

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

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

Registration No. 333-109199

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## 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**

(State or other jurisdiction of  
incorporation or organization)

**2836**

(Primary standard industrial  
classification code number)

**13-3831168**

(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)

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

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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.

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.

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 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.

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

**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.**

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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

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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.

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

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

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	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

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## 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 valrocecide, which is currently in Phase 2 clinical trials for the treatment of epilepsy. Valrocecide 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. Valrocecide 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 valrocecide 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 valrocecide for the treatment of neuropathic pain. Valrocecide 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 valrocecide 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 valrocecide 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 valrocecide, 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](http://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.

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### 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
	1999	2000	2001	2002	2003	2002 (unaudited)	2003 (unaudited)	March 17, 1995 (Inception) to September 30, 2003 (unaudited)
	(\$ in thousands, except per share data)							
<b>Statement of Operations Data:</b>								
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)

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						Three Months Ended September 30,		Period From March 17, 1995
Net loss allocable to common stockholders	\$ (4,373)	\$ (6,925)	\$ (9,349)	\$ (21,236)	\$ (50,054)	(3,899)	(29,210)	(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)	(Inception) to September 30, 2003 (unaudited)
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 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

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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)		
<b>Consolidated Balance Sheet Data:</b>		
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

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## 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 valroceamide 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

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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 valroceamide 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 valroceamide, 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;

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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.

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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 valrocecimide. 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 RxPedit program to commercialize Fampridine-SR in spinal cord injury. The RxPedit 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 valroceamide, 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.

Valrocecimide 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 valrocecimide 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



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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.

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## 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.

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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.

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#### 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

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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	
<b>Stockholders' equity (deficit):</b>		
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)
<b>Total stockholders' equity</b>	<b>17,483</b>	<b>98,294</b>
<b>Total capitalization</b>	<b>\$ 50,187</b>	<b>\$ 106,819</b>

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

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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
		4.71
Pro forma as adjusted net tangible book value per share after the offering		4.71
		8.29
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		Average Price Per Share
	Number	%	Amount	%	
Existing stockholders	16,055,612	77.0	\$	%	\$
New investors(1)	4,800,000	23.0			
	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.

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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.

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### 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.

Statement of Operations Data:	Year Ended June 30,					Three months ended September 30,		Period from March 17, 1995 (inception) to September 30, 2003
	1999	2000	2001	2002	2003	2002 (unaudited)	2003 (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

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	Three months ended September 30,						Period from March 17, 1995	
Total other income (expense)	186	553	1,380	576	(28)	50	49	(inception) 1,455 September 30, 2003
Minority interest - Related party			699	580				(unaudited) 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)	

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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)

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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,					As of September 30, 2003	Pro Forma As of September 30, 2003
	1999	2000	2001	2002	2003	(unaudited)	(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

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### 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.

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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)							
<b>Clinical Development</b>							
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						2,000	2,000
<b>Total Clinical Development</b>		2,901	5,785	10,761	1,832	6,789	27,989

**Preclinical Research and Development**

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	Three Month Period					
	Ended September 30,					
Research Contracts	586	617	271	135	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
<b>Total Research and Development</b>	<b>6,142</b>	<b>11,146</b>	<b>17,527</b>	<b>3,498</b>	<b>9,874</b>	<b>56,049</b>

**Research and Development Related Party Expense Fampridine-SR**

Research and Development Related Party Expense Elan Fampridine-SR							
	2,223	4,687	2,265	669	2,799		35,150
<b>Total Related Party</b>	<b>2,223</b>	<b>4,687</b>	<b>2,265</b>	<b>669</b>	<b>2,799</b>		<b>35,150</b>

<b>Total</b>	<b>\$ 8,365</b>	<b>\$ 15,833</b>	<b>\$ 19,792</b>	<b>\$ 4,167</b>	<b>\$ 12,673</b>		<b>\$ 91,199</b>
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Conducting clinical trials is a lengthy, time-consuming and expensive process. The commencement and rate of completion of clinical trials for our products may be delayed by many factors, including:

lack of efficacy during the clinical trials;

unforeseen safety issues;

slower than expected rate of patient recruitment; or

government or regulatory delays.

In addition, we may encounter regulatory delays or rejections as a result of many factors, including results that do not support our claims, perceived defects in the design of clinical trials and changes in regulatory policy during the period of product development. We also rely on third-parties, such as Elan, for the supply of products and services which are critical to the FDA approval process. Our business, financial condition and results of operations may be materially adversely affected by any delays in, or termination of, our clinical trials or a determination by the FDA that the results of our trials are inadequate to justify regulatory approval. As part of our commercialization strategy, we may seek to establish collaborative relationships for some of our products in order to help us develop and market some of these product candidates. As a result of these risks and uncertainties, we are unable to estimate the specific timing and future costs of our clinical development programs or the timing of material cash inflows, if any, from our product candidates.

**Research and development Related party**

In cooperation with Elan, we have conducted a series of clinical trials during the past six years evaluating Fampridine-SR. Elan is an Acorda stockholder and is considered to be a related party. Related party research and development expenses have been included as a separate line item in our financial statements and in the table above. These expenses consist of the contracted development and supply of our lead product candidate, Fampridine-SR, license fees and acquisition expenses.

**General and Administrative Expenses**

General and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, sales and marketing, business development, information technology and human resource functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal and accounting services. We expect that our general and administrative expenses will increase as we add personnel and become subject to the reporting obligations applicable to public companies. From inception through September 30, 2003, we spent an aggregate of \$33.7 million, including stock-based compensation expenses of \$11.8 million, on general and administrative expenses.

***Stock-Based Compensation***

We have accounted for options granted to employees and directors in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation*, and related interpretations. As such, compensation expense is recorded on stock option grants based on the fair value of the options granted, which is estimated on the date of grant using an option-pricing model and it is recognized on a straight-line basis over the vesting period. Compensation expense for options granted to employees amounted to \$643,000, \$1.3 million and \$1.6 million for the years ended June 30, 2001, 2002 and 2003, respectively. Compensation expense for options granted to employees amounted to \$387,000, \$11.4 million and \$15.2 million for the three month periods ended September 30, 2002 and 2003 and for the period from March 17, 1995, the date of our inception, to September 30, 2003, respectively. Compensation expense for options granted to employees are classified between research and development and general and administrative expense based on employee job function.

We have accounted for stock options granted to non-employees on a fair-value basis in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation*, Emerging Issues Task Force Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, and FASB Interpretations No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans an Interpretation of APB Opinion No. 15 and 25*. As a result, the non-cash charge to operations for non-employee options with vesting or other performance criteria is affected each reporting period by changes in the fair value of our common stock. Compensation expense for options granted to non-employees amounted to \$94,000, \$75,000 and (\$6,000) for the years ended June 30, 2001, 2002 and 2003, respectively. Compensation expense for options granted to non-employees amounted to \$12,000, \$4,000 and \$1.9 million for the three month periods ended September 30, 2002 and 2003 and for the period from March 17, 1995 the date of our inception, to September 30, 2003, respectively. The amount of compensation expense to be recorded in the future for options granted to non-employees is subject to change each reporting period based upon changes in the fair value of our common stock, estimated volatility and risk free interest rate until the non-employee completes performance under the option agreement.

As of September 30, 2003, our unrecognized stock-based compensation related to stock options granted to employees outstanding as of September 30, 2003 amounted to approximately \$9.5 million which we estimate will be recognized as follows: \$2.4 million for the remaining nine months in the year ending June 30, 2004 and \$2.8 million, \$2.1 million, \$1.7 million, \$415,000 for each of the years ending June 30, 2005, 2006, 2007 and 2008, respectively. Our estimated stock-based compensation costs are not necessarily indicative of the compensation costs that will be recognized in the future periods and the results for the three month period ended September 30, 2003 should not be considered indicative of results expected for the full

year, as we may record additional deferred stock-based compensation if we grant additional options or change the terms of the options granted to our employees.

