ACORDA THERAPEUTICS INC
Form S-1/A
December 16, 2003

QuickLinks -- Click here to rapidly navigate through this document

As filed with the Securities and Exchange Commission on December 16, 2003

Registration No. 333-109199

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 4
to

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ACORDA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2836**	**13-3831168**
(State or other jurisdiction of incorporation or organization)	(Primary standard industrial classification code number)	(I.R.S. employer identification number)

15 Skyline Drive
Hawthorne, New York 10532
(914) 347-4300
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Ron Cohen
Chief Executive Officer
15 Skyline Drive
Hawthorne, New York 10532
(914) 347-4300
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies To:

Fran Stoller
Mitchell Nussbaum
Loeb & Loeb LLP
345 Park Avenue
New York, New York 10154
(212) 407-4000

Danielle Carbone
Shearman & Sterling LLP
599 Lexington Avenue
New York, New York 10022
(212) 848-4000

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

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, as amended (the "Securities Act") check the following box. o

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) 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. o

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. o

If this form is a post-effective amendment filed pursuant to Rule 462(d) 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. o

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

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

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

Prospectus

SUBJECT TO COMPLETION, DATED DECEMBER 16, 2003

Shares

Common Stock

Acorda Therapeutics, Inc. is offering 4,800,000 shares of common stock. This is our initial public offering, and no public market currently exists for our shares. We anticipate that the initial public offering price will be between $12.00 and $14.00 per share. After the offering, the market price for our shares may be outside this range.

We have applied to list our common stock on The Nasdaq National Market under the symbol "ACRD."

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 8.

	Per Share	Total
Offering price	$	$

Discounts and commissions to underwriters	$	$
Offering proceeds to Acorda Therapeutics, Inc., before expenses	$	$

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

We have granted the underwriters the right to purchase up to 720,000 additional shares of common stock to cover any over-allotments. The underwriters can exercise this right at any time within 30 days after the offering. The underwriters expect to deliver the shares of common stock to investors on or about , 2003.

Banc of America Securities LLC

Lazard

U.S. Bancorp Piper Jaffray

RBC Capital Markets

, 2003

TABLE OF CONTENTS

SUMMARY

This summary highlights information contained elsewhere in this prospectus that we believe is most important to understanding how our business is currently being conducted. You should read the entire prospectus carefully before making an investment decision.

OUR BUSINESS

Overview

Acorda Therapeutics is a late-stage biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that improve neurological function in people with spinal cord injury, multiple sclerosis and related disorders of the central nervous system. Our current product candidates target the treatment of a wide range of disorders affecting individuals with chronic spinal cord injury and multiple sclerosis, including spasticity, muscle weakness, loss of bowel and bladder control and sexual dysfunction, and epilepsy.

Approximately 500,000 people in the United States suffer from spinal cord injury and multiple sclerosis and we believe that the combined annual cost of treatment for these conditions exceeds $9 billion. Our goal is to become a fully integrated biopharmaceutical company commercializing multiple therapeutic products for these large and underserved markets while continuing to augment our product pipeline and to identify new applications for our core technologies.

Our Product Candidates

Our lead product candidate, Fampridine-SR, is a small molecule drug contained in a sustained release oral tablet form. Small molecule drugs have a lower molecular weight than larger molecular weight drugs such as proteins, which allows them to be taken orally. Laboratory studies in animal models have shown that fampridine, the active molecule of Fampridine-SR, improves impulse conduction in nerve fibers in which the surface insulating layer of the nerve, called myelin, has been damaged. This damage may be caused by physical trauma, in the case of spinal cord injury, or by the body's own immune system, in the case of multiple sclerosis. We are developing Fampridine-SR for use by people with spinal cord injury or multiple sclerosis.

We believe that clinical trials of fampridine and Fampridine-SR sponsored by us as well as numerous independent academic researchers are the first that have shown improved neurological function, including improvements in sensory, motor, bowel, bladder and sexual function, in people with chronic spinal cord injury or multiple sclerosis, based on our data and our review of other published data. In cooperation with Elan Corporation plc, or Elan, we have conducted a series of clinical trials during the past six years evaluating Fampridine-SR. Approximately 550 people have been treated with Fampridine-SR in 14 clinical trials, including eight clinical trials for spinal cord injury and six clinical trials for multiple sclerosis. In Phase 2 clinical trials, treatment with Fampridine-SR has been associated with a variety of neurological benefits, including improvements in spasticity, and bowel, bladder and sexual function, in people with spinal cord injury or multiple sclerosis.

We are currently conducting two Phase 3 clinical trials in people with spinal cord injury for the reduction of muscle stiffness, referred to as spasticity, and one late Phase 2 clinical trial in people with multiple sclerosis for the improvement of walking speed. Our goals are to submit a New Drug Application, or NDA, to the United States Food and Drug Administration, or the FDA, for Fampridine-SR for the treatment of spasticity in spinal cord injury in 2004 and for the treatment of lower extremity motor dysfunction in people with multiple sclerosis in 2005. While the approval time for an NDA can vary, according to the FDA, the median total approval time for new product applications submitted in

the FDA's 1999 fiscal year was 11.6 months. We plan to commercialize Fampridine-SR ourselves in the United States and Canada and with partners in various other markets throughout the rest of the world. We have received Orphan Drug designation from the FDA for Fampridine-SR for the treatment of both spinal cord injury and multiple sclerosis.

Our second most advanced product candidate is valrocemide, which is currently in Phase 2 clinical trials for the treatment of epilepsy. Valrocemide is a small molecule drug that has been the subject of unpublished preclinical and clinical trials conducted by our collaborator, Teva Pharmaceutical Industries Ltd., or Teva. Valrocemide has shown early Phase 2 clinical evidence of safety and indications of efficacy as an add-on therapy for partial seizures, a type of epilepsy, and evidence of efficacy in preclinical animal models of epilepsy and neuropathic pain, which is pain caused by damage or disease within the nervous system. We plan to move valrocemide into late Phase 2 clinical trials for epilepsy and early Phase 2 clinical trials for bipolar disorder in 2004. We may also pursue clinical development of valrocemide for the treatment of neuropathic pain. Valrocemide is being co-developed and co-promoted with Teva and its affiliates in the United States.

We have a robust pipeline of preclinical programs targeting neurological dysfunction. These programs include two distinct therapies to stimulate remyelination, which is the repair of damaged myelin, Glial Growth Factor 2, which we refer to as GGF-2, and remyelinating antibodies. GGF-2 has been shown in various published studies to stimulate remyelination in animal models of multiple sclerosis and to have a variety of other effects in neural protection and repair. Our remyelinating antibody program involves monoclonal antibodies that have demonstrated the ability to stimulate repair of myelin in three different animal models of multiple sclerosis. We have also developed a nerve regeneration program based on the concept of breaking down part of the matrix of scar tissue that forms as a result of injury. This matrix is believed to limit the regeneration of nerve fibers in the central nervous system. In addition, we have initiated a regenerative antibody program to identify novel approaches to stimulate nerve fiber regeneration in the central nervous system. To support our research and development efforts, we have substantial laboratory capabilities employing both tissue culture methods and predictive animal models of spinal cord injury repair. These capabilities allow us to rapidly screen and validate potentially useful therapeutic approaches to repair damaged spinal cords.

Our product development programs include a patent portfolio comprising 24 U.S. patents and 40 U.S. patent applications and numerous foreign counterparts, of which we are the assignee or have in-licensed.

