained the worldwide, exclusive rights to specified technology relating to ganglioside conjugate vaccines, including GMK, and its use to treat or prevent cancer. In general, the Sloan-Kettering license agreement terminates upon the later to occur of the expiration of the last to expire of the licensed patents or 15 years from the date of the first commercial sale of a licensed product pursuant to the agreement, unless sooner terminated. Patents that are presently issued expire in 2014; however, pending patent applications that we have also licensed and patent term extensions may extend the license period, when and if the patent applications are allowed and issued or patent term extensions are granted. In addition to the patents and patent applications, we have also licensed from Sloan-Kettering the exclusive rights to use relevant technical information and know-how. A number of Sloan-Kettering physician-scientists also serve as consultants to Progenics.

Our license agreement requires us to achieve development milestones. The agreement states that we are required to have filed for marketing approval of a drug by 2000 and to commence manufacturing and distribution of a drug by 2002. We have not achieved these milestones due to delays that we believe could not have been reasonably avoided. The agreement provides that Sloan-Kettering shall not unreasonably withhold consent to a revision of the milestone dates under specified circumstances, and we believe that the delays referred to above satisfy the criteria for a revision of the milestone dates. Sloan-Kettering has not consented to a revision of the milestone dates; however, we are in discussions with them in this regard.

As of June 30, 2003, we have paid to Sloan-Kettering \$1.0 million under this agreement. In addition, we are obligated to pay royalties based on the sales of products under the license. We have a \$200,000 minimum royalty payment obligation in any given calendar year, which is fully creditable against currently earned royalties payable by us to Sloan-Kettering in such year based on sales of licensed products.

We are also a party to a license agreement with Sloan-Kettering under which we obtained an exclusive, worldwide license to specified patent rights relating to DHA. The license continues for 20 years or to the end of the term for which the patent rights are granted. The presently issued patents expire in 2019; however, patent applications filed in the United States and internationally that we have also licensed and patent term extensions may extend the period of our license rights, when and if such patent applications are allowed and issued or patent term extensions are granted. As of June 30, 2003 we have paid to Sloan-Kettering \$100,000. If we achieve certain milestones specified under the agreement, we will be obligated to pay Sloan-Kettering an additional \$3.25 million. We are also required to pay royalties based on the sale of products we develop under the license.

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### Columbia University

We are party to a license agreement with Columbia University under which we obtained exclusive, worldwide rights to specified technology and materials relating to CD4. In general, the license agreement terminates (unless sooner terminated) upon the expiration of the last to expire of the licensed patents, which is presently 2020; however, patent applications that we have also licensed and patent term extensions may extend the period of our license rights, when and if the patent applications are allowed and issued or patent term extensions are granted.

Our license agreement requires us to achieve development milestones. Among others, the agreement states that we are required to have filed for marketing approval of a drug by 2001. We have not achieved this milestone due to delays that we believe could not have been reasonably avoided. The agreement provides that Columbia shall not unreasonably withhold consent to a revision of the milestone dates under specified circumstances, and we believe that the delays referred to above satisfy the criteria for a revision of the milestone dates. Columbia has not consented to a revision of the milestone dates; however, we are in discussions with them in this regard.

As of June 30, 2003, we have paid to Columbia \$800,000 under this agreement. In addition, we are obligated to pay Columbia \$225,000 upon the earlier to occur of June 1, 2004 or our achievement of our final milestone under the agreement. We are also required to pay annual maintenance fees of \$50,000 and royalties based on the sale of products we develop under the license.

### Aquila Biopharmaceuticals

We have entered into a license and supply agreement with Aquila Biopharmaceuticals, Inc., a wholly owned subsidiary of Antigenics, pursuant to which Aquila agreed to supply us with all of our requirements for the QS-21 adjuvant for use in ganglioside-based cancer vaccines, including GMK. QS-21 is the lead compound in the Stimulon family of adjuvants developed and owned by Aquila. In general, the license agreement terminates upon the expiration of the last to expire of the licensed patents, unless sooner terminated. In the United States the licensed patent will expire in 2008.

Our license agreement requires us to achieve development milestones. The agreement states that we are required to have filed for marketing approval of a drug by 2001 and to commence the manufacture and distribution of a drug by 2003. We have not achieved these milestones due to delays that we believe could not have been reasonably avoided. The agreement provides that Aquila shall not unreasonably withhold consent to a reasonable revision of the milestone dates under specified circumstances, and we believe that the delays referred to above satisfy the criteria for a revision of the milestone dates. Aquila has not consented to a revision of the milestone dates.

As of June 30, 2003, we have paid to Aquila \$758,000 under this agreement. We have no future cash payment obligations relating to milestones under the agreement, although we are required to pay Aquila royalties on the sale of products we develop under the license.

### **Protein Design Labs**

We have entered into a development and license agreement with Protein Design Labs, or PDL, for the humanization by PDL of PRO 140. Pursuant to the agreement, PDL granted us exclusive and nonexclusive worldwide licenses under patents, patent applications and know-how relating to the humanized PRO 140. In general, the license agreement terminates on the later of 10 years from the first commercial sale of a product developed under the agreement or the last date on which there is an unexpired patent or a patent application that has been pending for less than ten years, unless sooner terminated. Thereafter the license is fully paid. The last of the presently issued patents expires in 2014; however, patent applications filed in the United States and internationally that we have also licensed and patent term extensions may extend the period of our license rights, when and if such patent applications are allowed and issued or patent term extensions are granted. As of June 30, 2003, we have paid to PDL approximately \$1.72 million under this agreement. If all milestones specified under the agreement are achieved, we will be obligated to pay PDL an additional

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approximately \$4.5 million. We are also required to pay annual maintenance fees of \$150,000 and royalties based on the sale of products we develop under the license.

#### **UR Labs**

We have entered into an agreement with UR Labs to obtain worldwide exclusive rights to intellectual property rights related to MNTX. UR Labs has exclusively licensed MNTX from the University of Chicago, where it was discovered. In consideration for the license, we paid a nonrefundable, noncreditable license fee and are obligated to pay additional payments upon the occurrence of defined milestones associated with the MNTX product development and commercialization program. As of June 30, 2003 we have paid to UR Labs \$500,000 under this agreement. If we satisfy all future development milestones specified in the agreement, we will be obligated to pay UR Labs an additional \$1.2 million. Furthermore, we are required to pay royalties based upon net sales of the licensed products (but at a rate of not less than \$100,000 per year after product approval in the United States). The UR Labs agreement may be terminated under specified circumstances that include our failure to achieve specified development milestones; however, the consent of UR Labs to appropriate revisions to the development milestones shall not be unreasonably withheld under specified circumstances. If not terminated early, the agreement continues so long as we are obligated to pay royalties on the sale of a licensed product (including MNTX). If there is a valid patent relating to a licensed product in a particular country on the date of the first commercial sale in that country, we are obligated to pay royalties until the later of the expiration of the last to expire licensed patent or five years from the date of that sale. If a valid licensed patent does not exist in a particular country on the date of the first commercial sale of a licensed product in that country, we are obligated to pay royalties until seven years from the date of that sale. The last of the presently issued patents expire in 2017; however, patent applications filed in the United States and internationally that we have also licensed and patent term extensions may extend the period of our license rights, when and if such patent applications are allowed and issued or patent term extensions are granted.

### Abgenix

In February 2001, our joint venture with Cytogen entered into a worldwide exclusive licensing agreement with Abgenix to use Abgenix XenoMouse technology for generating fully human antibodies to the joint venture sproprietary PSMA antigen. In consideration for the license, the joint venture paid a nonrefundable, noncreditable license fee and is obligated to pay additional payments upon the occurrence of defined milestones associated with the development and commercialization program for products incorporating an antibody generated utilizing the XenoMouse technology. As of June 30, 2003, the joint venture has paid to Abgenix \$400,000 under this agreement. If the joint venture achieves certain milestones specified under the agreement, it will be obligated to pay Abgenix an additional approximately \$6.7 million. Furthermore, the joint venture is required to pay royalties based upon net sales of any antibody products. This agreement may be terminated, after an opportunity to cure, by Abgenix for cause upon 30 days prior written notice. The joint venture has the right to terminate this agreement upon 30 days prior written notice. If not terminated early, this agreement continues until the later of the expiration of the XenoMouse technology patents that may result from pending patent applications or seven years from the first commercial sale of the products.

### AlphaVax Human Vaccines

In September 2001, the joint venture entered into a worldwide exclusive license agreement with AlphaVax Human Vaccines to use the AlphaVax Replicon Vector system to create a therapeutic prostate cancer vaccine incorporating the joint venture proprietary PSMA antigen. In consideration for the license, the joint venture paid a nonrefundable, noncreditable license fee and is obligated to pay additional payments upon the occurrence of certain defined milestones associated with the development and commercialization program for products incorporating AlphaVax system. As of June 30, 2003, the joint venture has paid to AlphaVax \$400,000 under this agreement. If the joint venture achieves certain milestones specified under the agreement, it will be obligated to pay AlphaVax an additional approximately \$5.4 million. Furthermore, the

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joint venture is required to pay annual maintenance fees until the first commercial sale and royalties based upon net sales of any products developed using AlphaVax[] system. This agreement may be terminated, after an opportunity to cure, by AlphaVax under specified circumstances that include the joint venture[]s failure to achieve milestones; however, the consent of AlphaVax to revisions to the due dates for the milestones shall not be unreasonably withheld. The joint venture has the right to terminate the agreement upon 30 days prior written notice. If not terminated early, this agreement continues until the later of the expiration of the patents relating to AlphaVax[] system or seven years from the first commercial sale of the products developed using AlphaVax[] system. The last of the presently issued patents expire in 2015; however, patent applications filed in the United States and internationally that we have also licensed and patent term extensions may extend the period of our license rights, when and if such patent applications are allowed and issued or patent term extensions are granted.