***Beneficial Conversion Feature***

In May 2003, we completed a private placement of 112,790,233 shares of Series J convertible preferred stock for an aggregate purchase price of approximately \$55.3 million. As a result of this financing, our Series A through Series I preferred stockholders' original conversion price was reduced as a result of anti-dilution adjustments, which resulted in a beneficial conversion of \$80.7 million in accordance with EITF No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios* and EITF No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*. The beneficial conversion of \$20.9 million, recorded as an immediate charge to additional paid-in capital, related to our Series A, Series B, Series C, Series F and Series H convertible preferred stock, which are not mandatorily redeemable and may be converted to common stock at any time at the option of the holders. The remaining beneficial conversion of \$59.9 million related to our Series E and Series I convertible preferred stock, which are mandatorily redeemable at any time on or after June 30, 2008, is being accreted ratably over the mandatory redemption period. Such accretion for the year ended June 30, 2003 and for the three month period ended September 30, 2003 amounted to \$1.7 million and \$2.9 million, respectively, and is charged to additional paid-in capital.

In addition, the issuance of our Series J mandatorily redeemable convertible preferred stock resulted in a beneficial conversion of approximately \$40 million in accordance with EITF No. 98-5. The beneficial conversion is calculated using an estimate of the fair value of our common stock on the date of issuance of Series J preferred stock of approximately \$10.14 per share of common stock, which was calculated based on the estimated per common share valuation of our company at the date the accompanying consolidated financial statements were prepared and the stock price appreciation in comparable public companies from May 2003 to August 2003 (see Note 3 to our consolidated financial statements included in this prospectus). The beneficial conversion is being accreted ratably over the mandatory redemption period. The charge to paid-in capital for the year ended June 30, 2003 and for the three month period ended September 30, 2003 amounted to \$1.1 million

and \$1.9 million, respectively.

The unamortized portion of the beneficial conversion at September 30, 2003 was \$92.2 million. Upon the closing of this offering, we will recognize a one time non-cash charge to additional paid in capital, reflecting the unamortized portion of the beneficial conversion feature as a result of the automatic conversion of the convertible preferred stock and mandatorily redeemable convertible preferred stock to common stock upon completion of this offering.

#### ***Other Income (Expense)***

Interest income consists of interest earned on our cash, cash equivalents and short-term investments. Interest expense consists of interest expense on our GE Capital notes payable. Interest expense Related party consists of amortization of debt discount and accrued interest on our \$7.5 million aggregate principal amount of convertible notes payable to Elan International Services, Ltd., or EIS, an affiliate of Elan outstanding as of September 30, 2003. Other income primarily consists of a gain on an option transaction.

#### **Results of Operations**

We have a limited history of operations. We anticipate that our quarterly results of operations will fluctuate for the foreseeable future due to several factors, including the timing and amount of payments made or received pursuant to licensing or collaboration agreements, progress of our research and development efforts, and the timing and outcome of regulatory approvals. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses. As of September 30, 2003, we had an accumulated deficit of approximately \$114 million. We anticipate incurring additional losses, which we expect will increase, for the foreseeable future.

#### ***Three Month Period Ended September 30, 2003 Compared to Three Month Period Ended September 30, 2002***

##### ***Grant Revenue***

Grant revenue for quarter ended September 30, 2003 was \$202,000 compared to \$0 for the three month period ended September 30, 2002. Grant revenue is recognized when related research expenses are incurred and our performance obligations under the terms of the respective contract are satisfied. To the extent expended, grant revenue related to purchase of equipment is deferred and amortized over the shorter of its useful life or the life of the related contract. For the three month period ended September 30, 2003, we deferred approximately \$57,000 in revenue, as it relates to funding for the purchase of equipment. From inception through September 30, 2003, we have recognized grant revenue of approximately \$3.8 million of which \$3.7 million has been received by us as of September 30, 2003.

##### ***Operating Expenses Incurred in the Development Stage***

##### ***Research and Development***

Research and development expenses for the three month period ended September 30, 2003 were \$9.9 million compared to \$3.5 million for the three month period ended September 30, 2002, an increase of approximately \$6.4 million or 182%. Total research and development expense includes non-cash stock based compensation expense of \$2.2 million for the three month period ended September 30, 2003, as compared to \$126,000 for the quarter ended September 30, 2002, an increase of approximately \$2.1 million primarily attributable to our stock option grants to employees in September 2003, which included immediate vesting on a certain number of the options granted (see Note 14 to our consolidated financial statements included in this prospectus). The increase in research and development expenses for the three month period ended September 30, 2003 was primarily attributed to acceleration in patient enrollment in both the Phase 2 clinical trial for multiple sclerosis and two Phase 3 clinical trials for spinal cord injury. The spinal cord injury study expenses increased from \$1.2 million for the three month period ended September 30, 2002 to \$1.9 million for the three month period ended September 30, 2003, an increase of approximately \$700,000. The multiple sclerosis study expenses increased from \$145,000 for the three month period ended September 30, 2002 to \$1.4 million for the three month period ended September 30, 2003, an increase of \$1.3 million. Expenses related to the Phase 2 clinical trial for multiple sclerosis and the two Phase 3 clinical trials for spinal cord injury and outside contract work for drug stability testing increased by approximately \$333,000 compared to the three month period ended September 30, 2002. Expenses related to preclinical research and development work increased by approximately \$1.4 million compared to the three month period ended September 30, 2002, primarily due to an increase in headcount. In addition, we expensed an upfront payment relating to the collaboration agreement entered into with Teva Pharmaceutical Industries Ltd. in September 2003 in the amount of \$2 million.

*Research and Development Related party*

The cost of the drug development and supply of Fampridine-SR increased by \$130,000 or 19% to \$799,000 for the three month period ended September 30, 2003 compared to \$669,000 for the three month period ended September 30, 2002. This increase in expense was due to increased development activities by Elan related to Fampridine-SR for the three month period ended September 30, 2003. In addition, we recognized research and development related-party expense of \$2 million as the consideration paid to Elan-related entities for the purchase of an additional equity ownership interest in MS Research and Development Corporation (see Note 14 to our consolidated financial statements included in this prospectus).

*General and Administrative*

General and administrative expenses for the three month period ended September 30, 2003 were \$10.8 million compared to \$1.8 million for the three month period ended September 30, 2002, an increase of approximately \$9 million, or 511%. Total general and administrative expenses included non-cash stock based

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compensation expense of \$9.2 million for the three month period ended September 30, 2003, as compared to \$274,000 for the three month period ended September 30, 2002, an increase of approximately \$8.9 million. The increase in general and administrative expenses for the three month period ended September 30, 2003 of approximately \$9 million was primarily attributable to the \$8.9 million increase in stock compensation expense related to our stock option grants to employees in September 2003, which included immediate vesting on certain number of the options granted (see Note 14 to our consolidated financial statements included in this prospectus).

*Other Income (Expense)*

*Interest Income (Expense) Net*

Other expenses for the three month period ended September 30, 2003 consisted of approximately \$19,600 of interest on our GE Capital note payable compared with \$11,900 for the three month period ended September 30, 2002, an increase of \$7,700. Interest expense Related party decreased \$4,000 to \$88,000 for the three month period ended September 30, 2003 from \$92,000 for the three month period ended September 30, 2002. Interest expense Related party for the three month period ended September 30, 2003 primarily consisted of accrued interest of \$43,800 and approximately \$44,200 on amortization of debt discount relating to the EIS convertible promissory notes. Interest income increased by \$29,000 or approximately 23% to \$157,000 for the three month period ended September 30, 2003 from \$128,000 from the three month period ended September 30, 2002. The increase in interest income was primarily attributable to higher average cash balances invested for the three month period ended September 30, 2003.

*Beneficial conversion feature, accretion of issuance costs, preferred dividends and fair value of warrants issued to convertible preferred stockholders*

Charges related to preferred stock increased from \$14,000 for the three month period ended September 30, 2002 to \$6 million for the three month period ended September 30, 2003. For the three month period ended September 30, 2002, charges primarily comprised accretion of issuance costs on our Series E and Series I mandatorily redeemable convertible preferred stock (see Note 7 to our consolidated financial statements included in this prospectus). For the three month period ended September 30, 2003, charges primarily comprised the accrual of the preferred dividend of \$1.1 million on our Series J mandatorily redeemable convertible preferred stock, and the accretion of the beneficial conversion feature of \$4.9 million on our Series E, Series I and Series J mandatorily redeemable convertible preferred stock. (see Note 3 and Note 7 to our consolidated financial statements included in this prospectus).