The FDA has not approved any of our product candidates for marketing. The preclinical and clinical study results described in this prospectus relating to Fampridine-SR and valrocemide are preliminary findings only and have not established that either of these products are safe and effective. We may not achieve the clinical results in Phase 3 studies in large groups of patients that we deem necessary to submit an NDA for Fampridine-SR or valrocemide and the FDA may not approve any NDA we may submit. Even if the FDA approves either of these drugs we may not be able to market them successfully. While the information regarding our early preclinical and clinical results may be useful to you in evaluating our company's current stage of development and our near-term and long-term prospects, you should note that of the large number of drugs in development, only a small percentage successfully complete the FDA regulatory approval process and are commercialized. An assessment of our product candidates must be made in this context and after careful review of the numerous risks to which our business is subject, which are highlighted in the section entitled "Risk Factors" immediately following this prospectus summary.

Our Focus

Our core initial focus on the development of treatments for spinal cord injury has led, and we believe will continue to lead, to the identification and development of therapies applicable to other central nervous system disorders. Since many of the mechanisms of tissue damage and repair in spinal cord injury are shared by other conditions, such as multiple sclerosis, stroke and traumatic brain injury, we believe our core technologies may have potentially broad applicability for these and other central nervous system indications.

Our strategy is to focus on the identification, development and marketing of a broad range of central nervous system therapeutics, using our scientific and clinical expertise in spinal cord injury as a strategic point of access. In order to implement this strategy, in addition to completing our clinical development

programs for Fampridine-SR and valrocemide, and advancing our preclinical programs, we plan to pursue the following initiatives:

continue to in-license preclinical and clinical programs;

expand sales and marketing capabilities; and

pursue additional commercial alliances.

To keep us apprised of the latest technological advances and to help us identify and evaluate business development opportunities, we have established an advisory team and network of well-recognized scientists, clinicians and opinion leaders in the fields of spinal cord injury and multiple sclerosis. In addition, we have recruited 80 spinal cord injury rehabilitation centers and 24 multiple sclerosis rehabilitation centers in the United States and Canada to conduct our clinical trials. Our clinical management team has extensive experience in the areas of spinal cord injury and multiple sclerosis and works closely with this network.

Corporate Information

We were incorporated in 1995 as a Delaware corporation. Our principal executive offices are located at 15 Skyline Drive, Hawthorne, New York 10532. Our telephone number is (914) 347-4300. Our website is *www.acorda.com*. The information on our website is not part of this prospectus. We have registered "Acorda Therapeutics" and our logo as trademarks in the United States. Other trademarks mentioned in this prospectus are the property of their respective owners.

THE OFFERING

Common stock offered	4,800,000 shares
Common stock outstanding after this offering	20,859,779 shares
Use of proceeds	We intend to use the net proceeds of this offering for research and development, including preclinical development and clinical trials, marketing and for general corporate purposes. See "Use of Proceeds."
Proposed Nasdaq National Market symbol	ACRD
Risk factors	See "Risk Factors" and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

The number of shares of common stock to be outstanding after this offering is based on the number of shares outstanding as of November 25, 2003 and reflects or assumes the following:

a one-for-12 reverse stock split that we effected on December 15, 2003;

the automatic conversion of all of our outstanding convertible preferred stock and mandatorily redeemable convertible preferred stock into 15,806,617 shares of common stock immediately prior to the consummation of this offering; and

no exercise of the underwriters' over-allotment option.

In the table above, the number of shares of common stock outstanding after this offering excludes as of November 25, 2003:

1,708,509 shares of common stock issuable upon the exercise of outstanding options and warrants to purchase our common stock, at a weighted average exercise price of $6.01 per share;

361,842 shares of common stock issuable upon conversion of outstanding convertible promissory notes; and

39,294 shares of common stock reserved for issuance under our stock option plan.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following table presents a summary of our historical financial information. You should read this information in conjunction with our consolidated financial statements and related notes and the information under "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

	Year Ended June 30,					Three Months Ended September 30,		Period From March 17, 1995 (Inception) to September 30, 2003 (unaudited)
	1999	2000	2001	2002	2003	2002 (unaudited)	2003 (unaudited)	
	($ in thousands, except per share data)							
Statement of Operations Data:								
Grant revenue	$ 1,036	$ 756	$ 462	$ 132	$ 474	$	$ 202	3,839
Operating expenses incurred in the development stage:								
Research and development	3,083	4,777	6,142	11,146	17,527	3,498	9,874	56,049
Research and development Related party	1,152	2,024	2,223	4,687	2,265	669	2,799	35,150
General and administrative	1,342	1,406	3,489	6,636	6,388	1,768	10,801	33,656
Total operating expenses	5,577	8,207	11,854	22,469	26,180	5,935	23,474	124,855
Operating loss	(4,541)	(7,451)	(11,392)	(22,337)	(25,706)	(5,935)	(23,272)	(121,016)
Other income (expense):								
Interest expense					(78)	(12)	(20)	(98)
Interest expense Related party	(425)	(448)	(444)	(408)	(369)	(92)	(88)	(2,668)
Interest income	611	1,001	1,824	984	393	128	157	5,195
Other income					26	26		26
Total other income (expense)	186	553	1,380	576	(28)	50	49	2,455
Minority interest Related party			699	580				4,279
Net loss	(4,355)	(6,898)	(9,313)	(21,181)	(25,734)	(5,885)	(23,223)	(114,282)
Beneficial conversion feature, accretion of issuance costs, preferred dividends and fair value of warrants issued to convertible preferred stockholders	(18)	(27)	(36)	(55)	(24,320)	(14)	(5,993)	(30,946)

						Three Months Ended September 30,		Period From March 17, 1995 (Inception) to September 30, 2003 (unaudited)
Net loss allocable to common stockholders	$ (4,373)	$ (6,925)	$ (9,349)	$ (21,236)	$ (50,054)	(5,899)	$ (29,216)	(145,228)
Net loss per share allocable to common stockholders basic and diluted	$ (18.83)(3)	$ (29.34)(3)	$ (39.08)	$ (86.05)	$ (201.03)	$ (23.69)	$ (117.34)	
Pro forma net loss per share allocable to common stockholders basic and diluted (unaudited)(1)					$ (17.67)		$ (1.45)	
Weighted average shares of common stock outstanding used in computing net loss per share allocable to common stockholders basic and diluted	232 (3)	236 (3)	239	247	249	249	249	
Weighted average shares of common stock outstanding used in computing pro forma net loss per share allocable to common stock-holders basic and diluted (unaudited)(1)(2)					8,321		16,056	

(1) The pro forma net loss per share and weighted average shares of common stock used in computing pro forma net loss per share allocable to common stockholders for the year ended June 30, 2003 and for the three month period ended September 30, 2003 are calculated as if all our convertible preferred stock and mandatorily redeemable convertible preferred stock were converted into common stock as of the beginning of the year ended June 30, 2003 or from their respective dates of issuance, if issued after the

beginning of the year ended June 30, 2003. The pro forma net loss per share allocable to common stockholders for the year ended June 30, 2003 has been computed assuming the offering was completed at the beginning of the fiscal year presented and has been adjusted to give effect to the following: (a) recognition of the unamortized portion of a beneficial conversion charge of $97.1 million; (b) recognition of the unamortized portion of issuance costs relating to Series E, Series I and Series J preferred stock of $479,000; and (c) reversal of accrued preferred dividends on Series J preferred stock of $630,000 (see Note 2 to the consolidated financial statements). The pro forma net loss per share allocable to common stockholders for the three month period ended September 30, 2003 reflects the reversal of the accrued preferred dividend of $1.1 million, amortized beneficial conversion charge of $4.9 million and amortized issuance costs of $24,000, assuming that the automatic conversion occurred as of the beginning of the fiscal year ended June 30, 2003.