### **Rights and Obligations**

We have the right generally to defend and enforce patents licensed by us, either in the first instance or if the licensor chooses not to do so. In addition, our license agreement with UR Labs regarding MNTX gives us the right to prosecute and maintain the licensed patents. We bear the cost of engaging in all of these activities with respect to our license agreements with Sloan-Kettering for GMK, Columbia for our HIV product candidates subject to the Columbia license and UR Labs for MNTX. With most of our other license agreements, the licensor bears the cost of engaging in all of these activities, although we may share in those costs under certain circumstances. Historically, our costs of defending patent rights, both our own and those we license, have not been material.

The licenses to which we are a party impose various milestone, commercialization, sublicensing, royalty and other payment, insurance, indemnification and other obligations on us and are subject to certain reservations of rights. Failure to comply with these requirements could result in the termination of the applicable agreement, which would likely cause us to terminate the related development program and cause a complete loss of our investment in that program.

# **Patents and Proprietary Technology**

Our policy is to protect our proprietary technology, and we consider the protection of our rights to be important to our business. In addition to seeking U.S. patent protection for many of our inventions, we generally file patent applications in Canada, Japan, Western European countries and additional foreign countries on a selective basis in order to protect the inventions that we consider to be important to the development of our foreign business. Generally, patents issued in the United States are effective for:

	the longer of 17 years from the date of issue or 20 years from the earliest effective filing date of the
	corresponding patent application, if the patent application was filed prior to June 8, 1995; and
	20 years from the earliest filing date for patent applications filed on or after June 8, 1995.
In add	lition, in certain instances, the patent term can be extended to recapture a portion of the term lost during
the Fl	DA regulatory review period. The duration of foreign patents varies in accordance with the provisions of
applic	cable local law.

We also rely on trade secrets, proprietary know-how and continuing technological innovation to develop and maintain a competitive position in our product areas. We require our employees, consultants and corporate partners who have access to our proprietary information to sign confidentiality agreements.

Currently our patent portfolio relating to our proprietary technologies in the HIV, cancer and symptom management areas is comprised, on a worldwide basis, of 90 patents that are issued or allowed and 128 pending patent applications, which we either own directly or of which we are the exclusive licensee. The issued patents that we own expire on dates ranging from 2012 through 2021. However, we have filed a number of United States and foreign patent applications related to MNTX, our HIV attachment technology, our technology directed to PRO 542 and PRO 140, our ProVax technology and clinical uses of these technologies. We have also filed a number of United States and foreign patent applications, one of which is

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owned jointly with the Aaron Diamond AIDS Research Center, relating to the discovery of an HIV co-receptor, CCR5. Patent term extensions and these pending patent applications may extend the period of patent protection afforded our products in development, when and if such patent term extensions and patent applications are allowed and issued or patent term extensions are granted.

Our patent portfolio includes United States and foreign patents and pending patent applications that relate to our products in development in the HIV, cancer, symptom management and supportive care areas and of which we are the exclusive licensee. This portion of our patent portfolio is described in more detail below.

Under a license agreement with UR Labs, Inc., we obtained worldwide exclusive rights to specified technology relating to MNTX. This technology is the subject of issued U.S. and European patents and several related U.S. and foreign patent applications filed by the University of Chicago relating to certain compositions, formulations and uses of MNTX. The last of the presently issued patents expire in 2017; however, patent applications that we have also licensed and patent term extensions may extend the period of patent protection, when and if such patent applications are allowed and issued or patent term extensions are granted. Furthermore, we have continued to expand the patent coverage relating to MNTX with the filing of new patent applications that may extend the patent protection period for MNTX when and if such patent applications are allowed and issued.

Under a license agreement with Sloan-Kettering, we obtained worldwide exclusive rights to specified technology relating to ganglioside conjugate vaccines, including GMK, and its use to treat or prevent cancer. This technology is the subject of a patent filed by Sloan-Kettering in the United States and 25 foreign countries claiming composition of matter and methods of production and use of specified ganglioside conjugate vaccines for the treatment or prevention of human cancer. The currently issued patents expire in 2014. However, pending patent applications that we have also licensed and patent term extensions may extend the period of patent protection, when and if such patent applications are allowed and issued or patent term extensions are granted.

Under a license agreement with Columbia University, we obtained worldwide, exclusive rights to specified technology relating to CD4. This technology is the subject of issued U.S. and European patents and several related U.S. and foreign patent applications filed by Columbia University. The issued patents and the patent applications claim composition of matter and methods of production and use of specified CD4-based products for the treatment or prevention of HIV infection. The issued patents covered by this license agreement expire on dates ranging from 2007 to 2020; however, patent applications that we have also licensed and patent term extensions may extend the period of patent protection, when and if such patent applications are allowed and issued or patent term extensions are granted.

Under a license agreement with Sloan-Kettering, we obtained worldwide exclusive rights to specified technology relating to dehydroascorbic acid and its use to increase the concentration of vitamin C in tissues, including the brain, for treating neurodegenerative and neurovascular diseases. This technology is the subject of issued U.S. patents claiming methods for increasing the vitamin C concentration in the cells of a patient by administering dehydroascorbic acid to the patient. The issued patents expire in 2019; however, patent applications filed in the United States and internationally that we have also licensed and patent term extensions may extend the period of patent protection, when and if such patent applications are allowed and issued or patent term extensions are granted.

The research, development and commercialization of a biopharmaceutical often involves alternative development and optimization routes, which are presented at various stages in the development process. The preferred routes cannot be predicted at the outset of a research and development program because they will depend upon subsequent discoveries and test results. There are numerous third-party patents in our field, and it is possible that to pursue the preferred development route of one or more of our products we will need to obtain a license to a patent, which would decrease the ultimate profitability of the applicable product. If we cannot negotiate a license, we might have to pursue a less desirable development route or terminate the program altogether.

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# **Scientific Advisory Boards**

An important component of our scientific strategy is our collaborative relationship with leading researchers in cancer and virology. Some of these researchers are members of our two Scientific Advisory Boards, one in cancer and one in virology. The members of each SAB attend periodic meetings and provide us with specific expertise in both research and clinical development. In addition, we have collaborative research relationships with some of our individual SAB members. All members of our SABs are employed by employers other than us and may have commitments to or consulting or advisory agreements with other entities that may limit their availability to us. These companies may also compete with us. Several members of the SABs have, from time to time, devoted significant time and energy to our affairs. However, no member is regularly expected to devote more than a small portion of time to Progenics. In general, our scientific advisors are granted stock options in Progenics and receive financial remuneration for their services.

The following table sets forth information with respect to our Scientific Advisory Boards.

# Cancer Scientific Advisory Board

Alan N. Houghton, M.D. Chairman, Immunology Program, Sloan-Kettering and Professor,

(Chairman) Weill/Cornell Medical College (WCMC)

Angus G. Dalgleish, M.D., Ph.D. Chairman and Professor of Medical Oncology, St. George St. George

London

Samuel J. Danishefsky, Ph.D. Kettering Professor and Head, Bioorganic Chemistry, Sloan-Kettering and

Professor of Chemistry, Columbia University

Philip O. Livingston, M.D. Member, Sloan-Kettering and Professor, WCMC

John Mendelsohn, M.D. President, The University of Texas M. D. Anderson Cancer Center David A. Scheinberg, M.D., Ph.D. Vincent Astor Chair and Chairman, Molecular Pharmacology and

Chemistry Program, Sloan-Kettering and Professor, WCMC

David B. Agus, M.D. Research Director, Prostate Cancer Institute, Cedars-Sinai Medical

Center

### Virology Scientific Advisory Board

Stephen P. Goff, Ph.D. (Chairman) Professor of Biochemistry, Columbia University
Lawrence A. Chasin, Ph.D. Professor of Biological Sciences, Columbia University

Leonard Chess, M.D. Professor of Medicine, Columbia University
Wayne A. Hendrickson, Ph.D. Professor of Biochemistry, Columbia University

Sherie L. Morrison, Ph.D. Professor of Microbiology, University of California at Los Angeles Robin A. Weiss, Ph.D. Professor and Director of Research, The Institute of Cancer Research,

Royal Cancer Hospital, London

### Other Scientific Consultants

David W. Golde, M.D. Member, Sloan-Kettering and Professor, WCMC

Jonathan Moss, M.D., Ph.D. Professor, Department of Anesthesia and Critical Care, and Vice

Chairman for Research, University of Chicago Medical Center

Thomas P. Sakmar, M.D. Professor and Head of Laboratory of Molecular Biology and Biochemistry,

The Rockefeller University

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### **Government Regulation**

Progenics and our products are subject to comprehensive regulation by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state and local entities regulate, among other things, the preclinical and clinical testing, safety, effectiveness, approval, manufacture, labeling, marketing, export, storage, record keeping, reporting, advertising and promotion of our products. None of our product candidates has received marketing or other approval from the FDA or any other similar regulatory authority.

FDA approval of our products, including a review of the manufacturing processes and facilities used to produce such products, will be required before our products may be marketed in the United States. The process of obtaining approvals from the FDA can be costly, time consuming and subject to unanticipated delays. The FDA may not grant approvals of our proposed products, processes, or facilities on a timely basis, or at all. If we experience delays in obtaining, or do not obtain, approvals for our products, commercialization of our products would be slowed or stopped. Moreover, even if we obtain regulatory approval, the approval may include significant limitations on indicated uses or conditions to use for which the product could be marketed or other significant marketing restrictions.

The process required by the FDA before our products may be approved for marketing in the United States generally involves:

	preclinical laboratory and animal tests performed under the FDA social Good Laboratory Practices Regulations
	submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin;
	adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication;
	submission to the FDA of a marketing application; and
inform preclu Practi regard IND a make	FDA review of the marketing application in order to determine, among other things, whether the product is safe and effective for its intended uses. nical tests include laboratory evaluation of product chemistry and animal studies to gain preliminary nation about a product spharmacology and toxicology and to identify any safety problems that would not testing in humans. Products must generally be manufactured according to current Good Manufacturing uses, and preclinical safety tests must be conducted by laboratories that comply with FDA regulations ding good laboratory practices. The results of the preclinical tests are submitted to the FDA as part of an application. An IND is a submission which the sponsor of a clinical trial of an investigational new drug must to the FDA and which must become effective before clinical trials may commence. The IND submission include, among other things:
	a description of the sponsor□s investigational plan;
	protocols for each planned study;
	chemistry, manufacturing and control information;
	pharmacology and toxicology information; and
effect obtair	a summary of previous human experience with the investigational drug. s the FDA objects to, makes comments or raises questions concerning an IND, the IND will become ive 30 days following its receipt by the FDA and initial clinical studies may begin, although companies often affirmative FDA approval before beginning such studies. Submission of an IND may not result in FDA rization to commence clinical trials.