***Year Ended June 30, 2003 Compared to Year Ended June 30, 2002***

*Grant Revenue*

Grant revenue for the year ended June 30, 2003 was \$474,000 compared to \$132,000 for the year ended June 30, 2002. Grant revenue is recognized when the related research expenses are incurred and our performance obligations under the terms of the respective contract are satisfied. To the extent expended, grant revenue related to purchase of equipment is deferred and amortized over the shorter of its useful life or the life of the related contract. For the year ended June 30, 2003, we deferred approximately \$95,000 in revenue, as it relates to funding for the purchase of equipment. Since inception through June 30, 2003, we have recognized grant revenue of approximately \$3.6 million of which approximately \$3.4 million has been received by us as of June 30, 2003.

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### *Operating Expenses Incurred in the Development Stage*

#### Research and Development

Research and development expenses for the year ended June 30, 2003 were \$17.5 million compared to \$11.1 million for the year ended June 30, 2002, an increase of approximately \$6.4 million or 57.2%. Total research and development expenses include non-cash stock-based compensation expense of \$478,000 for the

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year ended June 30, 2003, as compared to \$455,000 for the year ended June 30, 2002, an increase of approximately \$23,000 or 5.0%. The increase in research and development expenses for the year ended June 30, 2003 was primarily attributable to acceleration in patient enrollment in both the Phase 2 clinical trial in multiple sclerosis and two Phase 3 clinical trials in spinal cord injury. The spinal cord injury study expenses increased from \$3.4 million for the year ended June 30, 2002 to \$5.8 million for the year ended June 30, 2003, an increase of \$2.4 million. The multiple sclerosis study expenses increased from \$908,000 for the year ended June 30, 2002 to \$1.6 million for the year ended June 30, 2003, an increase of \$705,000. Expenses related to these clinical studies and outside contract work for drug stability testing increased by approximately \$1.0 million from the year ended June 30, 2002. Expenses incurred in the development of our remyelinating agents and the associated costs increased by approximately \$1.2 million from the year ended June 30, 2002. Expenses related to preclinical research and development work increased by approximately \$1.4 million compared to the year ended June 30, 2002 primarily due to an increase in head count.

#### Research and Development Related party

The cost of the drug development and supply of Fampridine-SR decreased by \$2.4 million, or 51.7%, to \$2.3 million for the year ended June 30, 2003 compared to \$4.7 million for the year ended June 30, 2002. This decrease in expense is due to reduced development activities by Elan related to Fampridine-SR during the year ended June 30, 2003.

#### General and Administrative

General and administrative expenses for the year ended June 30, 2003 were \$6.4 million compared to \$6.6 million for the year ended June 30, 2002, a decrease of approximately \$248,000, or 3.7%. Total general and administrative expenses include non-cash stock based compensation expense of \$1.1 million for the year ended June 30, 2003, as compared to \$951,000 for the year ended June 30, 2002, an increase of approximately \$144,000, or 15.2%. The decrease in general and administrative expenses was primarily due to management's decision to defer spending for market research and medical communications until we had reached a later stage of clinical development of Fampridine-SR.

#### *Other Income (Expense)*

#### Interest Income (Expense) Net

Interest expense others for the year ended June 30, 2003 consists of approximately \$78,000 on our GE Capital notes payable. Interest expense Related party decreased \$39,000, or 9.5%, to \$369,000 for the year ended June 30, 2003 from \$408,000 for the year ended June 30, 2002. Interest expense Related party for the year ended June 30, 2003 primarily consists of accrued interest of \$150,000 and approximately \$219,000 on amortization of debt discount relating to the EIS convertible promissory notes. Interest income decreased \$591,000, or 60.1%, to \$393,000 for the year ended June 30, 2003 from \$984,000 for the year ended June 30, 2002. The decrease in interest income was attributable to lower average cash balances and lower interest earned on cash balances in the year ended June 30, 2003.

#### Other Income

We recorded other income of \$26,000 for the year ended June 30, 2003 as compared with \$0 for the year ended June 30, 2002. During the first quarter of 2003, we entered into a foreign currency option transaction to sell U.S. dollars to British Pounds amounting to approximately \$295,000, with a strike price of \$1.4280. The option expiration date was January 31, 2003. The Company's primary purpose for entering into this transaction was to cover an exchange gain or loss on a British Pound denominated contract to be entered into with a foreign company. The gain of \$26,000 relating to this option transaction is classified as other income.

#### Minority Interest

Minority interest decreased to \$0 for the year ended June 30, 2003 as compared with \$580,000 for the year ended June 30, 2002. Elan's ownership interest in MS Research and Development Corporation, a joint venture owned approximately 83% by Acorda and approximately 17% by Elan and another minority

stockholder, is reflected as minority interest in our consolidated financial statements. In the year ended June 30, 2003, Elan ceased funding its share of the joint venture's expenses, therefore there is no minority interest for the year ended June 30, 2003. The assets of this joint venture have been transferred to us. See "R&D and Product Collaborations, Alliances and License Agreements".

Beneficial conversion feature, accretion of issuance costs, preferred dividends and fair value of warrants issued to convertible preferred stockholders

Charges related to preferred stock increased from \$55,000 for the year ended June 30, 2002 to \$24.3 million for the year ended June 30, 2003. For the year ended June 30, 2002 charges primarily comprised accretion of issuance costs on Series E and Series I mandatorily redeemable convertible preferred stock (see Note 7 to our consolidated financial statements included in this prospectus). For the year ended June 30, 2003 charges primarily comprised accretion of issuance costs of \$66,000 on Series E, Series I and Series J mandatorily redeemable convertible preferred stock, accrual of preferred dividend of \$630,000 on Series J mandatorily redeemable convertible preferred stock, accretion of beneficial conversion feature of \$22.5 million on Series A through Series I preferred stock for reset in conversion price and accretion of beneficial conversion feature of \$1.1 million on Series J preferred stock (see Notes 3 and 7 to our consolidated financial statements included in this prospectus).

*Year Ended June 30, 2002 Compared to Year Ended June 30, 2001*

*Grant Revenue*

Grant revenue for the year ended June 30, 2002 was \$132,000 compared to \$462,000 for the year ended June 30, 2001, a decrease of approximately \$331,000, or 71.5%. The decrease is primarily due to lower grants received and recognized for the year ended June 30, 2002.

*Operating Expenses Incurred in the Development Stage*

Research and Development

Research and development expenses for the year ended June 30, 2002 were \$11.1 million compared to \$6.1 million for the year ended June 30, 2001, an increase of approximately \$5.0 million, or 81.3%. The research and development expenses include non-cash stock based compensation expense of \$455,000 for the year ended June 30, 2002, as compared to \$286,000 for the year ended June 30, 2001, an increase of approximately \$169,000, or 59.4%, primarily due to options granted to employees. Spinal cord injury clinical study expenses increased from \$1.6 million in fiscal 2001 to \$3.4 million for the year ended June 30, 2002, an increase of approximately \$1.8 million. This increase was due to the increased clinical trial activity for the year ended June 30, 2002. Expenses incurred for salaries and benefits totaled approximately \$2.7 million for the year ended June 30, 2002 as compared with \$1.8 million for the year ended June 30, 2001, an increase of approximately \$900,000 due to increases in research and development headcount. Expenses incurred in the development of our remyelinating agents and other internal costs increased by approximately \$700,000 from the year ended June 30, 2001. We recognized a non-cash charge of \$618,000 in research and development expense for the year ended June 30, 2002 on the estimated fair value of a five-year warrant to purchase 100,000 shares of Series B preferred stock of \$321,000 and \$296,666 as a beneficial conversion charge on issuance of Series C convertible preferred stock (see Note 10 to our consolidated financial statements included in this prospectus).

Research and Development Related party

The cost of the drug development and supply of Fampridine-SR increased by \$2.4 million, or 110.8%, to \$4.7 million for the year ended June 30, 2002 compared to \$2.2 million for the year ended June 30, 2001. This increase in expense was due to increased development activities by Elan related to Fampridine-SR for the year ended June 30, 2002.