(2) The weighted average shares of our common stock outstanding used in computing the pro forma net loss per share allocable to common stockholders is calculated based on the number of: (a) Series A through Series I equivalent shares of common stock from the beginning of the fiscal year ended June 30, 2003; (b) additional equivalent shares of common stock issuable under Series A through Series I, as a result of adjusting the conversion prices as a result of anti-dilution provisions as of the date of adjustment; and (c) Series J equivalent shares of common stock issuable from the date of issuance of the Series J preferred stock.

(3) Unaudited.

The pro forma as adjusted consolidated balance sheet data below reflects the net proceeds of approximately $56.6 million from the issuance and sale of 4,800,000 shares of our common stock in this offering at an assumed initial public offering price of $13.00 per share (the midpoint of the estimated initial public offering price range), after deducting the underwriter discounts and commissions and estimated offering expenses and the assumed conversion of our outstanding convertible preferred stock and mandatorily redeemable convertible preferred stock into 15,806,617 shares of our common stock, which will occur upon completion of this offering.

	September 30, 2003	
	Actual (unaudited)	Pro Forma as Adjusted (unaudited)
	($ in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 8,033	65,092
Restricted cash	254	254
Short-term investments	43,836	43,836
Working capital	47,075	103,707
Total assets	57,024	113,276
Deferred revenue	57	57
Current portion of notes payable	317	317
Non-current portion of notes payable	530	530
Long-term convertible notes payable principal amount plus accrued interest, less unamortized debt discount Related party	7,995	7,995
Mandatorily redeemable preferred stock	24,179	
Total stockholders' equity	$ 17,483	98,294

RISK FACTORS

Risks Related To Our Business

We have a history of operating losses and may never be profitable

As of September 30, 2003, we had an accumulated deficit of approximately $114 million. As a result of our significant research and development, clinical development, general and administrative, sales and marketing and business development expenses and the lack of any products to generate revenue, we have generated operating losses since our inception. We expect to continue to incur losses for at least the next several years and expect that our losses will increase as we expand our research and development activities and incur significant clinical testing costs. To date, our working capital has primarily been generated through financing activities consisting of the sale of shares of our preferred stock and the issuance of convertible debt securities.

Our prospects for achieving profitability will depend on how successful we are in executing our business plan to:

- obtain FDA approval for our late-stage product candidates;
- market and commercialize our late-stage product candidates;
- continue to develop and test our other existing product candidates; and
- attract in-licensing and other business development opportunities, strategic partnerships and collaborative arrangements.

If we are not successful in executing our business plan, we may never generate revenues or achieve profitability.

The results of our late stage clinical trials may be insufficient to obtain the FDA approval required to commercialize any products in the United States

The clinical trial results described in this prospectus relating to Fampridine-SR and valrocemide are preliminary findings only and have not established that either of these products are safe and effective in large groups of patients. The results of Phase 3 trials of these products may not be adequate for the filing of a New Drug Application with the FDA. Fampridine-SR is currently in Phase 3 clinical trials for the treatment of

spasticity in spinal cord injury. We expect to have results from the Phase 3 clinical trials by the end of the first quarter of 2004 and expect to file our NDA with the FDA shortly thereafter. If we fail to achieve the primary endpoints in our Phase 3 clinical trials or the results are ambiguous, we will have to determine whether to redesign our Fampridine-SR in spinal cord injury development program and protocols and continue with additional testing, or cease activities in this area. Redesigning the program could be extremely costly and time-consuming. A substantial delay in obtaining FDA approval or termination of the Fampridine-SR spinal cord injury program could result in a delay in our ability to generate revenue. We face the same risk of failure to meet our primary endpoints with respect to our Fampridine-SR in multiple sclerosis and valrocemide clinical trial programs.

Our other product candidates are in early stages of development and may never be commercialized

Research, development and preclinical testing are long, expensive and uncertain processes. Other than Fampridine-SR and valrocemide, none of our other product candidates have reached clinical trial testing. Our GGF-2 product candidate and our remyelinating antibodies are in preclinical testing. Our nerve regeneration programs are in the research stage. Our future success depends, in part, on our ability to complete preclinical development of our other product candidates and advance them to the clinical trials.

Our product development programs may be curtailed, redirected or eliminated at any time for some or all of the following reasons:

adverse or ambiguous results;

undesirable side effects which delay or extend the trials;

inability to locate, recruit and qualify a sufficient number of patients for our trials;

regulatory delays or other regulatory actions;

difficulties in obtaining sufficient quantities of the particular product candidate or any other components needed for our preclinical testing or clinical trials;

change in the focus of our development efforts; and

re-evaluation of our clinical development strategy.

If we are unsuccessful in advancing our early stage product candidates into clinical testing for any reason, our business prospects will be harmed.

Our product candidates may not gain market acceptance among physicians, patients and the medical community thereby limiting our potential to generate revenue

Even if we obtain regulatory approval for our products, market acceptance will depend on our ability to demonstrate to physicians and patients the benefits of our products in terms of safety, efficacy, convenience, ease of administration and cost effectiveness. In addition, we believe market acceptance depends on the effectiveness of our marketing strategy, the pricing of our products and the reimbursement policies of government and third-party payors. Physicians may not prescribe our products, and patients may determine, for any reason, that our product is not useful to them. If any of our product candidates fail to achieve market acceptance our ability to generate revenue will be limited.

Our operations could be curtailed if we are unable to obtain any required additional financing on favorable terms, if at all

On September 30, 2003, after giving effect to this offering on a pro forma as adjusted basis, we would have had approximately $ million in cash, cash equivalents and short-term investments. We anticipate this will be sufficient to fund our operations for at least the

next 18 months. Our product candidates are in various stages of development, and all will require significant further investment to develop, test and obtain regulatory approval prior to commercialization. We may need to seek additional financing to continue our product development activities, and could require substantial funding to commercialize any of the products that we successfully develop. We do not currently have any funding commitments or arrangements with third parties to provide funding. We may not be able to raise additional capital on favorable terms, if at all.

To the extent that we are able to raise additional capital through the sale of equity securities, the issuance of those securities could result in dilution to our stockholders. In addition, if we incur debt financing, we will be required to make cash payments to the principal and interest on such indebtedness, which could substantially reduce our cash balance. If we are unable to successfully commercialize Fampridine-SR, introduce other product candidates, or otherwise obtain sufficient financing on favorable terms when and if needed, we may be required to reduce, defer or discontinue one or more of our product development programs. Our inability to continue development of any one or more of our product candidates may result in an inability to generate revenue, which would harm our business prospects.

We face an inherent risk of liability in the event that the use or misuse of our products result in personal injury or death

The use of our product candidates in clinical trials, and the sale of any approved products, may expose us to product liability claims, which could result in financial losses. Our clinical liability insurance coverage may not be sufficient to cover claims that may be made against us. In addition, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our

management and other resources and adversely effect or destroy the prospects for commercialization of the product that is the subject of any such claim.

If we use biological and hazardous materials in a manner that causes injury, we may be liable for damages

Our research and development activities involve the controlled use of potentially harmful biological materials, hazardous materials and chemicals, and are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials. If we fail to comply with environmental regulations, we could be subject to criminal sanctions and/or substantial liability for any damages that result, and any substantial liability could exceed our resources.