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	v Drug Application, or NDA, is an application to the FDA to market a new drug. The NDA must contain, g other things:
	information on chemistry, manufacturing and controls;
	information on non-clinical pharmacology and toxicology studies;
	human pharmacokinetics and bioavailability data; and
[] The n	clinical data. ew drug may not be marketed in the United States until the FDA has approved the NDA.
must demo	ogics License Application, or BLA, is an application to the FDA to market a biological product. The BLA contain, among other things, data derived from nonclinical laboratory and clinical studies which instrate that the product meets prescribed standards of safety, purity and potency, and a full description of facturing methods. The biological product may not be marketed in the United States until a biologic license and.
The F	DA may not approve any NDA or BLA we submit in a timely manner or at all.
the su FDA[] study must condu amon	al trials involve the administration of the investigational new drug to healthy volunteers or to patients under pervision of a qualified principal investigator. Clinical trials must be conducted in accordance with the second Clinical Practice requirements under protocols that detail, among other things, the objectives of the the parameters to be used to monitor safety, and the effectiveness criteria to be evaluated. Each protocol be submitted to the FDA as part of the IND. Further, each clinical study must be approved by and acted under the auspices of an Institutional Review Board. The Institutional Review Board will consider, gother things, ethical factors, the safety of human subjects, the possible liability of the institution and the need consent disclosure which must be made to participants in the clinical trial.
1, wh	al trials are typically conducted in three sequential phases, although the phases may overlap. During phase en the drug is initially administered to human subjects, the product is tested for safety, dosage tolerance, ption, metabolism, distribution and excretion. Phase 2 involves studies in a limited patient population to:
	evaluate preliminarily the efficacy of the product for specific, targeted indications;
	determine dosage tolerance and optimal dosage; and
-	identify possible adverse effects and safety risks. se 1/2 clinical trial involves an evaluation of safety with some measure of efficacy. A phase 2b trial also to optimize the dose in anticipation of subsequent clinical trials.

When a new product is found to have an effect and to have an acceptable safety profile in phase 2 evaluation, phase 3 trials are undertaken in order to further evaluate clinical efficacy and to further test for safety within an expanded patient population. The FDA may suspend clinical trials at any point in this process if it concludes that clinical subjects are being exposed to an unacceptable health risk.

The results of the preclinical studies and clinical studies, the chemistry and manufacturing data, and the proposed labeling, among other things, are submitted to the FDA in the form of an NDA or BLA, approval of which must be obtained prior to commencement of commercial sales. The FDA may refuse to accept the application for filing if certain administrative and content criteria are not satisfied, and even after accepting the application for review, the FDA may require additional testing or information before approval of the application. Our analysis of the results of our clinical studies is subject to review and interpretation by the FDA, which may differ from our analysis. Our data or our interpretation of data may not be accepted by the FDA. In addition, for both NDAs and BLAs, the application will not be approved until the FDA conducts a manufacturing inspection and approves the applicable manufacturing process for the drug or biologic. In any event, the FDA must deny an NDA or BLA if applicable regulatory requirements are not ultimately satisfied.

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In addition, we may encounter delays or rejections based upon changes in applicable law or FDA policy during the period of product development and FDA regulatory review. Moreover, if regulatory approval of a product is granted, such approval may be made subject to various conditions, including post-marketing testing and surveillance to monitor the safety of the product, or may entail limitations on the indicated uses or conditions for use for which it may be marketed. Finally, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

Our products must be manufactured in FDA-registered facilities subject to inspection. We must be in compliance with current Good Manufacturing Practices, which impose procedural and documentation requirements upon us with respect to manufacturing and quality control activities. To ensure full compliance with these regulations, we must spend funds, time and effort in the areas of production and quality control. If we fail to comply with current Good Manufacturing Practices we may be subject to fines, injunctions, civil penalties, product recalls or seizures, total or partial suspension of production, failure of the government to grant approval for marketing, withdrawal, suspension or revocation of marketing approvals, and criminal prosecution. Any failure to comply with current Good Manufacturing Practices could have a material adverse effect on our business, financial condition and results of operations.

Both before and after approval is obtained, a product, its manufacturer, and the sponsor of the marketing application for the product are subject to comprehensive regulatory oversight. Violations of regulatory requirements at any stage, including the preclinical and clinical testing process, the approval process, or thereafter, may result in various adverse consequences, including FDA delay in approving or refusal to approve a product, withdrawal of an approved product from the market or the imposition of criminal penalties against the manufacturer or sponsor. In addition, later discovery of previously unknown problems may result in restrictions on such product, manufacturer, or sponsor, including withdrawal of the product from the market. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

Whether or not FDA approval has been obtained, approval of a pharmaceutical product by comparable government regulatory authorities in foreign countries must be obtained prior to marketing such product in such countries. The approval procedure varies from country to country, and the time required may be longer or shorter than that required for FDA approval. Although there are some procedures for unified filing for certain European countries, in general, each country has its own procedures and requirements. We do not currently have any facilities or personnel outside of the United States.

In addition to regulations enforced by the FDA, we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and various other present and potential future federal, state or local regulations. Our research and development involves the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds. Although we believe that our safety procedures for storing, handling, using and disposing of such materials comply with the standards prescribed by applicable regulations, we cannot completely eliminate the risk of accidental contaminations or injury from these materials. In the event of such an accident, we could be held liable for any legal and regulatory violations as well as damages that result. Any such liability could have a material adverse effect on Progenics.

#### **Manufacturing**

We currently manufacture PRO 542, PRO 140, GMK and PSMA protein vaccines in our two pilot production facilities in Tarrytown, New York. One of these facilities is for the production of vaccines and the other is for the production of recombinant proteins. We are preparing to install a 1,000-liter bioreactor that will utilize a new cell line. This facility, which we expect will be operational during 2004, is designed to provide us with an additional source of clinical supplies of PRO 542 in support of the clinical program. We believe that our existing production facilities will be sufficient to meet our initial needs for clinical trials for these product candidates. However, these facilities may be insufficient for all of our late-stage clinical trials for these product candidates and would be insufficient for commercial- scale requirements. We may be

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required to further expand our manufacturing staff and facilities, obtain new facilities or contract with third parties or corporate collaborators to assist with production.

We currently rely on single-source third party manufacturers for the supply of both bulk and finished form MNTX. While we believe that our existing arrangements with such single-source third party manufacturers are stable, reliable and adequate for the balance of our clinical trial and initial commercial supply requirements, we are actively engaged in a program to further expand such relationships, as well as to identify additional manufacturers for bulk and finished form MNTX as supplements and backup to our current arrangements.

In the event we decide to establish a full-scale commercial manufacturing facility for any or all of our products, we would need to spend substantial additional funds and will be required to hire and train significant numbers of employees and comply with the extensive FDA regulations applicable to such a facility.

#### **Sales and Marketing**

We plan to market products for which we obtain regulatory approval through co-marketing, co-promotion, licensing and distribution arrangements with third-party collaborators. We may also consider contracting with a third-party professional pharmaceutical detailing and sales organization for our products. We believe that our current approach allows us maximum flexibility of selecting the marketing method that will both increase market penetration and commercial acceptance of our products and enable us to avoid expending significant funds to develop a large sales and marketing organization. Cytogen has certain marketing rights with respect to the products covered by our joint venture.

#### Competition

Competition in the biopharmaceutical industry is intense and characterized by ongoing research and development and technological change. We face competition from many companies and major universities and research institutions in the United States and abroad. We will face competition from companies marketing existing products or developing new products for diseases targeted by our technologies. Many of our competitors have substantially greater resources, experience in conducting preclinical studies and clinical trials and obtaining regulatory approvals for their products, operating experience, research and development and marketing capabilities and production capabilities than we do. Our products under development may not compete successfully with existing products or products under development by other companies, universities and other institutions. Our competitors may succeed in obtaining FDA approval for products more rapidly than we do. Drug manufacturers that are first in the market with a therapeutic for a specific indication generally obtain and maintain a significant competitive advantage over later entrants. Accordingly, the speed with which we can develop products, complete the clinical trials and approval processes and ultimately supply commercial quantities of the products to the market is expected to be an important competitive factor.

With respect to MNTX, there are currently no FDA approved products for reversing the debilitating side effects of opioid pain therapy or for the treatment of post-operative bowel dysfunction. We are, however, aware of a product candidate called alvimopan in advanced clinical development by Adolor Corporation in partnership with Glaxo. This product candidate targets these therapeutic indications, but its effects are limited solely to the lumen of the gastrointestinal tract, whereas MNTX is available systemically.

With respect to our products for the treatment of HIV infection, three classes of products made by our competitors have been approved for marketing by the FDA for the treatment of HIV infection and AIDS: reverse transcriptase inhibitors, protease inhibitors and entry inhibitors. These drugs have shown efficacy in reducing the concentration of HIV in the blood and prolonging asymptomatic periods in HIV-positive individuals, especially when administered in combination.

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With respect to GMK, the FDA and certain other regulatory authorities have approved high-dose alpha-interferon for marketing as a treatment for patients with high-risk melanoma. High-dose alpha interferon has demonstrated efficacy for this indication.