General and Administrative

General and administrative expenses for the year ended June 30, 2002 were \$6.6 million compared to \$3.5 million for the year ended June 30, 2001, an increase of approximately \$3.1 million, or 90.2%. Total general and administrative expenses include non-cash stock based compensation expense of \$951,000 for the year ended June 30, 2002, as compared to \$452,000 for the year ended June 30, 2001, an increase of approximately \$499,000, or 110.5%. Expenses incurred for public relations, marketing research, medical communications, salaries, benefits and the other related sales and marketing operating costs totaled \$1.9 million in the year ended June 30, 2002 as compared with \$325,000 for the year ended June 30, 2001, an increase of approximately \$1.6 million, or 492.3%, primarily due to the creation of the sales and marketing department in the fourth quarter of the year ended June 30, 2001 and the business development department in the year ended June 30, 2002. Expenses incurred for salaries, benefits and other business development operating costs totaled \$700,000 for the year ended June 30, 2002.

*Other Income (Expense)*

Interest Income (Expense) Net

Interest expense Related party decreased \$36,000, or 8.1%, to \$408,000 for the year ended June 30, 2002 from \$444,000 for the year ended June 30, 2001. Interest expense Related party for the year ended June 30, 2002 primarily related to amortization of debt discount of approximately \$258,000 and accrued interest of \$150,000 relating to the EIS convertible promissory notes. Interest income decreased \$840,000, or 46.1%, to \$984,000 for the year ended June 30, 2002 from \$1.8 million for the year ended June 30, 2001. The decrease in interest income was attributable to lower average cash balances and lower interest earned on cash balances for the year ended June 30, 2002.

Minority Interest

Minority interest decreased \$118,000, or 16.9%, to \$580,000 for the year ended June 30, 2002 as compared with \$699,000 for the year ended June 30, 2001. The minority interest for the year ended June 30, 2002 represents the 19.9% interest in MS Research and Development Corporation owned by Elan and another party.

**Liquidity and Capital Resources**

We have incurred annual operating losses since inception, and, as of September 30, 2003, we have incurred an accumulated deficit of approximately \$114 million, including non-cash charges of \$18.1 million related to grants of stock options, warrants, and common stock. Since our inception, we have financed our operations primarily through the proceeds of private placements of our securities and, to a lesser extent, from government grants. From our inception through September 30, 2003, we raised aggregate net proceeds of \$136 million through the proceeds of private placements of equity securities. In addition, in fiscal 1997, EIS loaned us an aggregate of \$7.5 million pursuant to two convertible promissory notes to partly fund our research and development activities. In fiscal 2003, we financed certain of our fixed assets through two financing agreements with GE Capital in the aggregate amount of approximately \$1.2 million.

At September 30, 2003, cash and cash equivalents and short-term investments were approximately \$51.9 million compared to \$60.6 million at June 30, 2003. Our cash and cash equivalents consist of highly liquid investments with original maturities of three months or less at date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions and high-quality government and investment grade corporate bonds. Also, we maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. Our short-term investments consist of corporate debt securities with original maturities greater than three months and less than one year.

Our future cash requirements include, but are not limited to, supporting our clinical trial efforts and continuing our other research and development programs. Since inception we have entered into various

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agreements with institutions and contract research organizations to conduct and monitor our current clinical trials. Under these agreements, at September 30, 2003 we have estimated our payments to be approximately \$3.6 million over the remaining term of the clinical trials. Through September 30, 2003, approximately \$91.2 million has been expensed as research and development expenses in the accompanying consolidated statements of operations, of which \$35.2 million has been paid to Elan and \$22.3 million has been paid related to contract and licensing expense to third parties (other than Elan) for clinical development. The timing of our expense recognition and future payments related to these agreements are subject to the enrollment of patients and performance by the applicable institution of certain services. As we expand our clinical trials, we will enter into additional agreements and significant additional expenditures will be required as we complete our clinical trials, apply for regulatory approvals, continue development of our product candidates and expand our operations and bring our products to market. In



addition, we have entered into various other research and license agreements through September 30, 2003 which, as of September 30, 2003, upon accomplishment of certain milestones, will require payments by us aggregating up to approximately \$46.0 million (which includes approximately \$30.0 million of payments under the agreements entered into in September 2003) over the life of the contracts. The timing of these payments will depend on when the milestones are achieved. Upon regulatory approval, these agreements also require us to make royalty payments as a percentage of product sales.

Net cash used in operations was \$8.1 million, \$18.1 million and \$24.5 million for the years ended June 30, 2001, 2002 and 2003, respectively and \$5.9 million and \$7.6 million for the quarters ended September 30, 2002 and 2003, respectively. Cash used by operations for the quarter ended September 30, 2003 was primarily attributable to a net loss of \$23.2 million. The cash used in operations for the quarter ended September 30, 2003 was offset by an increase in amounts due to Elan of \$2.4 million primarily due to \$2 million payable for the purchase of an additional equity ownership interest in MSR&D (see Note 14 to our consolidated financial statements included in this prospectus) and a \$442,000 increase in development activities by Elan related to Fampridine-SR; an increase in accounts payable, accrued expenses and other current liabilities of \$1.7 million primarily due to clinical trial expense accrual increase of \$1.1 million and IPO related expense accruals of \$379,000; stock compensation expense of \$11.4 million and depreciation and amortization expense of \$196,000. Cash was used by operations for the quarter ended September 30, 2002 primarily due to a net loss of approximately \$5.9 million; decrease in accounts payable, accrued expenses and other current liabilities of \$414,000 primarily due to timing of our payments and decrease in Elan accounts payable balance by \$195,000 due to a slight decrease in activities during the period related to the development of Fampridine-SR by Elan. The cash used in operations for the quarter ended September 30, 2002 was offset by stock compensation expense of \$399,000; depreciation and amortization expense of \$169,000 and amortization of debt discount relating to our \$7.5 million aggregate principal amount convertible notes payable to EIS of \$55,000.

Cash was used by operations for the year ended June 30, 2003 due to a net loss of \$25.7 million; a decrease in amounts due to Elan of \$593,000, primarily due to lower drug development charges from Elan for the year ended June 30, 2003; an increase in prepaid expenses and other current assets of \$402,000 primarily due to a \$50,000 increase in prepaid insurance premiums as a result of increases in general liability insurance and product liability insurance associated with the clinical trial programs, a \$154,000 increase in interest receivable on our short term investments, and an increase in other receivables of \$78,000; and an increase in grant receivable of \$214,000 primarily due to an increase in grant revenue during the current fiscal year by approximately \$342,000. The cash used in operations for the year ended June 30, 2003 was offset by stock compensation expense of \$1.6 million; depreciation and amortization expense of \$740,000 and amortization of debt discount relating to our \$7.5 million aggregate principal amount convertible notes payable to EIS of \$219,000.

Cash was used by operations for the year ended June 30, 2002 due to a net loss of approximately \$21.2 million and minority interest of \$580,000. The cash used in operations for the year ended June 30, 2002 was partially offset by stock compensation expenses of \$1.4 million; expensing of warrants and beneficial conversion charge on Series C preferred stock issued to Elan on completion of Phase 2 clinical trials of \$618,000;

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an increase in due to Elan of \$580,000 primarily due to increased drug development charges from Elan as the program progressed in the year ended June 30, 2002; depreciation and amortization expense of \$417,000; amortization of debt discount relating to our \$7.5 million aggregate principal amount of convertible promissory notes payable to EIS of \$258,000; increase in accounts payable and accrued expenses and other current liabilities of \$224,000 due to higher expenses incurred as research and development projects progress.

Net cash used in investing activities for the quarter ended September 30, 2003 was \$31.9 million and was primarily due to the net reinvestment of \$31.6 million of surplus cash into marketable securities. In addition, we purchased property and equipment of \$249,000 in the quarter ended September 30, 2003. Net cash used in investing activities for the quarter ended September 30, 2002 was \$2.2 million and was primarily due to the purchase of short-term corporate debt securities for \$2 million. In addition we purchased \$269,000 of property and equipment.

Net cash used in investing activities for the year ended June 30, 2003 was \$10.2 million and was due primarily to the net reinvestment of \$9.4 million of surplus cash into marketable securities. In addition, we purchased property and equipment of \$748,000 in fiscal 2003. Net cash used in investing activities for the year ended June 30, 2002 was \$5.1 million and was primarily due to purchase of short-term investment of \$2.8 million and purchase of purchased property and equipment of \$2.2 million in the year ended June 30, 2002. We incurred significant expenses in acquisition of property and equipment in the year ended June 30, 2002 as a result of the expansion of our office and laboratory facilities. We had no material commitments to purchase property and equipment at June 30, 2003.