The loss of our key management and scientific personnel may hinder our ability to execute our business plan

As a small company with 70 employees, our success depends on the continuing contributions of our management team and scientific personnel, and maintaining relationships with the members of our Scientific Advisory Board and the network of centers in the United States and Canada that conducts our clinical trials. We are highly dependent on the services of Dr. Ron Cohen, our Chairman, President and Chief Executive Officer, as well as the other principal members of our management and scientific staff. Our success depends in large part upon our ability to attract and retain highly qualified personnel. We face intense competition in our hiring efforts with other pharmaceutical and biotechnology companies, as well as universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain qualified personnel. The loss of one or more of such individuals, or our inability to attract additional qualified personnel, could substantially impair our ability to implement our business plan.

Risks Related to Obtaining Regulatory Approval

The pharmaceutical industry is subject to stringent regulation, and failure to obtain regulatory approval will prevent commercialization of our products

Our research, development, preclinical and clinical trial activities and the manufacture and marketing of any products that we may successfully develop are subject to an extensive regulatory approval process by the FDA and other regulatory agencies abroad. The process of obtaining required regulatory approvals for drugs is lengthy, expensive and uncertain, and any such regulatory approvals may entail limitations on the indicated usage of a drug, which may reduce the drug's market potential.

The results of preclinical and Phase 1 and Phase 2 clinical studies are not necessarily indicative of whether a product will demonstrate safety and efficacy in large patient populations. Of the large number of drugs in development, only a small percentage result in the submission of

an NDA to the FDA and even fewer are approved for commercialization.

In order to obtain FDA approval to commercialize any product candidate, an NDA must be submitted to the FDA, including the results of adequate and well controlled clinical trials, demonstrating, among other things, that the product candidate is safe and effective for use in humans for each target indication. Our regulatory submissions may be delayed, or we may cancel plans to make submissions for product candidates for a number of reasons, including:

negative or ambiguous preclinical or clinical trial results;

changes in regulations or the adoption of new regulations;

unexpected technological developments; and

developments by our competitors that are more effective than our product candidates.

Accordingly, our submissions to the FDA may not be made in the timeframe that we have planned, or at all, and our submissions may not be approved by the FDA. Even if regulatory clearance is obtained, post-market evaluation of our products could result in restrictions on our product's marketing or withdrawal of our product from the market as well as possible civil and criminal sanctions.

Clinical trials are subject to oversight by institutional review boards and the FDA to ensure compliance with the FDA's good clinical practice regulations, as well as other requirements for good clinical practices and the protection of research subjects. We depend, in part, on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third-party organizations to perform data collection and analysis, all of which must maintain both good laboratory and good clinical practices. If any such standards are not complied with in our clinical trials, we, an institutional review board, or the FDA may suspend or terminate such trial, which would severely delay our development and possibly end the development of such product candidate. We also currently and in the future will depend upon third party manufacturers of our products to qualify for FDA approval and to comply with Good Manufacturing Practices. We cannot be certain that our present or future manufacturers and suppliers will comply with current Good Manufacturing Practices. The failure to comply with Good Manufacturing Practices may result in the termination of clinical studies, restrictions in the sale of, or withdrawal of the products from the market. Compliance by third parties with these standards and practices is outside of our direct control.

In addition, we are subject to regulation under other state and federal laws, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other local, state, federal and foreign regulation. We cannot predict the impact of such regulation on us, although it could impose significant restrictions on our business and additional expenses to comply.

If the FDA does not accept the measure we are using in our clinical trials for Fampridine-SR in multiple sclerosis, FDA approval for treatment of patients with multiple sclerosis will be significantly delayed

We are using the Timed 25 Foot Walk to measure improvement in walking speed in people taking Fampridine-SR for multiple sclerosis in our Phase 2 clinical trials. Although we have discussed the use of this endpoint with the FDA, the FDA does not provide certainty with respect to the appropriateness of a testing measure. To our knowledge, the FDA has not approved a drug based on this measure to date. Although the results of our Phase 2 clinical testing may demonstrate a statistically significant, clinically meaningful benefit to patients when using Fampridine-SR in multiple sclerosis, the FDA may decide, after it has reviewed the submitted data, that the Timed 25 Foot Walk is an insufficient measure to determine whether this product should receive FDA approval, and may require us to re-design our clinical trials using different measures. If we are required to identify new measures to test our primary endpoints, we will face substantial delays in our current timeline to commercialize and launch Fampridine-SR in multiple sclerosis and will incur additional costs associated with these activities. Any delays in regulatory approval will delay commercialization of Fampridine-SR in multiple sclerosis, which would harm our business prospects.

Risks Related to Our Dependence on Third Parties

Since we rely on Elan to manufacture Fampridine-SR, and on our other manufacturers to manufacture our other product candidates, we may be unable to control the availability of our product candidates

Our supply agreement with Elan obligates us to purchase at least 75% of our yearly supply of Fampridine-SR from Elan. We are in the process of qualifying a second manufacturing source in the event that Elan is unable or unwilling, due to financial difficulties or otherwise, to fulfill our manufacturing and supply needs. If we are unable to qualify a second manufacturing source, and Elan ceases to manufacture the product for us, we could experience substantial delays before we are able to qualify another supplier. Any significant delays in product shipments could slow the current progress of our clinical trials and, if we receive approval to commercialize Fampridine-SR, would materially adversely affect our ability to commercialize Fampridine-SR. In addition, if we do not purchase at least 100% of our requirements from Elan under the

supply agreement we are required to make certain compensatory payments to Elan which could increase our total manufacturing costs.

We are also substantially dependent upon Elan to complete the chemistry, manufacturing and controls section of the NDA for Fampridine-SR in spinal cord injury. If Elan fails to provide this section in a complete and timely manner we could incur delays in filing our NDA for Fampridine-SR in spinal cord injury.

We are also wholly dependent on third parties to manufacture our other product candidates, including valrocemide. If we lose and are unable to replace these manufacturers, we will be unable to continue developing and testing our other product candidates.

If we must obtain the active pharmaceutical ingredient in Fampridine-SR from new suppliers, we may face serious delays in manufacturing Fampridine-SR

We do not have direct contractual relationships with the suppliers of fampridine, the active pharmaceutical ingredient in Fampridine-SR, which we refer to as API. Currently, we rely on Elan's contracts with third parties to supply API. If Elan or an alternative manufacturer is unable to obtain API supplies from these suppliers for any reason, a new supplier would have to be identified. Although other suppliers of API are readily available, a change to a supplier that was not previously approved in our NDA may require formal approval by the FDA before we could use their API in our product. Any delays in obtaining API to manufacture Fampridine-SR, or delays in obtaining necessary FDA approvals to use their API, would delay the commercialization of Fampridine-SR.

We do not have an internal sales force, and if the agreement to commercialize Fampridine-SR with third party providers is not successful, we could face substantial delays in marketing Fampridine-SR

We do not currently have our own internal sales force and will rely on third parties to commercialize Fampridine-SR. We have agreements with Cardinal Health and inChord Communications to use their RxPedite program to commercialize Fampridine-SR in spinal cord injury. The RxPedite program involves the development and implementation of a marketing plan to launch Fampridine-SR and provides for a sales force to market the product. If our agreements with Cardinal and inChord are terminated for any reason, it could be time consuming to identify another party to assist us, and we would be subject to a material disruption in our commercialization and marketing process. Without an active sales force, there could be serious delays in marketing Fampridine-SR. Disruption of the commercialization or marketing of Fampridine-SR would have a material adverse effect on our ability to generate revenues.