A significant amount of research in the biopharmaceutical field is also being carried out at academic and government institutions. An element of our research and development strategy is to in-license technology and product candidates from academic and government institutions. These institutions are becoming increasingly sensitive to the commercial value of their findings and are becoming more aggressive in pursuing patent protection and negotiating licensing arrangements to collect royalties for use of technology that they have developed. These institutions may also market competitive commercial products on their own or in collaboration with competitors and will compete with us in recruiting highly qualified scientific personnel. Any resulting increase in the cost or decrease in the availability of technology or product candidates from these institutions may adversely affect our business strategy.

Competition with respect to our technologies and product candidates is and will be based, among other things, on:

	efficacy and safety of our products;
	timing and scope of regulatory approval;
	product reliability and availability;
	marketing and sales capabilities;
	capabilities of our collaborators;
	reimbursement coverage from insurance companies and others;
	degree of clinical benefits of our product candidates relative to their costs;
	method of administering a product;
	price; and
_	patent protection.  ompetitive position will also depend upon our ability to attract and retain qualified personnel, to obtain

Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes, and to secure sufficient capital resources for the often substantial period between technological conception and commercial sales. Competitive disadvantages in any of these factors could materially harm our business and financial condition.

#### **Product Liability**

The testing, manufacturing and marketing of our products involves an inherent risk of product liability attributable to unwanted and potentially serious health effects. To the extent we elect to test, manufacture or market products independently, we will bear the risk of product liability directly. We have obtained product liability insurance coverage in the amount of \$5.0 million per occurrence, subject to a deductible and a \$5.0 million aggregate limitation. In addition, where the local statutory requirements exceed the limits of our existing insurance or local policies of insurance are required, we maintain additional clinical trial liability insurance to meet these requirements. This insurance is subject to deductibles and coverage limitations. We may not be able to continue to maintain insurance at a reasonable cost, or in adequate amounts.

#### **Human Resources**

At June 30, 2003, we had 110 full-time employees, 18 of whom, including Dr. Maddon, hold Ph.D. degrees or foreign equivalents and four of whom, including Dr. Maddon, hold M.D. degrees. At such date, 81 employees were engaged in research and development, medical and regulatory affairs and manufacturing activities and 29 were engaged in finance, legal, administration and business development. We consider our

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relations with our employees to be good. None of our employees is covered by a collective bargaining agreement.

#### **Facilities**

We sublease approximately 48,000 square feet of laboratory, manufacturing and office space in Tarrytown, New York. We sublease this space pursuant to a sublease which terminates in June 2005. We have two pilot production facilities within these leased facilities for the manufacture of products for clinical trials. The base monthly rent for our sublease is \$65,000 from January 1, 2003 through June 30, 2005, plus additional utility charges.

On September 30, 2003 we executed a lease for approximately 33,800 square feet of additional laboratory, manufacturing and office space in Tarrytown, New York. The commencement dates of the lease for these spaces range from October 23, 2003 to March 15, 2004, subject to certain acceleration provisions with regard to some of the spaces. The lease expires on December 31, 2009, with an option to renew for two additional five-year terms. The base monthly rent for the lease will be approximately \$74,000 from commencement until August 31, 2007 and approximately \$79,000 from September 1, 2007 until December 31, 2009.

We are negotiating to lease additional space which, together with the newly executed lease, would provide us with approximately 49,000 square feet. We believe that these facilities will be adequate for our current needs, although we may in the future expand our facilities for additional research and development and manufacturing capability.

#### **Legal Proceedings**

We are not a party to any material legal proceedings.

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#### **MANAGEMENT**

#### **Directors, Executive Officers and Key Management**

Our directors, executive officers and key management are as follows:

Name	Age	Position
Paul J. Maddon, M.D., Ph.D. (1)	44	Chairman of the Board, Chief Executive Officer and Chief Science Officer
Ronald J. Prentki (1)	45	President and Director
Robert J. Israel, M.D.	46	Senior Vice President, Medical Affairs
Robert A. McKinney	47	Vice President, Finance & Operations and Treasurer
Philip K. Yachmetz	46	Vice President, General Counsel and Secretary
Richard W. Krawiec, Ph.D.	55	Vice President, Investor Relations & Corporate
		Communications
William C. Olson, Ph.D.	41	Vice President, Research & Development
Kenneth G. Surowitz, Ph.D.	44	Vice President, Regulatory Affairs & Quality
Thomas A. Boyd, Ph.D.	52	Vice President, Preclinical Development and Project
		Management
Charles A. Baker (1)(2)(3)(4)	71	Director
Kurt W. Briner (1)(3)(4)	59	Director
Mark F. Dalton (2)(4)	53	Director
Stephen P. Goff, Ph.D. (4)	52	Director
Paul F. Jacobson (1)(2)(3)(4)	49	Director
David A. Scheinberg, M.D., Ph.D. (4)	47	Director

<sup>(1)</sup> Member of Executive Committee

**Paul J. Maddon, M.D., Ph.D.** is our founder and has served, since our inception, in various capacities, including as our Chairman of the Board of Directors, Chief Executive Officer, President and Chief Science Officer. From 1981 to 1988, Dr. Maddon performed research at the Howard Hughes Medical Institute at Columbia University in the laboratory of Dr. Richard Axel. Dr. Maddon serves on several scientific review committees at the National Institutes of Health and is a member of the editorial board of *AIDS Research and Human Retroviruses*. Dr. Maddon also serves on the board of directors of Epixis SA, a French biotechnology company. He received a B.A. in biochemistry and mathematics and an M.D. and a Ph.D. in biochemistry and molecular biophysics from Columbia University. Dr. Maddon has been an Adjunct Assistant Professor of Medicine at Columbia University since 1989.

Ronald J. Prentki has been our President since July 1998 and became a director in September 1998. Prior thereto, he was Vice President of Business Development and Strategic Planning at Hoffmann-La Roche Inc. from 1996 to 1998. Mr. Prentki spent from 1990 to 1996 at Sterling Winthrop (subsequently acquired by Sanofi Pharmaceuticals), most recently serving as Vice President of Business Development. From 1985 to 1990 Mr. Prentki was with Bristol-Myers Squibb International Division, initially supporting the marketing of that company oncology products and later as Director of Cardiovascular Products. Mr. Prentki received a B.S. in Microbiology and Public Health from Michigan State University and an M.B.A. from the University of Detroit.

**Robert J. Israel, M.D.** joined us as Vice President, Medical Affairs in October 1994 and was promoted to Senior Vice President, Medical Affairs in 2002. From 1991 to 1994, Dr. Israel was Director, Clinical Research-Oncology and Immunohematology at Sandoz Pharmaceuticals Corporation, now known as Sandoz, a Novartis company. From 1988 to 1991, he was Associate Director, Oncology Clinical Research at

<sup>(2)</sup> Member of Compensation Committee

<sup>(3)</sup> Member of Audit Committee

<sup>(4)</sup> Member of Director Search and Nominating Committee

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Schering-Plough Corporation. Dr. Israel is a licensed physician and is board certified in both internal medicine and medical oncology. He received a B.A. in physics from Rutgers University and a M.D. from the University of Pennsylvania and completed an oncology fellowship at Sloan-Kettering. Dr. Israel has been a consultant to the Solid Tumor Service at Sloan-Kettering since 1987.

Robert A. McKinney joined us in September 1992. Mr. McKinney served as Director, Finance and Operations and Treasurer from 1992 to January 1993, when he was appointed Vice President, Finance and Operations and Treasurer of Progenics. From 1991 to 1992, he was Corporate Controller at VIMRx Pharmaceuticals, Inc., a biotechnology research company. From 1990 to 1991, Mr. McKinney was Manager, General Accounting at Micrognosis, Inc., a software integration company. From 1985 to 1990, he was an audit supervisor at Coopers & Lybrand LLP, an international accounting firm. Mr. McKinney studied finance at the University of Michigan, received a B.B.A. in accounting from Western Connecticut State University, and is a Certified Public Accountant.

Philip K. Yachmetz joined us in September 2000 as General Counsel and Secretary and was promoted to Vice President in January 2002. Prior to joining Progenics, Mr. Yachmetz had been Senior Vice President, Business Development, General Counsel and Secretary of CytoTherapeutics, Inc. from 1998 to 1999, where he also was Acting Chief Financial Officer and Treasurer during 1999. From 1997 to 1998, Mr. Yachmetz was a Principal and Managing Director of Millennium Venture Management LLC, a business consulting group servicing the healthcare and high technology industries. Mr. Yachmetz was, from 1996 to 1997, Director, Legal & Corporate Affairs and Secretary of PlayNet Technologies, Inc., an Internet-based entertainment company. From January 1989 to October 1996, Mr. Yachmetz served as Senior Counsel of Hoffmann-La Roche Inc. Mr. Yachmetz received a B.A. in Political Science from George Washington University and a J.D. from California Western School of Law and is admitted to practice law in New York and New Jersey.

**Richard W. Krawiec, Ph.D.** joined us in February 2001 as Vice President, Investor Relations and Corporate Communications. Prior to joining Progenics, Dr. Krawiec served as Vice President of Investor Relations and Corporate Communications of Cytogen Corporation from 2000 to 2001. Prior to Cytogen, Dr. Krawiec headed these departments at La Jolla Pharmaceuticals, Inc. during 1999, at Amylin Pharmaceuticals, Inc. from 1993 to 1998 and IDEC Pharmaceuticals, Inc. previously thereto. Previously, Dr. Krawiec was the founder and Editor-In-Chief of *Biotechnology Week* magazine and the Managing Editor and founder of *Biotechnology Newswatch*. Dr. Krawiec received a B.S. in Biology from Boston University and a Ph.D. in Biological Sciences from the University of Rhode Island.

*William C. Olson, Ph.D.* joined us in May 1994 serving in various roles of increasing responsibility through his promotion to Vice President, Research and Development in January 2001. From 1989 to 1992, Dr. Olson served as a Research Scientist at Johnson & Johnson, and from 1992 until 1994 he was a Development Scientist at MicroGeneSys, Inc., a biotechnology company. Dr. Olson received a Ph.D. from the Massachusetts Institute of Technology and a B.S. from the University of North Dakota. Both degrees were awarded in the field of chemical engineering.