Net cash used by financing activities for the period ended September 30, 2003 was \$882,000, which was primarily related to offering costs incurred which we expect to be offset against proceeds on the completion of the offering contemplated in this prospectus and repayment of GE notes payable in the amount of \$75,000. Net cash provided by financing activities for the period September 30, 2002 was \$1.2 million primarily

from the financing agreements entered into with GE Capital Corporation for the financing of equipment.

Net cash provided by financing activities in the years ended June 30, 2002 and 2003 was \$2.1 million and \$55.9 million, respectively, and was primarily due to proceeds from issuance of preferred stock. In May 2003, we completed a private placement of 112,790,233 shares of Series J mandatorily redeemable convertible preferred stock at \$0.49 per share for an aggregate purchase price of approximately \$55.3 million. Issuance costs of \$334,000 related to this financing were netted against proceeds received. In the year ended June 30, 2003, we entered into two financing agreements with GE Capital and received aggregate proceeds in the amount of \$1.2 million, \$241,000 of such proceeds have been repaid in fiscal 2003. In the year ended June 30, 2002, we received proceeds from the issuance of preferred stock of approximately \$1.3 million. Proceeds from the issuance of preferred stock primarily consisted of the issuance of 150,000 Series B preferred stock for an aggregate purchase price of \$300,000 and 333,333 Series C preferred stock for an aggregate purchase price of \$1.0 million to Elan as part of our January 1997 License and Supply Agreement.

We expect to incur losses from operations for the foreseeable future. We expect to incur increasing research and development expenses, including expenses related to additions to personnel and clinical trials. We expect that our general and administrative expenses will increase in the future as we expand our business development, legal and accounting staff, add infrastructure and incur additional costs related to being a public company, including directors' and officers' insurance, investor relations programs and increased professional fees. Our future capital requirements will depend on a number of factors, including the continued progress of our research and development of product candidates, the timing and outcome of regulatory approvals, payments received or made under collaborative agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the acquisition of licenses to new products or compounds, the status of competitive products, the availability of financing and our success in developing markets for our product candidates. We believe our existing cash and cash equivalents, together with the net proceeds from the issuance of our Series J preferred stock and this offering, will be sufficient to fund our operating expenses, debt repayments and capital equipment requirements for the next 18 months from the date of this prospectus.

We have no credit facility or other committed sources of capital. To the extent our capital resources are insufficient to meet future operating requirements, we will need to raise additional capital or incur indebtedness to fund our operations. We may be unable to obtain additional debt or equity financing on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate some of our research and development programs, reduce our commercialization efforts or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently. Any future funding may dilute the ownership of our equity investors.

### **Contractual Obligations and Commitments**

In September 2003, we entered into several agreements with Elan, including an agreement to license Elan's sustained release formulation of aminopyridines, including Fampridine-SR. We are obligated to make milestone payments to Elan, which includes a payment upon approval of an NDA for Fampridine-SR, of up to \$15 million over the life of the contract and royalty payments as a percentage of product sales.

In September 30, 2003, we entered into various other research, license and collaboration agreements which will also require milestone payments upon the achievement of certain milestones of up to an aggregate of approximately \$32 million over the life of the contracts and royalty payments as a percentage of product sales.

Under the terms of the employment agreement with our Chief Executive Officer and Chief Financial Officer, we are obligated to pay severance under certain circumstances. See "Management Employment Contracts, Termination of Employment and Change-in-Control Arrangements."

In August and September 2002, we entered into two financing agreements with GE Capital in the aggregate amount of approximately \$1.2 million, bearing annual fixed interest rates of 8.57% and 8.88% to finance purchase of certain property and equipment. Borrowings are secured by security interest in certain of our property and equipment. We are required to pay monthly installments until October 2006. Future payment obligations for the remainder of the current fiscal year ending June 30, 2004 and each of the three years subsequent to June 30, 2004 are: \$284,000 in 2004, \$379,000 in 2005, \$260,000 in 2006 and \$60,000 in 2007.

EIS loaned us an aggregate of \$7.5 million pursuant to two convertible promissory notes. One promissory note in the amount of \$5 million bears interest at a rate of 3% beginning on the first anniversary of the note. The unpaid principal is convertible into shares of our Series D preferred stock at a conversion price of \$12.50 per share. Principal and interest are repayable, if not converted, ratably over a seven-year period beginning one year after we receive certain regulatory approval for the products to be developed, subject to limitations related to gross margin

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on product sales. If it is determined by Elan and us that regulatory approval will not likely occur, all principal and interest will be forgiven. If our license and supply agreements with Elan are terminated for any other reason, the principal and interest is repayable ratably over 15 years.

The other promissory note in the amount of \$2.5 million is non-interest bearing. This promissory note is convertible after January 22, 1999 into either shares of Series B preferred stock at a conversion price of \$2.00 per share or into an undesignated series of preferred stock at a conversion price equal to 80% of the most recently completed equity financing, as defined, whichever conversion price is greater. This promissory note is repayable by us, if not converted by EIS, ratably over a seven-year period beginning one year after we receive certain regulatory approval for the products to be developed. If it is determined by us and Elan that regulatory approval will not likely occur or if our license and supply agreements with Elan are terminated for any other reason, the note is repayable ratably over 15 years.

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The following table summarizes our contractual obligations as of September 30, 2003. This table should be read in conjunction with the accompanying notes to our consolidated financial statements:

Twelve Month Period Ending September 30,	Notes Payable(1)	Operating Leases
	(\$ in thousands)	
2004	\$ 379	\$ 642
2005	379	642
2006	218	642
2007	7	642
2008		214
Total	\$ 983	\$ 2,782

(1) The notes payable represents the principal and interest payables on the GE Capital notes payable and does not include the \$7.5 million aggregate principal amount of convertible notes payable to EIS as these notes are payable on a contingent event.

### Subsequent Events

For a discussion of material events that have taken place subsequent to June 30, 2003, please refer to Note 13, Note 14 and Note 15 to our consolidated financial statements included in this prospectus.

### Quantitative and Qualitative Disclosures about Market Risk

Our financial instruments consist of cash and cash equivalents, short-term investments, grant receivable, notes payable, convertible notes payable and accounts payable. The estimated fair values of all of our financial instruments, excluding convertible notes payable to EIS, approximate their carrying amounts at September 30, 2003. The terms of these notes are disclosed at Note 10 to the consolidated financial statements.

We have cash equivalents and marketable securities at September 30, 2003, which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rates change. Due to the short-term nature of our investments in money market funds and corporate debt securities, the carrying value of our cash equivalents and marketable securities approximate their fair value at September 30, 2003.

We maintain an investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk,

our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not own derivative financial instruments. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative or other financial instruments.

### **Effects of Inflation**

Our most liquid assets are cash, cash equivalents and short-term investments. Because of their liquidity, these assets are not directly affected by inflation. Because we intend to retain and continue to use our

equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

### **Critical Accounting Policies and Estimates**

The following discussion of critical accounting policies identifies the accounting policies that require application of management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. It is not intended to be a comprehensive list of all of our significant accounting policies, which are more fully described in Note 2 of the notes to the consolidated financial statements included in this prospectus. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles, with no need for management's judgment in their application. There are also areas in which the selection of an available alternative policy would not produce a materially different result. We have identified the following as our areas of critical accounting policies: research and development, income taxes, and stock warrants and option accounting.

#### ***Research and Development***

Research and development expenses include the costs associated with our internal research and development activities including, salaries and benefits, occupancy costs, and research and development conducted for us by third parties, such as sponsored university-based research, and clinical trial vendors. In addition, research and development expenses include expenses related to grant revenue and the cost of clinical trial drug supply shipped to our clinical study vendors. We account for our clinical study costs by estimating the total cost to treat a patient in each clinical trial and recognizing this cost as we estimate when the patient receives treatment, beginning when the patient enrolls in the trial. This estimated cost includes payments to the trial site and patient-related costs, including laboratory costs related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, and the length of the treatment period for each patient. As actual costs become known to us, we adjust our accrual; such changes in estimate may be a material change in our clinical study accrual, which could also materially affect our results of operations.