We depend in part upon the performance of our licensees and collaborative partners in developing our product candidates, and any failure on their part to perform or satisfy their obligations to us could lead to delays in the development or commercialization of our product candidates

Our efforts to develop, obtain regulatory approval for and commercialize our existing and any future product candidates depend in part upon the performance of our licensees and collaborative partners. Currently, we have license and collaborative agreements with Elan, Rush-Presbyterian St. Luke's Medical Center, Teva, Canadian Spinal Research Organization, Cornell Research Foundation, Inc., Mayo Clinic Foundation and CeNeS Pharmaceuticals plc. We do not have day-to-day control over the activities of our licensees or collaborative partners and therefore, we face the risk that they may not fulfill their obligations to us. We also face the risk that our licensors and collaborators will not properly maintain and defend our intellectual property rights. Further, our licensees and collaborators may encounter conflicts of interest, changes in business strategy or other business issues, or they may acquire or develop rights to competing products, all of which could limit our ability to commercialize our product candidates and affect our ability to generate product revenues.

Disagreements with our licensees or collaborators could require or result in litigation or arbitration, which could be time consuming and expensive. If we fail to maintain our existing agreements or establish

new agreements as necessary, we could be required to undertake development, manufacturing and commercialization activities solely at our own expense. This would significantly increase our capital requirements and may also delay the commercialization of our product candidates.

Risks Related to Our Intellectual Property

If we fail to meet our obligations under our license agreements, or our agreements are terminated for any other reasons, including if Elan were to file for bankruptcy in Ireland, where our rights as a licensee would become uncertain, we may lose our rights to in-licensed technologies

We have licensed the rights for most of our products. We could lose the rights to Fampridine-SR, for example, in countries in which we have a license, which include the United States, Japan, the United Kingdom, France, Italy or Germany if we fail to file regulatory approvals or launch a product in such countries within specified periods, or if we fail to fulfill our payment obligations under the license agreement. Furthermore, if Elan were to file for bankruptcy in Ireland, there is the possibility, because the bankruptcy laws of Ireland may be different than those of the United States with respect to license arrangements, that our licensed rights could be transferred, altered or terminated, or we could incur substantial expenses to keep our license effective. If we lose our rights to Fampridine-SR, our prospects for generating revenue and recovering our substantial investment in the development of this product would be materially harmed.

Our rights to the development, use and marketing of all of our other product candidates are also governed by license agreements that we entered into with licensors of these technologies. Our failure to achieve milestones, or meet any of our financial or other obligations under these license agreements could result in the loss of our rights to these technologies. If we lose our rights under any of these license agreements, we would be unable to continue our product development programs, which may result in lost revenue and would harm our business prospects.

If we cannot protect our intellectual property, our ability to develop and commercialize our products will be severely limited

Our success will depend in part on our and our licensors' ability to obtain, maintain and enforce patent protection for each party's technologies, compounds and products, if any, resulting from these technologies. Without protection for the intellectual property we use, other companies could offer substantially identical products for sale without incurring the sizable discovery, development and licensing costs that we have incurred. Our ability to recover these expenditures and realize profits upon the sale of products could be diminished.

In addition to our 24 United States patents, we have 40 patent applications filed and pending in the United States and numerous counterpart applications filed abroad for our own technologies, and for technologies that we have developed from our in-licensed programs. The process of obtaining patents can be time consuming and expensive with no certainty of success. Even if we spend the necessary time and money, a patent may not issue or it may insufficiently protect the technology it was intended to protect. We can never be certain that we were the first to develop the technology or that we were the first to file a patent application for the particular technology because many U.S. patent applications are confidential until a patent issues, and publications in the scientific or patent literature lag behind actual discoveries. The degree of future protection for our proprietary rights will remain uncertain if our pending patent applications are not approved for any reason or if we are unable to develop additional proprietary technologies that are patentable. Furthermore, third parties may independently develop similar or alternative technologies, duplicate some or all of our technologies, design around our patented technologies or challenge our issued patents or the patents of our licensors.

In any litigation in which our patents or our licensors' patents are asserted, a court may determine that the patents are invalid or unenforceable. Even if the validity or enforceability of these patents is upheld by a court, a court may not prevent alleged infringement on the grounds that such activity is not covered by the patent claims. Any litigation, whether to enforce our rights to use our or our licensors' patents or to defend

against allegations that we infringe third party rights, will be costly, time consuming, and may distract management from other important tasks.

As is commonplace in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. To the extent our employees are involved in research areas which are similar to those areas in which they were involved at their former employers, we may be subject to claims that such employees and/or we have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of the former

employers. Litigation may be necessary to defend against such claims, which could result in substantial costs and be a distraction to management and which may have a material adverse effect on us, even if we are successful in defending such claims.

We also rely in our business on trade secrets, know-how and other proprietary information. We seek to protect this information, in part, through the use of confidentiality agreements with employees, consultants, advisors and others. Nonetheless, those agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information and prevent their unauthorized use or disclosure. To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, disputes may arise as to the proprietary rights to such information which may not be resolved in our favor. The risk that other parties may breach confidentiality agreements or that our trade secrets become known or independently discovered by competitors, could adversely affect us by enabling our competitors, who may have greater experience and financial resources, to copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies.

If third parties claim that we infringed their patents or proprietary rights, our ability to continue to develop and successfully commercialize our product candidates could be delayed

Third parties may claim that we or our licensors or suppliers are infringing their patents or are misappropriating their proprietary information. Certain patents relating to the manufacture, use, and/or sale of valproic acid derivatives are owned by third parties. In the event of a successful claim against us or our licensors or suppliers for infringement of the patents or proprietary rights of others relating to valrocemide, which is a valproic acid derivative, or any of our other product candidates, we may be required to:

pay substantial damages;

stop using our technologies;

stop certain research and development efforts;

develop non-infringing products or methods; and

obtain one or more licenses from third parties.

A license required under any such patents or proprietary rights may not be available to us, or may not be available on acceptable terms. If we or our licensors or suppliers are sued for infringement we could encounter substantial delays in, or be prohibited from developing, manufacturing and commercializing our product candidates.

Risks Related to Our Industry

If our competitors develop and market products that are more effective than ours, or obtain marketing approval before we do, our commercial opportunity will be reduced or eliminated

Competition in the pharmaceutical and biotechnology industries is intense and is expected to increase. Several biotechnology and pharmaceutical companies, as well as academic laboratories, universities and other research institutions, are involved in research and/or product development for various treatments for spinal cord injury, multiple sclerosis, epilepsy and bipolar disorder. For example, we are aware that Aventis is

developing a sodium/potassium channel blocker, HP 184, with a potential indication in spinal cord injury. We believe that HP 184 is now in clinical trials and any resulting product could compete with Fampridine-SR. Many of our competitors have significantly greater research and development capabilities, experience in obtaining regulatory approvals and manufacturing, marketing, financial and managerial resources than

we have.

Our competitors may succeed in developing products that are more effective than the ones we have under development or that render our proposed products or technologies noncompetitive or obsolete. In addition, our competitors may achieve product commercialization before we do. If any of our competitors develop a product that is more effective, or are able to obtain FDA approval for commercialization before we do, we may not be able to achieve significant market acceptance for our products, which would have a material adverse effect on our ability to generate revenues and recover the substantial development costs we have incurred and will continue to incur.

Our products will also compete with numerous existing drugs used to treat symptoms related to spinal cord injury and multiple sclerosis. Although the mechanism by which Fampridine-SR is believed to achieve its effects is different than current treatments, these treatments are well-known and widely prescribed by health care providers who may be reluctant to prescribe a new product to their patients.