Kenneth G. Surowitz, Ph.D. joined us in January 1999. Dr. Surowitz served as Senior Director, Quality & Regulatory Affairs from January 1999 to January 2000, when he was appointed Vice President, Quality & Regulatory Affairs of Progenics. From 1988 to 1999, Dr. Surowitz was employed at the Wyeth-Lederle Vaccines and Pediatrics unit of American Home Products Corp. in a number of positions within the organization, most recently as Director of Global Regulatory Affairs. From 1985 to 1988, he was employed as a Product Development Microbiologist at Procter and Gamble. Dr. Surowitz received Ph.D. and M.S. degrees from Ohio State University in the field of microbiology and an A.B. degree from Lafayette College in biology.

**Thomas A. Boyd, Ph.D.** joined us in January 2000 as Senior Director, Project Management and was promoted to Vice President, Preclinical Development and Project Management in January 2002. From 1996 through 2000, Dr. Boyd was Associate Director, R&D Project Management at Boehringer Ingelheim Pharmaceuticals, Inc. and held various positions with Wyeth-Ayerst Research and Alteon, Inc. prior thereto.

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He received his Ph.D. from Brown University in physiology and biophysics and an A.B. degree from the College of Arts and Sciences, Cornell University.

Charles A. Baker is a business advisor to biotechnology companies. He is the former Chairman, President and Chief Executive Officer of The Liposome Company, Inc., a biotechnology company located in Princeton, New Jersey, a position he held from 1989 until his retirement in 2000. Mr. Baker is currently a director of Regeneron Pharmaceuticals, Inc., a biotechnology company, and Alcide Corporation, an animal health and food safety company. Mr. Baker has 41 years of pharmaceutical industry experience and has held senior management positions at Pfizer, Abbott Laboratories and Squibb Corporation. Mr. Baker received a B.A. from Swarthmore College and a J.D. from Columbia University.

*Kurt W. Briner* is the retired President and Chief Executive Officer of Sanofi Pharma S.A. in Geneva, Switzerland, a position he held from 1988 until his retirement in 2000, and he has nearly 31 years experience in the pharmaceutical industry. Mr. Briner is currently also a director of Novo Nordisk Danmark and Altana Pharma, each a European based pharmaceutical company. He attended Humanistisches Gymnasium in Basel and Ecole de Commerce in Basel and Lausanne.

*Mark F. Dalton* has been the President and a director of Tudor Investment Corporation, an investment advisory company, and its affiliates since 1988. From 1979 to 1988, he served in various senior management positions at Kidder, Peabody & Co. Incorporated, including Chief Financial Officer. Mr. Dalton is currently a director of several private companies as well as a closed-end investment fund listed on the Dublin Stock Exchange. Mr. Dalton received a B.A. from Denison University and a J.D. from Vanderbilt University Law School.

**Stephen P. Goff, Ph.D.** has been a member our Virology Scientific Advisory Board since 1988 and has been its Chairman since April 1991. Dr. Goff has been the Higgins Professor in the Departments of Biochemistry and Microbiology at Columbia University since June 1990. He received an A.B. in biophysics from Amherst College and a Ph.D. in biochemistry from Stanford University. Dr. Goff performed post-doctoral research at the Massachusetts Institute of Technology in the laboratory of Dr. David Baltimore.

**Paul F. Jacobson** is a private investor and has been a general partner of Starting Point Venture Partners, a private investment fund, since 1999. Previously Mr. Jacobson was Managing Director of fixed income securities at Deutsche Bank from January 1996 to November 1997. He was President of Jacobson Capital Partners from 1993 to 1996. From 1986 to 1993, Mr. Jacobson was a partner at Goldman, Sachs & Co., where he was responsible for government securities trading activities. Mr. Jacobson received a B.A. from Vanderbilt University and an M.B.A. from Washington University.

**David A. Scheinberg, M.D., Ph.D.** has been a member of our Cancer Scientific Advisory Board since 1994. Dr. Scheinberg has been associated with Sloan-Kettering since 1986, where he is the Vincent Astor Chair and Chairman, Molecular Pharmacology and Chemistry Program; Chief, Leukemia Service; and Doris Duke Distinguished Clinical Science Professor. He also holds the position of Professor of Medicine and Molecular Pharmacology, Weill-Cornell Medical College. He received a B.A. from Cornell University and an M.D. and a Ph.D. in pharmacology and experimental therapeutics from The Johns Hopkins University School of Medicine.

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#### **Summary Compensation Table**

The following table sets forth information regarding the aggregate compensation we paid during the three fiscal years ended December 31, 2002 to our chief executive officer and our four other most highly compensated executive officers (collectively, the [named executive officers[):

			Annual Compensation <sup>1</sup>			Stock	
Name and Principal Position	Fiscal Year		Salary		Bonus	Option Grants (# of shares)	 Other <sup>2</sup>
Paul J. Maddon, M.D., Ph.D. Chairman of the Board, Chief Executive Officer and Chief Science Officer	2002 2001	\$	473,800 460,000	\$	110,000 110,000	108,000 □	\$ 12,729 12,229
Ronald J. Prentki	2000		450,000		100,000		12,229
President	2002 2001 2000	\$	326,510 317,000 264,000	\$	100,000 250,000 70,000	325,000 60,000	\$ 11,000 10,500 17,500
Robert A. McKinney Vice President, Finance and			•		•	ŕ	•
Operations and Treasurer	2002 2001 2000	\$	166,350 156,200 142.000	\$	40,000 40,000 27,000	25,000 25,000 50,000	\$ 11,900 11,600 15,130
Philip K. Yachmetz Vice President, General Counsel			,		•	·	
and Secretary	2002 2001 2000 <sub>3</sub>	\$	207,675 195,000 47.500	\$	50,000 45,000 35.000	35,000 10,000 50.000	\$ 11,000 58,400 5.800
Robert J. Israel, M.D. Senior Vice President, Medical Affairs	2002 2001 2000	\$	252,800 238,500 225,000	\$	75,000 60,000 50,000	35,000 25,000 50,000	\$ 35,198 <sub>4</sub> 36,098 <sub>4</sub> 40,663 <sub>4</sub>
	2000		443,000		30,000	30,000	40,0034

<sup>(1)</sup> Annual compensation consists of base salary and bonus. As to each individual named, the aggregate amounts of all perquisites and other personal benefits, securities and property not included in the summary compensation table above or described below do not exceed the lesser of \$50,000 or 10% of the annual compensation.

<sup>(2) [</sup>Other compensation] consisted of matching contributions made by us under a defined contribution plan available to substantially all employees and amounts to pay the after-tax cost of premiums on life insurance and long-term disability policies. As to Mr. Yachmetz only, compensation for 2001 also includes a special bonus paid pursuant to his offer of employment to cover certain expenditures by Mr. Yachmetz and an associated tax gross-up.

<sup>(3)</sup> Mr. Yachmetz became an executive officer in September of 2000 with an annual base salary of \$190,000.

<sup>(4)</sup> Includes \$23,963 forgiven under a loan from us in 2000, \$24,498 in 2001 and \$23,298 in 2002.

#### PRINCIPAL STOCKHOLDERS

The following table sets forth certain information, as of June 30, 2003, except as noted, regarding the beneficial ownership of our common stock by (i) each person or group known to us to be the beneficial owner of more than 5% of our common stock outstanding, (ii) each of our directors, (iii) each of our executive officers named below and (iv) all of our directors and executive officers as a group. Except as otherwise specified, the named beneficial owner has sole voting and investment power over the shares listed.

	Number Of	Percentage of Shares Beneficially Owned <sup>2</sup>			
Name <sup>1</sup>	Shares Beneficially Owned <sup>2</sup>	Before Offering	After Offering		
Entities affiliated with Tudor Investment Corporation <sup>3</sup> 1275 King Street, Greenwich, CT 06831	2,342,388	18.1%	14.9%		
Paul Tudor Jones, II <sup>4</sup> 1275 King Street, Greenwich, CT 06831	2,888,513	22.3%	18.4%		
Entities affiliated with Arnold H. Snider and Deerfield Capital, L.P. <sup>5</sup> 450 Lexington Avenue, New York, NY 10017	1,000,000	7.7%	6.4%		
Paul J. Maddon, M.D., Ph.D. <sup>6</sup>	1,674,276	12.0%	10.0%		
Ronald J. Prentki <sup>7</sup>	407,075	3.1%	2.5%		
Charles A. Baker <sup>8</sup>	73,481	*	*		
Kurt W. Briner <sup>9</sup>	95,000	*	*		
Mark F. Dalton <sup>10</sup>	2,481,888	19.1%	15.8%		
Stephen P. Goff, Ph.D. <sup>11</sup>	121,000	*	*		
Paul F. Jacobson <sup>12</sup>	243,100	1.9%	1.5%		
David A. Scheinberg, M.D., Ph.D. <sup>13</sup>	207,938	1.6%	1.3%		
Robert J. Israel, M.D. 14	183,381	1.4%	1.2%		
Robert A. McKinney <sup>15</sup>	122,161	*	*		
Philip K. Yachmetz <sup>16</sup>	37,092	*	*		
All directors and executive officers as a group <sup>17</sup>	5,646,392	37.1%	31.4%		

<sup>\*</sup> Less than one percent.

- (2) Except as indicated and pursuant to applicable community property laws, each stockholder possesses sole voting and investment power with respect to the shares of common stock listed. The number of shares of common stock beneficially owned includes the shares issuable pursuant to stock options to the extent indicated in the footnotes in this table. Shares issuable upon exercise of these options are deemed outstanding for computing the percentage of beneficial ownership of the person holding the options but are not deemed outstanding for computing the percentage of beneficial ownership of any other person.
- (3) The number of shares owned by entities affiliated with Tudor Investment Corporation (TIC) consists of 1,820,068 shares held of record by The Tudor BVI Portfolio Ltd., a company organized under the law of the Cayman Islands (Tudor BVI), 287,813 shares held of record by TIC, 193,126 shares held of record by Tudor Arbitrage Partners L.P. (TAP), 25,981 shares held of record by Tudor Proprietary Trading, L.L.C. (TPT), and 15,400 shares held of record by Tudor Global Trading LLC (TGT). In addition, because TIC provides investment advisory services to Tudor BVI, it may be deemed to beneficially own the shares held by such entity. TIC disclaims beneficial ownership of such shares. TGT is the general partner of TAP. Tudor Group Holdings LLC (TGH) is the sole member of TGT and

<sup>(1)</sup> Unless otherwise specified, the address of each beneficial owner is c/o the Company, 777 Old Saw Mill River Road, Tarrytown, New York 10591.