#### ***Income Taxes***

As part of the process of preparing our financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. We account for income taxes by the liability method. Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We have not recorded any tax provision or benefit for the years ended June 30, 2002 and 2003 and for the quarter ended September 30, 2003. We have provided a valuation allowance for the full amount of our net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carry-forwards cannot be sufficiently assured at September 30, 2003. As of June 30, 2003, we had available net operating loss carry-forwards of approximately \$75.6 million for federal and state income tax purposes, which are available to offset future federal and state taxable income, if any, and expire between 2009 and 2023 and research and development tax credit carry-forwards of approximately \$704,000 for federal income tax reporting purposes which are available to reduce federal income taxes, if any, through 2017. Since our inception, we have incurred substantial losses and expects to incur substantial and recurring losses in future periods. The Tax Reform Act of 1986, the Act, provides for a limitation of the annual use of NOL and

research and development tax credit carry forwards (following certain ownership changes, as defined by the Act) that could significantly limit our ability to utilize these carry-forwards. We have experienced various ownership changes, as defined by the Act, as a result of past financings. Accordingly, our ability to utilize the aforementioned carry-forwards may be limited. Additionally, because U.S. tax laws limit the time during which these carry forwards may be applied against future taxes we may not be able to take full advantage of these attributes for federal income tax purposes.

### ***Stock Warrants and Options Accounting***

We account for options granted to employees and directors in accordance with Statement of Financial Accounting Standards ("SFAS") No. 123, *Accounting for Stock-Based Compensation*, and related interpretations. As such, compensation expense is recorded on stock option grants based on the fair value of the options granted, which is estimated on the date of grant using the Black-Scholes option-pricing model and it is recognized on a straight-line basis over the vesting period. We account for stock options granted to non-employees on a fair-value basis in accordance with SFAS No. 123, Emerging Issues Task Force Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, and FASB Interpretations No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans an Interpretation of APB Opinion No. 15 and 25*. As a result, the non-cash charge to operations for non-employee options with vesting or other performance criteria is affected each reporting period by changes in the estimated fair value of our common stock. The two factors which most affect charges or credits to operations related to stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded and the volatility of such fair value. If our estimates of the fair value of these equity instruments change, it would have the effect of changing compensation expenses. Because shares of our common stock have not been publicly traded, we estimate the fair value of our common stock considering, among other factors, the most recent previous sale of convertible preferred stock (convertible on a one-for-one basis, or one-for-twelve post reverse split, into common stock). We do not discount the issuance price of our preferred stock in estimating the fair value of our common stock.

### **Recent Accounting Pronouncements**

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* ("SFAS No. 146"). SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force ("EITF") Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity* (including Certain Costs Incurred in a Restructuring). SFAS No. 146 became effective January 1, 2003. The adoption of SFAS No. 146 did not impact our consolidated financial statements for the fiscal year ended June 30, 2003.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* ("SFAS No. 150"). SFAS No. 150 revises the accounting for certain financial instruments that, under previous guidance, issuers could account for as equity. SFAS No. 150 requires that those instruments be classified as liabilities in statements of financial position. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective for interim periods beginning after June 15, 2003. The adoption of SFAS No. 150 did not impact our consolidated financial statements for the fiscal year ended June 30, 2003.

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## **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 lead product candidate, Fampridine-SR, which is in Phase 3 clinical trials for spinal cord injury and Phase 2 clinical trials for multiple sclerosis, targets 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. Our other product candidates also target spinal cord injury and multiple sclerosis as well as other central nervous system disorders.

We estimate that approximately 500,000 people in the United States suffer from spinal cord injury and multiple sclerosis and 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 identify new applications for our core technologies.

### **Company Highlights**

*Lead product Fampridine-SR in late stage clinical trials for two conditions.* Clinical trials of our lead product candidate, Fampridine-SR, are the first, to our knowledge, that have demonstrated improved neurological function in people with chronic spinal cord injury or multiple sclerosis. We are currently conducting two Phase 3 clinical trials in subjects with spinal cord injury for the reduction of spasticity and one late Phase 2 clinical trial in subjects with multiple sclerosis for the improvement of walking speed.

*Broad product pipeline behind Fampridine-SR.* In addition to Fampridine-SR, we have a pipeline of clinical and preclinical programs. Our second most advanced product candidate is valroceamide, which is currently in Phase 2 clinical trials for the treatment of epilepsy. We also have four development phase and preclinical programs focused on repairing damaged components of the central nervous system in patients with spinal cord injury and multiple sclerosis.

*Broad applicability of product candidates.* 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, our core technologies have potentially broad applicability for these and other central nervous system indications.

*Extensive scientific and medical network.* 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 that keep us apprised of the latest technological advances and help us identify and evaluate business development opportunities. 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.

*Extensive spinal cord injury animal modeling capability and laboratory testing facility.* We have substantial animal 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 spinal cord injury.

### **Fampridine-SR**

Our lead product candidate, Fampridine-SR, is a small molecule drug, contained in a sustained release, oral tablet form. Laboratory studies have shown that fampridine, the active molecule of Fampridine-SR, improves impulse conduction in nerve fibers in which the insulating layer, 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 the treatment of both spinal cord injury and multiple sclerosis. We plan to commercialize Fampridine-SR ourselves in the United States and Canada and with partners in various markets throughout the rest of the world.

Key attributes of our Fampridine-SR program include:

clinical trials of Fampridine-SR in subjects with chronic spinal cord injury have demonstrated significant reductions in spasticity and indicated improvements in bladder, bowel and sexual function;

clinical trials in subjects with multiple sclerosis have shown improvements in walking speed and leg strength;

we believe Fampridine-SR is the first potential therapy in late-stage clinical development for chronic spinal cord injury which seeks to improve the function of damaged neurons; and

our goals are to submit an NDA for Fampridine-SR for the treatment of spasticity in spinal cord injury in 2004, which provides the potential for a market launch in 2005, and to file an NDA for Fampridine-SR for the treatment of lower extremity motor dysfunction in multiple sclerosis in 2005.

### ***Other Products in Our Pipeline***

Our other research and development programs are also focused on novel therapeutics for central nervous system disorders. Our product candidates include small molecules, antibodies, and other protein therapeutics.

#### *Valroceמידe*

We have entered into a collaboration agreement with Teva to co-develop and co-promote valroceמידe in the United States. Valroceמידe is a small molecule drug with early Phase 2 clinical evidence of safety and efficacy as an add-on therapy for partial seizures, a type of epilepsy, and preclinical evidence of activity in animal models of epilepsy and neuropathic pain. We plan to move valroceמידe 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 valroceמידe for the treatment of neuropathic pain.

#### *Remyelinating Agents*

Our preclinical programs include two distinct therapies to stimulate 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. We plan to develop GGF-2 initially for treatment of multiple sclerosis, pending successful completion of preclinical toxicology testing. 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 are currently in the process of final preclinical validation and selection of the lead candidate molecule for clinical development.

#### *Research Programs in Nerve Regeneration*

We have two research projects directed toward repair of the injured brain and spinal cord through stimulation of nerve fiber regeneration. The first, which we call the matrix modification program, targets the scar tissue that develops as a result of injury. A matrix of proteins and other molecules that forms in the scar is believed to prevent nerve fiber regeneration and limit functional recovery. Compounds that can break down

this scar matrix and enhance repair and functional recovery in a number of animal models have been identified. We have initiated a collaborative program to develop these compounds and we are in the process of building our intellectual property position with respect to this technology.

Our second program involves regenerative antibodies that react with central nervous system components and stimulate nerve fiber growth. This project arose from observations made in experiments on remyelinating antibodies.

### **Background and Market Opportunity**

#### ***Our Approach to the Market for the Treatment of Central Nervous System Disorders***

We are focused on identifying, developing and commercializing novel pharmaceutical products that address large and underserved central nervous system markets. We view spinal cord injury as a strategic point of access to a broad range of additional neurological conditions, particularly those resulting from focused cellular damage in the central nervous system, for the following reasons:

the initial cause of traumatic spinal cord injury is well understood, it occurs at one defined time, and treatment can usually be initiated shortly after injury is sustained;

chronic spinal cord injury is usually a stable condition, without ongoing deterioration;

good animal models of spinal cord injury exist;

many of the mechanisms of secondary tissue damage and potential repair in spinal cord injury are shared with other conditions, such as multiple sclerosis, stroke and traumatic brain injury, but the structure of the spinal cord is less complex than that of the brain;

a treatment that protects the spinal cord from the consequences of injury, regenerates neural connections, or optimizes function of surviving structures in the spinal cord is likely to also be applicable to many conditions affecting the brain; and

even relatively small and incremental improvements in central nervous system function can produce large positive effects on the quality of life for people with spinal cord injury and similar chronic neurological conditions.