Valrocemide is a new chemical entity derived from valproic acid, which is a commonly used anti-epileptic drug for the treatment of most seizure types. If valrocemide is not shown to have similar or better efficacy than valproic acid, and a more favorable side effect profile, the commercialization of the product may not be successful.

Risks Relating To The Offering

Our stock price may be volatile, and you may not be able to resell your shares at or above the initial offering price

Prior to this offering, there has been no public market for our common stock. We cannot predict the extent to which investor trading will lead to the development of an active and liquid trading market in our common stock. The initial public offering price of our common stock was determined by negotiations between the representatives of the underwriters and us and may not be indicative of future market prices. The market price for our common stock may decline below the initial offering price. Our stock price may experience substantial fluctuations and could fluctuate significantly due to a number of factors, including:

sales of substantial amounts of our stock;

announcements about us or about our competitors;

publicity regarding actual or potential medical results relating to products under development by us or our competitors;

conditions or trends in the pharmaceutical or biotechnology industries;

litigation and other developments relating to patents or other proprietary rights or those of our competitors;

governmental regulation and legislation in the United States and foreign countries;

change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations; and

variations in our anticipated or actual operating results.

Many of these factors are beyond our control. In addition, the stock markets in general, and Nasdaq and the market for biotechnological companies in particular, have experienced extreme price and volume fluctuations recently. These fluctuations often have been unrelated or disproportionate to the operating

performance of these companies. These broad market and industry factors may adversely affect the market price of our common stock, regardless of our actual operating performance.

As a new investor, you will experience immediate and substantial dilution in the net tangible book value of your investment

Investors purchasing shares of our common stock in this offering will pay more for their shares than the amount paid by existing stockholders who acquired shares prior to this offering. Accordingly, if you purchase common stock in this offering, you will incur immediate dilution in pro forma net tangible book value of approximately $ per share. If the holders of outstanding options or warrants exercise these options or warrants, you will incur further dilution. See "Dilution."

Future sales of our common stock, or the perception that these sales may occur, could adversely impact our stock price

Sales of substantial amounts of our common stock in the public market after this offering could adversely affect the price of our common stock. After the consummation of this offering, our current stockholders will be subject to a 180-day lock up on the sale of their shares. After the lock-up expires, at least 5,641,669 shares of our common stock will become freely tradable, 10,413,942 shares of common stock will be tradable subject to Rule 144, and holders of 15,806,617 shares of our common stock will have rights to cause us to file a registration statement on their behalf and to include their shares in registration statements that we may file on our behalf or on behalf of other stockholders. By exercising their registration rights, and selling a large number of shares, these holders could cause the price of our common stock to decline.

Provisions in our certificate of incorporation and by-laws will have anti-takeover effects that could discourage, delay or prevent our stockholders from replacing or removing current directors and management

Following this offering, our certificate of incorporation and by-laws will contain provisions that could make it more difficult for a third party to acquire us, and may have the effect of preventing or hindering any attempt by our stockholders to replace our current directors. These provisions include:

- authorizing the issuance of "blank check" preferred stock; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

Since management is appointed by the board of directors, any inability to effect a change in the board of directors may also result in the entrenchment of management.

FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled "Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business," contains forward-looking statements. These statements relate to future events or to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "potential," "continue," or the negative of these terms or other comparable terminology. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond our control and which could materially affect actual results, levels of activity, performance or achievements. Factors that may cause actual results to differ materially from current expectations, which we describe in more detail elsewhere in this prospectus under the heading "Risk Factors", include, but are not limited to:

- unfavorable results of our product candidate development efforts;
- unfavorable results of our preclinical or clinical testing;

delays in obtaining, or failure to obtain FDA approvals;

increased regulation by the FDA and other agencies;

the outcome of plans for manufacturing, sales and marketing;

the introduction of competitive products;

impairment of license, patent or other proprietary rights;

failure to achieve market acceptance of our products;

the impact of present and future collaborative agreements;

failure to implement our strategy; and

deteriorating financial performance.

If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may vary significantly from what we projected. Any forward-looking statement you read in this prospectus reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, growth strategy and liquidity. We assume no obligation to publicly update or revise these forward-looking statements for any reason, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

The safe harbor for forward-looking statements contained in the Securities Litigation Reform Act of 1995 protects companies from liability for their forward looking statements if they comply with the requirements of the Act. The Act does not provide this protection for initial public offerings.

You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. We are not making offers to sell or seeking offers to buy these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information contained in this prospectus is accurate as of the date on the front of this prospectus only. Our business, financial condition, results of operations and prospects may have changed since that date.

USE OF PROCEEDS

We estimate that we will receive approximately $56.6 million in net proceeds from the sale of our common stock in this offering, or approximately $65.3 million if the underwriters' over-allotment option is exercised in full, based on an assumed initial public offering price of $13.00 per share (the midpoint of the estimated initial public offering price range) after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the proceeds of this offering approximately as follows:

$39 million for research and development, including preclinical development, clinical trials and the preparation and submission of the Fampridine-SR NDA;

$11 million in connection with Fampridine-SR commercialization activities; and

the balance for general corporate purposes, including working capital and the possible acquisition of pharmaceutical products and businesses that are complementary to our own. While we are engaged in preliminary discussions with respect to potential in-licensing opportunities, currently, we have no specific plans or commitments with respect to any acquisitions.

The amount and timing of our actual expenditures will depend on numerous factors, including the progress of our research and development activities, the progress of our clinical trials and regulatory approval process, the number and breadth of our product development programs, our ability to maintain our manufacturing and marketing collaborations and other arrangements, and any in-licensing and acquisition activities. Accordingly, we will retain broad discretion in the allocation and use of the proceeds of this offering.

Pending application of the net proceeds, we intend to invest them in short-term, investment-grade, interest-bearing instruments.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not intend to pay cash dividends for the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in current or future financing instruments and other factors our board of directors deems relevant.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term investments and capitalization as of September 30, 2003:

on an actual basis giving retroactive effect to the one-for-12 reverse stock split;

on a pro forma as adjusted basis to give effect to (i) the automatic conversion of all of our outstanding convertible preferred stock and mandatorily redeemable convertible preferred stock into 15,806,617 shares of common stock, which will occur upon the closing of this offering; and (ii) the net proceeds of approximately $56.6 million from the sale of 4,800,000 shares of common stock in this offering at an assumed initial public offering price of $13.00 per share (the midpoint of the estimated initial public offering price range) and after deducting the underwriting discounts and commissions and estimated offering expenses.