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- indirectly holds all of the membership interests of TPT. TGH is also the sole limited partner of TAP. TGH expressly disclaims beneficial ownership of the shares beneficially owned by each of such entities. TGT disclaims beneficial ownership of shares held by TAP. The number set forth does not include shares owned of record by Mr. Jones and Mr. Dalton. See Notes 4 and 10.
- (4) Includes 2,342,388 shares beneficially owned by entities affiliated with TIC. Mr. Jones is the Chairman and indirect principal equity owner of TIC, TPT and TGT, and the indirect principal equity owner of TAP. Mr. Jones may be deemed to be the beneficial owner of shares beneficially owned, or deemed beneficially owned, by entities affiliated with TIC. Mr. Jones disclaims beneficial ownership of such shares. See Note 3.
- (5) Based on a Schedule 13G/A dated February 11, 2003, the number of shares owned by entities affiliated with Arnold H. Snider and Deerfield Capital L.P. includes 560,000 shares held of record by Deerfield Capital L.P. and Deerfield Partners, L.P., each a Delaware limited partnership, and 440,000 shares held of record by Deerfield Management Company, a New York limited partnership, and Deerfield International Limited, a British Virgin Islands corporation.
- (6) Includes 1,037,274 shares issuable upon exercise of options exercisable within 60 days of June 30, 2003. Includes 64,695 shares transferred by Dr. Maddon to his spouse pursuant to a pre-nuptial agreement. Dr. Maddon disclaims beneficial ownership of such shares. Dr. Maddon anticipates that he will make additional transfers to his spouse in the future pursuant to his pre-nuptial agreement.
- (7) Includes 395,515 shares issuable upon exercise of options held by Mr. Prentki exercisable within 60 days of June 30, 2003.
- (8) Includes 18,481 shares owned by the Baker Family Limited Partnership and 55,000 shares issuable upon exercise of options held by Mr. Baker and exercisable within 60 days of June 30, 2003.
- (9) Includes 95,000 shares issuable upon exercise of options held by Mr. Briner exercisable within 60 days of June 30, 2003.
- (10) Includes 68,000 shares held of record directly by Mr. Dalton, 55,000 shares issuable upon exercise of options held by Mr. Dalton exercisable within 60 days of June 30, 2003 and 16,500 shares held of record by DF Partners, a family partnership of which Mr. Dalton is the managing general partner with a 5% interest. The remaining 95% partnership interest is held by certain family trusts. As to such 95% interest, Mr. Dalton disclaims beneficial interest. The number set forth includes 2,343,388 shares beneficially owned by entities affiliated with TIC. Mr. Dalton is President of TIC, TGH, TGT and TPT. Mr. Dalton disclaims beneficial ownership of shares beneficially owned, or deemed beneficially owned, by entities affiliated with TIC. See Note 3.
- (11) Includes 87,500 shares issuable upon exercise of options held by Dr. Goff exercisable within 60 days of June 30, 2003.
- (12) Includes 55,000 shares issuable upon exercise of options held by Mr. Jacobson exercisable within 60 days of June 30, 2003.
- (13) Includes 196,000 shares issuable upon exercise of options held by Dr. Scheinberg exercisable within 60 days of June 30, 2003.
- (14)Includes 178,750 shares issuable upon exercise of options held by Dr. Israel exercisable within 60 days of June 30, 2003.
- (15) Includes 118,750 shares issuable upon exercise of options held by Mr. McKinney exercisable within 60 days of June 30, 2003.
- (16)Includes 32,750 shares issuable upon exercise of options held by Mr. Yachmetz exercisable within 60 days of June 30, 2003.
- (17) Includes shares held by affiliated entities as set forth in the above table and 2,306,539 shares in the aggregate issuable upon the exercise of stock options exercisable within 60 days of June 30, 2003 held by officers or directors or entities deemed affiliates of certain directors.

#### UNDERWRITING

Citigroup Global Markets Inc., CIBC World Markets Corp., Lazard Frères & Co. LLC, Legg Mason Wood Walker, Incorporated and Punk, Ziegel & Company, L.P. are acting as representatives of the underwriters named below. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus supplement, each underwriter named below has agreed to purchase, and we have agreed to sell to that underwriter, the number of shares set forth opposite the underwriter name.

<u>Underwriter</u>	Number of Shares
Citigroup Global Markets Inc. CIBC World Markets Corp. Lazard Frères & Co. LLC Legg Mason Wood Walker, Incorporated Punk, Ziegel & Company, L.P.	
Total	2,750,000

The underwriting agreement provides that the obligations of the underwriters to purchase the shares included in this offering are subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all the shares (other than those covered by the over-allotment option described below) if they purchase any of the shares.

The underwriters propose to offer some of the shares directly to the public at the public offering price set forth on the cover page of this prospectus supplement and some of the shares to dealers at the public offering price less a concession not to exceed \$ per share. The underwriters may allow, and dealers may reallow, a concession not to exceed \$ per share on sales to other dealers. If all of the shares are not sold at the initial offering price, the representatives may change the public offering price and the other selling terms.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus supplement, to purchase up to 412,500 additional shares of common stock at the public offering price less the underwriting discount. The underwriters may exercise the option solely for the purpose of covering over-allotments, if any, in connection with this offering. To the extent the option is exercised, each underwriter must purchase a number of additional shares approximately proportionate to that underwriter initial purchase commitment.

We, our officers and directors, and certain of our other stockholders have agreed, subject to limited exceptions, that, for a period of 90 days from the date of this prospectus supplement, we and they will not, without the prior written consent of Citigroup, dispose of or hedge any shares of our common stock or any securities convertible into or exchangeable for our common stock. Citigroup in its sole discretion may release any of the securities subject to these lock-up agreements at any time without notice.

Our common stock is quoted on the Nasdaq National Market under the symbol [PGNX.]

The following table shows the underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters option to purchase additional shares of common stock.

	Paid by	Progenics
	No Exercise	Full Exercise
Per Share Total	\$ \$	\$ \$

In connection with this offering, Citigroup on behalf of the underwriters, may purchase and sell shares of common stock in the open market. These transactions may include short sales, syndicate covering transactions and stabilizing transactions. Short sales involve syndicate sales of common stock in excess of

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the number of shares to be purchased by the underwriters in the offering, which creates a syndicate short position.  $\square$ Covered $\square$  short sales are sales of shares made in an amount up to the number of shares represented by the underwriters $\square$  over-allotment option. In determining the source of shares to close out the covered syndicate short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. Transactions to close out the covered syndicate short involve either purchases of common stock in the open market after the distribution has been completed or the exercise of the over-allotment option. The underwriters may also make  $\square$ naked $\square$  short sales of shares in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of bids for or purchases of shares in the open market while the offering is in progress.

The underwriters also may impose a penalty bid. Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when Citigroup repurchases shares originally sold by that syndicate member in order to cover syndicate short positions or make stabilizing purchases.

Any of these activities may have the effect of preventing or retarding a decline in the market price of our common stock. They may also cause the price of our common stock to be higher than the price that would otherwise exist in the open market in the absence of these transactions. The underwriters may conduct these transactions on the Nasdaq National Market or in the over-the-counter market, or otherwise. If the underwriters commence any of these transactions, they may discontinue them at any time.

In addition, in connection with this offering, some of the underwriters (and selling group members) may engage in passive market making transactions in our common stock on the Nasdaq National Market, prior to the pricing and completion of the offering. Passive market making consists of displaying bids on the Nasdaq National Market no higher than the bid prices of independent market makers and making purchases at prices no higher than those independent bids and effected in response to order flow. Net purchases by a passive market maker on each day are limited to a specified percentage of the passive market maker saverage daily trading volume in our common stock during a specified period and must be discontinued when that limit is reached. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of those transactions. If the underwriters commence passive market making transactions, they may discontinue them at any time.

We estimate that the total expenses of this offering will be \$750,000.

The underwriters have performed investment banking and advisory services for us from time to time for which they have received customary fees and expenses. The underwriters may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business.

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters. The representatives may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. The representatives will allocate shares to underwriters that may make Internet distributions on the same basis as other allocations. In addition, shares may be sold by the underwriters to securities dealers who resell shares to online brokerage account holders.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, or to contribute to payments the underwriters may be required to make because of any of those liabilities.

#### **LEGAL MATTERS**

The validity of the common stock being offered hereby will be passed upon for us by Dewey Ballantine LLP, New York, New York. Certain legal matters will be passed upon for the underwriters by Hale and Dorr LLP, Boston, Massachusetts.

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

**SUBJECT TO COMPLETION DATED OCTOBER 24, 2003** 

#### PRELIMINARY PROSPECTUS

### 3,500,000 Shares

### **Common Stock**

From time to time, we may sell common stock in one or more issuances. This prospectus describes the general manner in which our common stock may be offered using this prospectus. We will specify in the accompanying prospectus supplement the terms of any offering. Our common stock is listed on the Nasdaq National Market under the symbol  $\Box PGNX. \Box$ 

You should review carefully and consider the information described under the heading  $\square$ Risk Factors $\square$  on page 1.

Our common stock may be sold directly by us to investors, through agents designated from time to time or through underwriters or dealers at prices and on terms to be determined at the time of offering. We will set forth the names of any underwriters or agents and any applicable commissions or discounts in the accompanying prospectus supplement. For additional information on the methods of sale you should refer to the section entitled  $\square$ Plan of Distribution.  $\square$  We will also set forth the use of the net proceeds we expect to receive from any sale of our common stock in the accompanying prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus or the accompanying prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

This prospectus may not be used to offer or sell any securities unless accompanied by a prospectus supplement.