Multiple sclerosis is a second major focus for the company because, like spinal cord injury, it involves critical damage to nerve fibers and their myelin within the central nervous system. Three of our product candidates, Fampridine-SR, GGF-2, and the remyelinating antibodies, address demyelination. Epilepsy is another development focus because it is also often caused by damage to neurons that produces a disturbance of normal control over excitability and communication between nerve cells.

### *The Challenge of Central Nervous System Disorders*

The spinal cord and brain together comprise the central nervous system. The billions of nerve cells that make up the central nervous system, in conjunction with the nerve bundles that run through all parts of the body, which is called the peripheral nervous system, transmit the electrical impulses necessary to sustain, regulate and monitor every aspect of human life. The spinal cord serves as the master link between the brain and the body. Nerve impulses travel between the brain and spinal cord via long, thin fibers, or axons, that transmit information. The spinal cord also acts as a conduit for information that regulates involuntary functions, such as breathing, blood pressure, temperature control, and bladder, bowel and sexual functions. The myelin sheath that surrounds nerve fibers in the brain and spinal cord provides insulation that facilitates the effective transmission of nerve impulses. It is composed of multiple layers of tightly packed cell membranes, and is vulnerable to damage in conditions like spinal cord injury and multiple sclerosis. Once the myelin sheath is damaged, it is often not effectively repaired. Although nerve fibers can survive in a demyelinated state, their ability to conduct nerve impulses may be completely lost or severely compromised.

### *Spinal Cord Injury*

Approximately 250,000 people in the United States live with the long-term consequences of spinal cord injury and approximately 10,000 to 12,000 new spinal cord injuries occur each year, typically in young men. The majority of people with spinal cord injury are injured under the age of 30 and live with permanent disability and multiple related medical conditions for more than 40 years. It is estimated by the Centers for Disease Control that the annual direct cost to the U.S. healthcare system for people with spinal cord injury exceeds \$9 billion. The National Spinal Cord Injury Database at the University of Alabama estimates that the average lifetime costs directly attributable to spinal cord injury for an individual injured at age 25 would vary from \$700,000 to \$2.8 million, depending on the severity of injury.

The spinal cord can be injured by physical trauma that bends the neck or body violently, such as vehicular or diving accidents, or by objects that penetrate or impact the spinal cord, such as a bullet or a knife. The spinal cord can also be injured by loss of blood flow due to damage to major blood vessels or during surgical procedures. When an area of the spinal cord is damaged, motor and sensory function are impaired throughout those parts of the body that are below the level of the injury.

Until recently, spinal cord injury was considered an untreatable and incurable condition. Within the last two decades, researchers have shown that the spinal cord is not severed in most people with spinal cord injury. Rather, stretching or compression of the cord causes nerve



fibers and blood vessels to tear and unleashes a secondary process of bleeding, loss of blood flow and inflammation that causes more tissue damage. The majority of people with spinal cord injury have some axons that survive within or around the site of injury. Because of these surviving axons, approximately 50% of people with spinal cord injury have some motor and/or sensory function remaining below the level of the injury and are said to have incomplete spinal cord injury. Those with no detectable function below the injury level are said to have complete spinal cord injury. Researchers have also shown that many axons that survive trauma are damaged and permanently lose part of their myelin, the insulating sheath that permits electrical impulses to be conducted rapidly down the axon. Loss of myelin insulation in surviving axons can cause nerve impulses to be delayed or lost entirely, resulting in impaired neurological function.

In addition to the more obvious impact of paralysis on mobility and independence, chronic spinal cord injury is associated with several life-altering conditions that vary depending on the individual and the extent of injury. These include spasticity, as well as persistent pain, loss of control of bowel and bladder functions, loss of sexual function, compromised breathing, loss of sensation, and unstable control of blood pressure, heart rate, and body temperature. We believe that novel therapies that offer even an incremental improvement of these conditions would have a meaningful impact on the quality of life for people with spinal cord injury.

#### Current Approaches to the Treatment of Spinal Cord Injury

There is no cure for spinal cord injury and no treatment available that is capable of improving neurological function. Currently, there are only treatments for some of the symptoms and conditions associated with spinal cord injury. In the early 1990s clinical trials showed that a very high dose of a common steroid, methylprednisolone, MP, resulted in some protection of function after acute spinal cord injury. The effect was small, but statistically significant. MP is believed to act as an antioxidant and thus prevents secondary damage to the tissue during the first few hours after injury. Treatment immediately after the injury with MP is the standard of care in the United States, though the benefits have been debated in recent years.

Treatments for symptoms of spinal cord injury are limited. Spasticity is most often treated with muscle relaxants such as baclofen, tizanidine, diazepam and dantrolene sodium. Although these medications appear to help in symptom relief in some people, they are often only partially effective and generally require dosing every two to four hours. In addition, these medications are often associated with unwanted side effects such as sedation, weakness and loss of normal muscle tone, or flaccidity. Treatments focused on maintaining the health of the bladder and kidneys include Ditropan for the relief of bladder spasticity and antibiotics for the

treatment of urinary tract infections. Loss of control over bowel function is treated with a number of prescription and non-prescription medications, often combined with a regular regimen of physical manipulation. Male sexual dysfunction may be treated with Viagra, which is useful in improving erectile function in some people. Loss of mobility is almost always accompanied by a loss of sensation leading to a high risk for skin breakdown and ulceration at pressure points. These conditions are treated with physical care and anti-infective drugs. Chronic pain is treated with a range of prescription and non-prescription drugs; however, neuropathic pain, which is common in spinal cord injury patients, is usually not relieved by normal pain medications because it is generated by disordered activity in the nervous system rather than by some physical source of tissue injury.

#### *Multiple Sclerosis*

According to The National Institutes of Health, it is believed that approximately 250,000 to 350,000 people in the United States have been diagnosed with multiple sclerosis, and approximately 10,000 people are newly diagnosed annually. Multiple sclerosis is more prevalent in Caucasians and women and is generally diagnosed between the ages of 20 and 50. The NIH estimates that the annual economic, social and medical cost of treating multiple sclerosis in the United States exceeds \$2.5 billion.

Multiple sclerosis is a degenerative central nervous system disorder, the cause of which is unknown, in which the immune system attacks and damages the insulating myelin sheath around nerve fibers in the brain and spinal cord. As in spinal cord injury, this myelin sheath damage blocks or diminishes conduction of electrical impulses. However, the loss of conduction caused by multiple sclerosis can occur at multiple sites in the central nervous system rather than at a specific point of injury as it does in spinal cord injury.

People with multiple sclerosis may suffer impairments in any number of neurological functions. These impairments vary from individual to individual, and over the course of time, depending on which parts of the brain and spinal cord are affected. Some of these impairments are also common in spinal cord injury including loss of sensation, loss of bowel and bladder control, sexual dysfunction, spasticity, neuropathic pain, and muscle paralysis. However, other aspects of multiple sclerosis are not characteristic of spinal cord injury, including severe fatigue or lack of stamina, dizziness, tremors, loss or disturbance of vision, and cognitive difficulties. The great majority of people with multiple sclerosis experience general weakness and difficulty walking.

Current Approaches to the Treatment of Multiple Sclerosis

Current therapies for multiple sclerosis are focused on the control of symptoms associated with exacerbations and progression of the disease. Many of the symptoms that result from multiple sclerosis are also common in spinal cord injury, including spasticity, and issues with bladder, bowel and sexual function. Similar approaches to treating symptoms in spinal cord injury are used in treating people with multiple sclerosis, often resulting in the occurrence of the same unwanted side effects. Treatments are defined as relapse management and disease course management.

*Relapse Management.* The majority of neurologists treating people with multiple sclerosis utilize intravenous high-dose corticosteroids for the treatment of sudden and severe relapses. Generally, people experiencing a severe relapse receive a four-day course of steroids on either an in-patient or out-patient basis. This treatment may shorten the time required for recovery from an acute relapse.