	As of September 30, 2003	
	Actual (unaudited)	Pro Forma As Adjusted (unaudited)
	($ in thousands, except per share amounts)	
Cash, cash equivalents and short-term investments	$ 51,868	$ 108,928
Long-term portion of notes payable	$ 530	$ 530

	As of September 30, 2003	
Long-term convertible notes payable principal amount plus accrued interest, less unamortized debt discount-Related party	7,995	7,995
Mandatorily Redeemable Convertible Preferred Stock, $.001 par value: 7,472,612 shares of Series E convertible preferred stock authorized, issued and outstanding at September 30, 2003; 10,204,047 shares of Series I convertible preferred stock authorized, issued and outstanding at September 30, 2003; 112,790,233 shares of Series J convertible preferred stock authorized, issued and outstanding at September 30, 2003; 0 shares issued and outstanding on a pro forma as adjusted basis	24,179	
Stockholders' equity (deficit):		
Convertible Preferred Stock, $.001 par value: Issued and outstanding as of September 30, 2003: 1,306,068 shares of Series A convertible preferred stock; 900,000 shares of Series B convertible preferred stock; 333,333 shares of Series C convertible preferred stock; 0 shares of Series D preferred stock; 2,300,000 shares of Series F convertible preferred stock; 0 shares of Series G preferred stock; 1,575,229 shares of Series H convertible preferred stock; 0 shares issued and outstanding on a pro forma as adjusted basis	6	
Common stock, $.001 par value; 260,000,000 shares authorized at September 30, 2003 and 75,000,000 shares authorized on a pro forma as adjusted basis; 248,995 shares issued and outstanding at September 30, 2003; 20,855,612 on a pro forma as adjusted basis		21
Additional paid-in capital	131,783	212,579
Deficit accumulated during the development stage	(114,282)	(114,282)
Other comprehensive loss	(24)	(24)
Total stockholders' equity	17,483	98,294
Total capitalization	$ 50,187	$ 106,819

The table above does not include the following amounts as of September 30, 2003:

- 1,666,940 shares of common stock issuable upon the exercise of outstanding options and warrants to purchase our common stock, at a weighted average exercise price of $6.01 per share;
- 361,842 shares of common stock issuable upon conversion of outstanding convertible promissory notes; and
- 85,030 shares of common stock reserved for issuance under our stock option plan.

DILUTION

Our net tangible book deficit attributable to common stockholders as of September 30, 2003 was approximately $4.5 million, or approximately ($18.27) per share based on 248,995 shares of common stock outstanding as of September 30, 2003, not taking into account the

automatic conversion of all of our outstanding convertible preferred stock and mandatorily redeemable convertible preferred stock into 15,806,617 shares of common stock upon the closing of this offering. Net tangible book deficit per share represents our total tangible assets reduced by our total liabilities, mandatorily redeemable convertible preferred stock, deferred offering costs and the liquidation value of our convertible preferred stock and divided by the number of shares of common stock outstanding. Dilution per share to new investors represents the difference between the amount per share that you pay in this offering and the pro forma as adjusted net tangible book value per share immediately after this offering.

Our pro forma as adjusted net tangible book value as of September 30, 2003 would have been approximately $98.3 million, or approximately $4.71 per share after giving effect to the increase of $20.81 attributable to the automatic conversion of our outstanding convertible preferred stock and mandatorily redeemable convertible preferred stock into 15,806,617 shares of common stock upon the closing of the offering and the increase of $2.17 per share attributable to the receipt of the estimated net proceeds of approximately $56.6 million from the sale by us of 4,800,000 shares. This represents an immediate increase in net tangible book value of $2.17 per share to existing stockholders and an immediate decrease in net tangible book value per share of $8.29 to you. The following table illustrates the dilution.

Assumed initial public offering price per share		$ 13.00
Net tangible book deficit per share as of September 30, 2003	$ (18.27)	
Pro forma increase in net tangible book value per share attributable to conversion of convertible preferred stock and mandatorily redeemable convertible preferred stock	20.81	
Increase in net tangible book value per share attributable to existing stockholders	2.17	
Pro forma as adjusted net tangible book value per share after the offering		4.71
Dilution per share to new investors	$ 8.29	

The following table sets forth, as of September 30, 2003, on a pro forma basis, the difference between the holders set forth below with respect to the number of shares of common stock purchased from us, the total consideration paid to us, and the average price per share paid.

	Shares Purchased		Total Consideration		
	Number	%	Amount	%	Average Price Per Share
Existing stockholders	16,055,612	77.0	$	%	$
New investors(1)	4,800,000	23.0			
Total	20,855,612	100.0%	$	%	

(1) Before the underwriters' commissions and our expenses.

The foregoing discussion and tables are based upon the number of shares issued and outstanding as of September 30, 2003 and excludes the following as of September 30, 2003:

- 1,666,940 shares of common stock issuable upon the exercise of outstanding options and warrants to purchase our common stock, at a weighted average exercise price of $6.01 per share;
- 361,842 shares of common stock issuable upon conversion of outstanding convertible promissory notes; and
- 85,030 shares of common stock reserved for issuance under our stock option plan.

The issuance of additional common stock will result in further dilution to new investors.

If the underwriters' over-allotment option is exercised in full, the number of shares of our common stock held by existing stockholders will be reduced to 74.4% of the aggregate number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors will be increased to 5,520,000 or 25.6% of the aggregate number of shares of common stock outstanding after this offering.

SELECTED CONSOLIDATED FINANCIAL AND OPERATING DATA

The selected consolidated statement of operations data for the years ended June 30, 2001, 2002 and 2003 and the selected consolidated balance sheet data presented below as of June 30, 2002 and 2003, other than the pro forma financial information, have been derived from our consolidated financial statements included in this prospectus, which consolidated financial statements have been audited by KPMG LLP, independent auditors. The selected consolidated statement of operations data presented below for the years ended June 30, 1999 and 2000, other than the net loss per share allocable to common stockholders and the weighted average shares of common stock outstanding used in computing net loss per share allocable to common stockholders, and selected consolidated balance sheet data presented below as of June 30, 1999, 2000 and 2001 have been derived from our audited Consolidated Financial Statements not included herein.

The selected consolidated statement of operations data for the three months ended September 30, 2002 and 2003 and cumulatively for the period from March 17, 1995 (Inception) to September 30, 2003 and the selected consolidated balance sheet data as of September 30, 2003, other than the pro forma financial information, are derived from our unaudited consolidated financial statements included elsewhere in this prospectus. The unaudited consolidated financial information include, in the opinion of the management, all adjustments, consisting of normal and recurring adjustments, that management considers necessary for a fair presentation, in all material respects, of its consolidated results for those periods. Our historical results are not necessarily indicative of the results to be expected in the future periods and the results for the three months period ended September 30, 2003 should not be considered indicative of results expected for the full year.

This data should be read in conjunction with our "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our Consolidated Financial Statements and the related notes included elsewhere in this prospectus.

	Year Ended June 30,					Three months ended September 30,		Period from March 17, 1995 (inception) to September 30, 2003 (unaudited)
Statement of Operations Data:	**1999**	**2000**	**2001**	**2002**	**2003**	**2002 (unaudited)**	**2003 (unaudited)**	
	($ in thousands, except per share data)							
Grant revenue	$ 1,036	$ 756	$ 462	$ 132	$ 474	$	$ 202	3,839
Operating expenses incurred in the development stage:								
Research and development	3,083	4,777	6,142	11,146	17,527	3,498	9,874	56,049
Research and development Related party	1,152	2,024	2,223	4,687	2,265	669	2,799	35,150
General and administrative	1,342	1,406	3,489	6,636	6,388	1,768	10,801	33,656
Total operating expenses	5,577	8,207	11,854	22,469	26,180	5,935	23,474	124,855
Operating loss	(4,541)	(7,451)	(11,392)	(22,337)	(25,706)	(5,935)	(23,272)	(121,016)
Other income (expense):								
Interest expense					(78)	(12)	(20)	(98)
Interest expense Related party	(425)	(448)	(444)	(408)	(369)	(92)	(88)	(2,668)
Interest income	611	1,001	1,824	984	393	128	157	5,195
Other income					26	26		26