The date of this prospectus is , 2003.

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You should rely only on the information contained in this prospectus and the accompanying prospectus supplement. No dealer, salesperson or other person is authorized to give information that is not contained in this prospectus or the accompanying prospectus supplement. This prospectus is not an offer to sell nor is it seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus and the accompanying prospectus supplement is correct only as of the date of the prospectus supplement relating to the offering, regardless of the time of the delivery of this prospectus and the accompanying prospectus supplement or any sale of these securities.

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#### ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission using a <code>[shelf]</code> registration process. Under the shelf process we may, from time to time, sell up to 2,750,000 shares of our common stock in one or more offerings. This prospectus describes the general manner in which our common stock may be offered by this prospectus. Each time we sell common stock we will provide a prospectus supplement that will contain more specific information about the shares offered. We may also add, update or change in the prospectus supplement any of the information contained in this prospectus. If there is any inconsistency between the information in this prospectus and the accompanying prospectus supplement, you should rely on the information in the prospectus supplement. This prospectus, together with the accompanying prospectus supplement, includes all material information relating to this offering. Please read carefully both this prospectus and the accompanying prospectus supplement together with the additional information described under the heading <code>[Where You Can Find More Information.]</code> This prospectus may not be used to offer to sell, to solicit an offer to buy, or to consummate a sale of our common stock unless it is accompanied by a prospectus supplement.

#### THE COMPANY

We are a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our principal programs are directed toward symptom management and supportive care, HIV infection and cancer. We do not have any FDA approved products and have not received any revenue from the sale of any of our product candidates under development. The mailing address of our principal executive offices is 777 Old Saw Mill River Road, Tarrytown, New York 10591, and our telephone number is (914) 789-2800.

#### **RISK FACTORS**

An investment in our common stock is speculative in nature and involves a high degree of risk. You should carefully consider the discussion of the material risks of investing in our common stock contained in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2003, which is incorporated by reference in this prospectus, starting on page 20 and in any report subsequently filed by us with the Securities and Exchange Commission and incorporated or deemed to be incorporated by reference in this prospectus, as well as in the accompanying prospectus supplement, in evaluating our company, our business and our prospects.

#### FORWARD-LOOKING STATEMENTS

This prospectus, the accompanying prospectus supplement and the documents we have filed with the Securities and Exchange Commission that are incorporated by reference into this prospectus and the accompanying prospectus supplement contain forward-looking statements that involve risks and uncertainties. Any statements contained, or incorporated by reference, in this prospectus or the accompanying prospectus supplement that are not statements of historical fact may be forward-looking statements. When we use the words <code>[anticipates,[]plans,[]expects[]]</code> and similar expressions, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. These factors include, among others, the uncertainties associated with product development, the risk that clinical trials will not commence or proceed as planned, the risks and uncertainties associated with dependence upon the actions of our corporate, academic and other collaborators and of government regulatory agencies, the risk that our licenses to intellectual property may be terminated because of failure to have satisfied performance milestones, the risk that products that appear promising in early clinical trials do not demonstrate efficacy in larger scale clinical trials, the risk that we may not be able to manufacture

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commercial quantities of our products, the uncertainty of future profitability and other factors referred to under the caption  $\square Risk\ Factors \square$  above.

We do not have a policy of updating or revising our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in, or incorporated by reference into, this prospectus as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

#### USE OF PROCEEDS

USE OF PROCEEDS	
Unless we indicate otherwise in the accompanying prospectus supplement, we currently intend to use the proceeds from the sale of our common stock to fund:	net
☐ clinical trials for product candidates;	
in-licensing of technology and establishment of research and development collaborations;	
<ul> <li>expansion of our research and development and manufacturing facilities; and</li> </ul>	
research and development. We also plan to use the proceeds for working capital and general corporate purposes, including potential acquisitions of technology or companies in complementary fields. Although in the ordinary course of our keengage in discussions regarding acquisitions, we are not currently a party to any definitive agreement regarding any material acquisition. We may set forth additional information on the use of net proceeds from the sale of shares of our common stock in a prospectus supplement relating to the specific offering. Pending of the net proceeds from this offering as described above, we intend to invest the net proceeds in interest bearing, investment-grade securities.	om the our use
The accompanying prospectus supplement may not identify precisely the amounts we plan to spend on eathe uses of proceeds listed above, nor have we determined the timing of these expenditures. The amounts actually expended for each purpose may vary significantly depending upon numerous factors, including:	
☐ the results of our research and development and product testing;	
our potential relationships with in-licensors and collaborators;	
☐ changes in the focus and direction of our research and development programs;	
<pre>potential acquisitions;</pre>	
☐ the cost of filing, prosecuting, defending and enforcing patent claims;	
☐ the regulatory approval process; and	
manufacturing, marketing and other costs associated with commercialization of our products.	
PLAN OF DISTRIBUTION	
We may sell our common stock through underwriters or dealers, through agents or directly to one or mor purchasers. The accompanying prospectus supplement will describe the terms of the offering of the secur including:	

☐ the name or names of any underwriters;

the purchase price of the common stock and the proceeds we will receive from the sale;
any over-allotment options under which underwriters may purchase additional securities from us;

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	any agency fees or underwriting discounts and other items constituting agents[] or underwriters[] compensation;
	any initial public offering price; and
stock deterr subject the pu syndic stock discou mater	any discounts or concessions allowed or reallowed or paid to dealers. erwriters are used in the sale, they will acquire the common stock for their own account and may resell the from time to time in one or more transactions at a fixed public offering price or at varying prices mined at the time of the sale. The obligations of the underwriters to purchase the common stock will be at to the conditions set forth in the applicable underwriting agreement. We may offer the common stock to ablic through underwriting syndicates represented by managing underwriters or by underwriters without a cate. Subject to certain conditions, the underwriters will be obligated to purchase all the shares of common offered by the prospectus supplement. We may change from time to time the public offering price and any ants or concessions allowed or reallowed or paid to dealers. We may use underwriters with whom we have a relationship. We will describe in the prospectus supplement naming the underwriter the nature of any relationship.
involv the pr	ay sell common stock directly or through agents we designate from time to time. We will name any agent ed in the offering and sale of common stock, and we will describe any commissions we will pay the agent in espectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a efforts basis for the period of its appointment.
comm delive condit	ay authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase on stock from us at the public offering price set forth in the prospectus supplement pursuant to delayed ry contracts providing for payment and delivery on a specified date in the future. We will describe the tions to these contracts and the commissions we must pay for solicitation of these contracts in the ectus supplement.
includ under	ay provide agents and underwriters with indemnification against civil liabilities related to this offering, ling liabilities under the Securities Act, or contribution with respect to payments that the agents or writers may make with respect to these liabilities. Agents and underwriters may engage in transactions or perform services for, us in the ordinary course of business.
shares	of the Securities and Exchange Commission may limit the ability of any underwriters to bid for or purchase s before the distribution of the shares is completed. However, underwriters may engage in the following ties in accordance with the rules:
	Stabilizing transactions. Underwriters may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum.
	Over-allotments and syndicate covering transactions. Underwriters may sell more shares of our common stock than the number of shares that they have committed to purchase in any underwritten offering. This over-allotment creates a short position for the underwriters. This short sales position may involve either <code>[covered]</code> short sales or <code>[naked]</code> short sales. Covered short sales are short sales made in an amount not greater than the underwriters over-allotment option to purchase additional shares in any underwritten offering. The underwriters may close out any covered short position either by exercising their over-allotment option or by purchasing shares in the open market. To determine how they will close the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market, as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are short sales in excess of the over-allotment option. The underwriters must close out any naked position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that, in the open market after pricing, there may be downward pressure on the price of the shares that

 $\square$  Penalty bids. If underwriters purchase shares in the open market in a stabilizing transaction or syndicate covering transaction, they may reclaim a selling concession from other underwriters and selling

could adversely affect investors who purchase shares in the offering.

group members who sold those shares as part of the offering.

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Passive market making. Market makers in the shares who are underwriters or prospective underwriters may make bids for or purchases of shares, subject to certain limitations, until the time, if ever, at which a stabilizing bid is made.

Similar to other purchase transactions, an underwriter spurchases to cover the syndicate short sales or to stabilize the market price of our common stock may have the effect of raising or maintaining the market price of our common stock or preventing or mitigating a decline in the market price of our common stock. As a result, the price of the shares of our common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of shares if it discourages resales of the shares.

If commenced, the underwriters may discontinue any of the activities at any time.

Any underwriters who are qualified market makers on the Nasdaq National Market may engage in passive market making transactions in the common stock on the Nasdaq National Market in accordance with Rule 103 of Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the common stock. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker bid, however, the passive market maker bid must then be lowered when certain purchase limits are exceeded.

In compliance with guidelines of the National Association of Securities Dealers, or NASD, the maximum consideration or discount to be received by any NASD member or independent broker dealer may not exceed 8% of the aggregate amount of the securities offered pursuant to this prospectus and any applicable prospectus supplement.

#### **LEGAL MATTERS**

The validity of the common stock being offered hereby will be passed upon for us by Dewey Ballantine LLP, New York, New York.

#### **EXPERTS**

The financial statements incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2002 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, independent accountants, given on the authority of said firm as experts in auditing and accounting.

#### WHERE YOU CAN FIND MORE INFORMATION

We are subject to the reporting requirements of the Securities Exchange Act of 1934 and in accordance with its requirements file annual and quarterly reports, proxy statements and other information with the Securities and Exchange Commission. These reports, proxy statements and other information may be inspected, and copies of these materials may be obtained upon payment of the prescribed fees, at the SEC□s Public Reference Room, 450 Fifth Street, Suite 1300, N.W., Washington, D.C. 20549. Please call the SEC at

1-800-SEC-0330 for further information regarding the Public Reference Room. In addition, we are required to file electronic versions of these materials with the SEC through the SEC□s Electronic Data Gathering, Analysis and Retrieval (EDGAR) system. The SEC maintains an internet site at http://www.sec.gov that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC.

We have filed with the SEC a Registration Statement on Form S-3 under the Securities Act of 1933 with respect to the common stock offered by this prospectus and the accompanying prospectus supplement. This

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prospectus and the accompanying prospectus supplement do not contain all of the information set forth in the Registration Statement and the exhibits and the schedules to the Registration Statement. For further information with respect to us and our common stock, you should read the Registration Statement, including its exhibits and schedules. Statements contained in this prospectus and the accompanying prospectus supplement, including documents that we have incorporated by reference, as to the contents of any contract or other document referred to are not necessarily complete, and, with respect to any contract or other document filed as an exhibit to the Registration Statement, each such statement is qualified in all respects by reference to the corresponding exhibit. Copies of the Registration Statement and its exhibits are on file at the offices of the SEC and may be obtained upon payment of the prescribed fee or may be examined without charge at the SEC\[ \]s Public Reference Room, at the address listed above, or via the EDGAR database.

The SEC allows us to incorporate by reference information into this prospectus and the accompanying prospectus supplement. This means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is considered to be part of this prospectus and the accompanying prospectus supplement, except for any information superseded by information contained directly in this prospectus and the accompanying prospectus supplement. This prospectus and the accompanying prospectus supplement incorporate by reference the documents set forth below that we have previously filed with the SEC. These documents contain important information about us and our financial condition.

	Our Annual Report on Form 10-K for the year ended December 31, 2002, as amended by a Form 10-K/A filed on October 22, 2003, File No. 0-23143;
	Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, File No. 0-23143;
	Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2003, as amended by a Form 10-Q/A filed on October 22, 2003, File No. 0-23143;
	Our Current Report on Form 8-K, dated July 14, 2003, File No. 0-23143; and
i) afte late o ncorp	Our Form 8-A, dated September 29, 1997, with respect to our common stock, File No. 0-23143. cuments filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 er the date of the filing of this registration statement and prior to its effectiveness and (ii) subsequent to the filing prospectus and prior to the completion of this offering of our common stock will be deemed to be corated by reference into this prospectus and the accompanying prospectus supplement and to be a part of from the date of filing of such documents.

Any statement contained in a document incorporated or deemed to be incorporated by reference into this prospectus or the accompanying prospectus supplement shall be deemed to be modified or superseded for purposes of this prospectus and the accompanying prospectus supplement to the extent that a statement contained in this prospectus or the accompanying prospectus supplement, or in any other subsequently filed document that is also incorporated or deemed to be incorporated by reference in this prospectus and the accompanying prospectus supplement, modifies or supersedes the earlier statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus or the accompanying prospectus supplement.

Documents incorporated by reference are available from us without charge, excluding all exhibits unless specifically incorporated by reference as an exhibit to this prospectus and the accompanying prospectus supplement. Prospective investors may obtain documents incorporated by reference in this prospectus and the accompanying prospectus supplement by requesting them in writing or by telephone from us at our executive offices at 777 Old Saw Mill River Road, Tarrytown, New York 10591, telephone number (914) 789-2800, Attention: Richard W. Krawiec, Ph.D.

# 2,750,000 Shares

### **Common Stock**

PROSPECTUS SUPPLEMENT, 2003

# Citigroup CIBC World Markets Lazard Legg Mason Wood Walker

**Incorporated** 

Punk, Ziegel & Company

#### **PART II**

#### INFORMATION NOT REQUIRED IN PROSPECTUS

#### **Item 14. Other Expenses of Issuance and Distribution**

Except for the SEC registration fee, the NASD filing fee and the Nasdaq listing fee, all expenses are estimated. All such expenses will be paid by the Registrant.

Registration Fee Securities and Exchange Commission NASD Filing Fee Nasdaq Listing Fee Accountants fees and expenses Legal fees and expenses Printing and engraving expenses Transfer agent and registrar fees Miscellaneous	\$ 4,898 7,623 22,500 200,000 300,000 140,000 20,000 54,979
Total	\$ 750,000

#### **Item 15. Indemnification of Directors And Officers**

Section 145(a) of the General Corporation Law of the State of Delaware (the [DGCL[]) provides that a Delaware corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that he is or was a director, officer, employee or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or enterprise, against expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if he acted in good faith and in a manner he 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 cause to believe his conduct was unlawful.

Section 145(b) of the DGCL provides that a Delaware corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that such person acted in any of the capacities set forth above, against expenses actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if he acted under similar standards, except that no indemnification may be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the court in which such action or suit was brought shall determine that despite the adjudication of liability, such person is fairly and reasonably entitled to be indemnified for such expenses which the court shall deem proper.

Section 145 of the DGCL further provides that to the extent a director or officer of a corporation has been successful in the defense of any action, suit or proceeding referred to in subsections (a) and (b) or in the defense of any claim, issue, or matter therein, he shall be indemnified against expenses actually and reasonably incurred by him in connection therewith; that indemnification provided for by Section 145 shall not be deemed exclusive of any other rights to which the indemnified party may be entitled; and that the corporation may purchase and maintain insurance on behalf of a director or officer of the corporation against any liability asserted against him or incurred by him in any such capacity or arising out of his status as such whether or not the corporation would have the power to indemnify him against such liabilities under such Section 145.

Section 102(b)(7) of the DGCL provides that a corporation in its original certificate of incorporation or an amendment thereto validly approved by stockholders may eliminate or limit personal liability of members of its board of directors or governing body for breach of a director significant fiduciary duty. However, no such

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provision may eliminate or limit the liability of a director for breaching his duty of loyalty, failing to act in good faith, engaging in intentional misconduct or knowingly violating a law, paying a dividend or approving a stock repurchase which was illegal, or obtaining an improper personal benefit. A provision of this type has no effect on the availability of equitable remedies, such as injunction or rescission, for breach of fiduciary duty. Progenics Restated Certificate of Incorporation contains such a provision.

Progenics Certificate of Incorporation and By-Laws provide that Progenics shall indemnify officers and directors, and to the extent authorized by the Board of Directors, employees and agents of Progenics, to the full extent permitted by and in the manner permissible under the laws of the State of Delaware. In addition, the By-Laws permit the Board of Directors to authorize Progenics to purchase and maintain insurance against any liability asserted against any director, officer, employee or agent of Progenics arising out of his capacity as such.

Progenics has entered into Indemnification Agreements with each of its officers and directors, pursuant to which Progenics has agreed to indemnify and advance expenses to such officers and directors to the fullest extent permitted by applicable law.

Progenics has obtained an insurance policy providing coverage for certain liabilities of its officers and directors.

#### Item 16. Exhibits

Exhibit Number	Description of Exhibit
1.1	The form or forms of underwriting agreement will be filed as an exhibit(s) to a Current Report of the
	Registrant on Form 8-K and incorporated herein by reference.
5.1	Opinion of Dewey Ballantine (previously filed).
23.1	Consent of PricewaterhouseCoopers LLP (regarding the Registrant).
23.2	Consent of PricewaterhouseCoopers LLP (regarding PSMA Development Company LLC).
23.3	Consent of Dewey Ballantine (included in Exhibit 5.1).
24.1	Power of Attorney (previously filed).

#### Item 17. Undertakings

The undersigned registrant does hereby undertake:

- (1) to file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
  - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which has been registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the □Calculation of Registration Fee□ table in the effective registration statement;
- (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; *Provided, however,* that paragraphs (i) and (ii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or

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furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

- (2) That, for purposes of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, (i) for purposes of determining any liability under the Securities Act of 1933, as amended, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933, as amended, shall be deemed to be part of this registration statement as of the time it was declared effective; and (ii) for the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at the time shall be deemed to be the initial bona fide offering thereof.
- (5) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933 each filing of the registrant sannual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions described in Item 15 above, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933, as amended, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933, as amended, and will be governed by the final adjudication of such issue.

#### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Amendment to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Tarrytown, State of New York, on October 24, 2003.

#### PROGENICS PHARMACEUTICALS, INC

/s/Paul J. Maddon, M.D., Ph.D.
Paul J. Maddon, M.D., Ph.D.
Chairman of the Board and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Amendment to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Capacity</u>	<u>Date</u>	
/s/ Paul J. Maddon, M.D., Ph.D.	Chairman of the Board and Chief	October 24, 2003	
Paul J. Maddon, M.D., Ph.D.	- Executive Officer (Principal Executive Officer)		
*	Vice President, Finance & Operations	October 24, 2003	
Robert A. McKinney	and Treasurer (Principal Financial and Accounting Officer)		
*	Director	October 24, 2003	
Charles A. Baker			
*	Director	October 24, 2003	
Kurt W. Briner			
*	Director	October 24, 2003	
Mark F. Dalton			
*	Director	October 24, 2003	
Stephen P. Goff, Ph.D.			
*	Director	October 24, 2003	
Paul F. Jacobson			
*	President and Director	October 24, 2003	
Ronald J. Prentki			
*	Director	October 24, 2003	

David A. Scheinberg, M.D., Ph.D.

\* By: /s/ Philip K. Yachmetz

Philip K. Yachmetz, Attorney-in-fact

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#### INDEX TO EXHIBITS

<u>Exhibit</u> <u>Number</u>	Description of Exhibit
1.1	The form or forms of underwriting agreement will be filed as an exhibit(s) to a Current Report of the
	Registrant on Form 8-K and incorporated herein by reference.
5.1	Opinion of Dewey Ballantine (previously filed).
23.1	Consent of PricewaterhouseCoopers LLP (regarding the Registrant).
23.2	Consent of PricewaterhouseCoopers LLP (regarding PSMA Development Company LLC).
23.3	Consent of Dewey Ballantine (included in Exhibit 5.1).
24.1	Power of Attorney (previously filed).
All schedu	ales have been omitted because they are not required or because the required information is given in
the Finan	cial Statements or Notes thereto.

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