						Three months ended September 30,		Period from March 17, 1995 (inception) to September 30, 2003 (unaudited)
Total other income (expense)	186	553	1,380	576	(28)	50	49	2,455
Minority interest Related party			699	580				4,279
Net loss	(4,355)	(6,898)	(9,313)	(21,181)	(25,734)	(5,885)	(23,223)	(114,282)
Beneficial conversion feature, accretion of issuance costs preferred dividends and fair value of warrants issued to convertible preferred stockholders	(18)	(27)	(36)	(55)	(24,320)	(14)	(5,993)	(30,946)
Net loss allocable to common stockholders	$ (4,373)	$ (6,925)	$ (9,349)	$ (21,236)	$ (50,054)	$ (5,899)	$ (29,216)	(145,228)
Net loss per share allocable to common stockholders basic and diluted	$ (18.83)(3)	$ (29.34)(3)	$ (39.08)	$ (86.05)	$ (201.03)	$ (23.69)	$ (117.34)	

Pro forma net loss per share allocable to common stockholders basic and diluted (unaudited)(1)				$ (17.67)		$ (1.45)		
Weighted average shares of common stock outstanding used in computing net loss per share allocable to common stockholders basic and diluted	232(3)	236(3)	239	247	249	249	249	
Weighted average shares of common stock outstanding used in computing pro forma net loss per share allocable to common stockholders basic and diluted (unaudited)(1)(2)				8,321		16,056		

(1)

The pro forma net loss per share and weighted average shares of common stock used in computing pro forma net loss per share allocable to common stockholders for the year ended June 30, 2003 and the three months ended September 30, 2003 are calculated as if all our convertible preferred stock and mandatorily redeemable convertible preferred stock were converted into common stock as of the beginning of the year ended June 30, 2003 or from their respective dates of issuance, if issued after the beginning of the year ended June 30, 2003. The pro forma net loss per share allocable to common stockholders for the year ended June 30, 2003 has been computed assuming the offering was completed at the beginning of the fiscal year presented and has been adjusted to give effect to the following: (a) recognition of the unamortized portion of a beneficial conversion charge of $97.1 million; (b) recognition of the unamortized portion of issuance costs relating to Series E, Series I and Series J preferred stock of $479,000; and (c) reversal of accrued preferred dividends on Series J preferred stock of $630,000 (see Note 2 to the consolidated financial statements). The pro forma net loss per share allocable to common stockholders for the three month period ended September 30, 2003 reflects the reversal of the accrued preferred dividend of $1.1 million, amortized beneficial conversion charge of $4.9 million and amortized issuance cost of $24,000 assuming that the automatic conversion occurred as of the beginning of the fiscal year ended June 30, 2003.

(2)

The weighted average shares of our common stock outstanding used in computing the pro forma net loss per share allocable to common stockholders is calculated based on (a) Series A through Series I equivalent shares of common stock from the beginning of the fiscal year; (b) additional equivalent shares of common stock issuable under Series A through Series I as a result of adjusting the conversion prices as a result of anti-dilution provisions as of the date of adjustment; and (c) Series J equivalent shares of common stock issuable from the date of issuance of the Series J preferred stock.

(3)

Unaudited.

Consolidated Balance Sheet Data:	As of June 30, 1999	2000	2001	2002	2003	As of September 30, 2003 (unaudited)	Pro Forma As of September 30, 2003 (unaudited)
	($ in thousands)						
Cash and cash equivalents	$ 16,862	$ 17,193	$ 48,083	$ 27,012	$ 48,319	$ 8,033	$ 8,033
Restricted Cash		232	243	250	253	254	254
Short-term investments				2,836	12,250	43,836	43,836
Working capital	16,873	15,894	46,115	27,097	58,975	47,075	47,075
Total assets	17,487	18,260	50,349	33,597	64,807	57,024	57,024
Deferred revenue					95	57	57
Current portion of notes payable					310	317	317
Non-current portion of notes payable					612	530	530
Long-term convertible notes payable principal amount plus accrued interest, less unamortized debt discount Related party	6,239	6,687	7,131	7,538	7,907	7,995	7,995
Mandatorily redeemable preferred stock	19,985	20,012	59,604	59,659	18,187	24,179	
Total stockholders' equity (deficit)	(9,045)	(10,438)	(19,041)	(36,910)	35,328	17,483	41,662

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

The following discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and related notes included in this prospectus. This discussion and analysis contains forward-looking statements that are subject to risks, uncertainties and other factors, including, but not limited to, those discussed under "Risk Factors" and elsewhere in this prospectus, that could cause our actual results, performance, prospects or opportunities to differ materially from those expressed in, or implied by, these forward-looking statements. See "Forward-Looking Statements".

Background

Since we commenced operations in 1995, we have devoted substantially all of our resources to the identification, development and commercialization of novel therapies that improve neurological function in people with spinal cord injury, multiple sclerosis and related disorders of the central nervous system. Our current lead product candidate targets the treatment of a wide range of disorders affecting individuals with spinal cord injury and multiple sclerosis, including spasticity, muscle weakness, loss of bowel and bladder control and sexual dysfunction. Our pipeline currently includes one product in Phase 3 clinical trials, two products in Phase 2 clinical trials and multiple preclinical products.

Revenue

We have not generated any revenue from product sales since our inception. If our development efforts result in clinical success, regulatory approval and successful commercialization of our products, we would expect to generate revenue from sales of our products, in-licensed products and from receipt of royalties on sales of out-licensed products. Since our inception through September 30, 2003, we have recognized $3.8 million in revenue from government grants.

Research and Development Expenses

Research and development expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers in conjunction with independently monitoring our clinical trials and acquiring and evaluating data in conjunction with our clinical trials, costs of contract manufacturing services, costs of materials used in clinical trials and research and development, depreciation of capital resources used to develop our products, costs of facilities and the legal costs of pursuing patent protection of our intellectual property. We expense research and development costs as incurred. We expect our research and development expenses to increase as we continue to develop our product candidates. From inception through September 30, 2003, we spent an aggregate of $91.2 million, including stock-based compensation expense of $5.4 million, on research and development including amounts paid to Elan, a related party, in the amount of $35.2 million.

The following table summarizes our research and development expenses for the fiscal years ended June 30, 2001, 2002, 2003 and for the three month period ended September 30, 2003. Included in this table is the research and development contract expense primarily relating to clinical trial studies and research services provided by outside laboratories and vendors recognized in connection with each product candidate currently in clinical development and all preclinical product candidates as a group. Many of our research and development costs, including personnel costs, related benefits and stock-based compensation, are not attributable to any individual project because we use these resources across several development projects.

Compensation expense for option grants are classified between clinical development and preclinical research and development based on employee job function.

	Years Ended June 30,			Three Month Period Ended September 30,		Period From March 17, 1995 (Inception) to September 30, 2003
	2001	2002	2003	2002	2003	
	($ in thousands)					
Clinical Development						
Contract Expense Spinal Cord Injury	$ 1,557	$ 3,329	$ 5,777	$ 1,242	$ 1,928	$ 14,344
Contract Expense Multiple Sclerosis	649	908	1,613	145	1,422	4,593
Other Contract Expense			1,015		333	1,348
Operating Expense	695	1,548	2,356	445	1,106	5,704
Licensing Expense Teva					2,000	2,000
Total Clinical Development	2,901	5,785	10,761	1,832	6,789	27,989
Preclinical Research and Development						

				Three Month Period Ended September 30,		
Research Contracts	586	617	271		135	3,655
Contract Expense		213	1,441	186	28	1,682
Operating Expense	2,655	4,531	5,054	1,480	2,922	22,723
Total Preclinical Research and Development	3,241	5,361	6,766	1,666	3,085	28,060
Total Research and Development	6,142	11,146	17,527	3,498	9,874	56,049

Research and Development Related Party Expense Fampridine-SR		
Research and Development Related Party Expense Elan Fampridine-SR	2,223	4,687