*Disease Course Management.* Drugs that modify the immune reactions associated with nerve damage in multiple sclerosis include Avonex, Betaseron, Copaxone, and Rebif. Other drugs that suppress the immune system include drugs initially approved to treat cancer such as Novantrone and methotrexate. However, these medications produce a slowing of deterioration, rather than a halting or reversal of the disease process. They do not restore lost neurological function.

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*Epilepsy*

In 1998, the Centers for Disease Control estimated that approximately 180,000 new cases of epilepsy are diagnosed annually in the United States. In 1995, the Epilepsy Foundation Report to the Nation stated that epilepsy and seizures affect approximately 2.3 million Americans of all ages. Both sources estimate annual costs of medical care as approximately \$12.5 billion.

Epilepsy is a condition defined by the presence of recurrent seizures that are not provoked by any immediate clinical cause, such as fever or trauma. Seizures are a manifestation of abnormal and excessive excitation of neurons in an area of the brain. There may be many different underlying causes of epilepsy, including genetic predisposition and localized chemical or mechanical damage to the brain. The cause is often not identified, particularly in children. Epilepsy may develop at any stage of life, but is most likely to develop in childhood, adolescence or in old age.

Current Approaches to the Treatment of Epilepsy

The diagnosis of a particular seizure type, and of a specific type of epilepsy, or epilepsy syndrome, determines the initial therapy. The decision to treat with anti-epileptic drugs, or AEDs, after an initial seizure is still controversial, although there is growing evidence that repeated seizures in themselves can further damage the affected area of the brain. This makes it important to limit seizure recurrence to the extent possible. The decision to treat is based on a consideration of the individual's risk of relapse and potential consequences of further seizures and of drug treatment, including the potential adverse effects of the available AEDs.

Most cases of epilepsy are managed with a single AED, and the choice of drug and dosage is typically adjusted individually based on the degree of seizure control and the type and degree of adverse responses. For partial onset seizures with secondary generalization, carbamazepine, phenytoin, valproic acid, phenobarbital and primidone have been used for many years. More recently approved drugs include felbamate, gabapentin, lamotrigine, topiramate and tiagabine. These drugs were approved as adjunctive treatment, based on studies in which they were tested as add-on therapy with older compounds. This clinical trial design is required by the ethical consideration of the need to maintain subjects on an established drug, even if it is only partially effective.

For people with more severe, generalized onset seizures, particularly tonic-clonic, myoclonic, absence, or photosensitive forms, valproic acid is often the drug of choice. The rare but potentially fatal risk of liver toxicity with valproic acid means that ethosuxamide is considered slightly safer, particularly in very young children, who are most at risk for this complication.

Many AEDs are associated with birth defects, which may be offset with folic acid administration. Also, AEDs tend to affect metabolism of other drugs in the liver and most are metabolized in the liver themselves, which complicates the use of drug combinations, particularly with other AEDs. Some drugs, such as phenytoin and valproic acid are significantly bound to proteins in the blood, which reduces their activity. This means that the effective dose can influence or be influenced by other drugs that affect protein binding, such as common aspirin.

*Other Disorders of the Central Nervous System*

Neurological injuries and degenerative diseases of the central nervous system, including stroke, traumatic brain injury, Parkinson's Disease and Alzheimer's Disease, are among the most devastating and costly of human ailments. These conditions are most often chronic and historically have been extremely difficult to treat.

These disorders, like spinal cord injury and multiple sclerosis, involve damage to nerve cells and nerve fibers and would likely benefit from similar approaches to tissue protection and repair. For example, the inflammation process that occurs naturally after many types of tissue injury may damage both injured and

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healthy central nervous system cells. Several of these conditions could benefit from treatments that inhibit aspects of this inflammatory process. As with spinal cord injury, these conditions could be treated with interventions that replace nerve cells, stimulate new nerve fiber growth, or increase the adaptability of connections within the nervous system.

### **Our Strategy**

Our strategy is to become an integrated biopharmaceutical company focused 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 implementing this strategy, we have the following initiatives in place:

*Complete the clinical development and obtain regulatory approval for Fampridine-SR in spinal cord injury, multiple sclerosis and other neurological disorders.* We have advanced Fampridine-SR into two Phase 3 clinical trials in people with spinal cord injury for spasticity and into one late Phase 2 clinical trial in people with multiple sclerosis for improvement in walking speed. Following our discussion with the FDA, our registration plan for Fampridine-SR in spinal cord injury initially addresses spasticity. We have also discussed with the FDA a proposal to seek approval of Fampridine-SR for improvement in walking speed and leg strength in people with multiple sclerosis, and we have designed the current Phase 2 clinical trial to potentially provide the first of two sets of pivotal data. We may also pursue subsequent approvals in additional central nervous system disorders.

*Complete the clinical development and obtain regulatory approval for valrocecide in epilepsy, bipolar and other neurological disorders.* We have entered a co-development and co-promotion agreement with Teva for valrocecide. Valrocecide is currently in Phase 2 clinical trials for epilepsy. We and Teva plan to continue to develop valrocecide in epilepsy and to initiate Phase 2 clinical trials in bi-polar disorder. In addition, we and Teva may pursue clinical development of valrocecide in neuropathic pain and other central nervous system disorders.

*Continue to develop and advance our pipeline of other products and programs to treat neurological disorders.* We have two preclinical programs focused on remyelination, and two research programs focused on nerve fiber regeneration. In order to advance these programs into clinical trials, we have established dedicated project management teams with experience in commercial therapeutic development, allocated internal laboratory resources and retained outside service providers to establish manufacturing and testing capabilities.

*Continue to in-license preclinical and clinical programs.* We plan to leverage our network of scientific advisors to identify additional business development opportunities. We will continue to use our internal animal modeling capability to evaluate these opportunities as potential candidates for in-licensing.

*Expand sales and marketing capabilities.* Building on our existing market analysis and commercialization plan, we plan to hire additional sales and marketing professionals who will be responsible for brand strategy and sales force management. We plan to build a field sales force through the RxPedito program under our contracts with subsidiaries of Cardinal Health and inChord Communications. Under this contract after one year we have the option to offer employment to any or all dedicated Acorda representatives employed by Cardinal, who would then transfer directly to our payroll. Other services will be provided under this agreement with Cardinal Health and inChord Communications, including publications planning, product warehousing, distribution, technical support, professional and consumer advertising, web marketing and promotion, and data

analysis.

*Pursue additional commercial alliances.* We intend to leverage our sales capabilities for co-promotion of additional in-licensed products. We also intend to license our products to partners in order to gain incremental revenues from expansion into areas and geographies beyond our current focus. Our selection criteria for co-promotion agreements include strategic fit, market size of the opportunity, our

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potential partner's level of internal expertise in the field, manufacturing requirements, clinical trial size and complexity and investment considerations.

## Our Product Pipeline

Product	Target Condition	Status	Marketing Rights
Fampridine-SR	Spinal Cord Injury	Phase 3	Worldwide
	Multiple Sclerosis	Phase 2	Worldwide
Valroceamide	Epilepsy	Phase 2	U.S. co-promotion
	Bipolar disorder	Phase 2 planned	U.S. co-promotion
GGF-2	Multiple Sclerosis	Preclinical	Worldwide
Remyelinating Antibodies	Multiple Sclerosis	Preclinical	Worldwide
Matrix Modifiers	Spinal Cord Injury	Research	Worldwide
Regenerative Antibodies	Spinal Cord Injury	Research	Worldwide

### *Fampridine-SR for Spinal Cord Injury and Multiple Sclerosis*

Our lead product candidate, Fampridine-SR, is a sustained release, oral tablet formulation of fampridine, suitable for twice daily dosing. It is based on a small molecule drug, fampridine, which acts to block potassium ion channels in nerve cell membranes. We believe that Fampridine-SR represents a fundamental shift in the treatment of both spinal cord injury and multiple sclerosis because it may improve neurological function rather than only treating the symptoms or slowing the progression of these diseases. We are currently conducting two Phase 3 clinical trials of Fampridine-SR for chronic spinal cord injury, and one Phase 2 clinical trial for multiple sclerosis.

Recent clinical research using imaging and post-mortem studies has shown that the majority of people with spinal cord injury do not have severed spinal cords and maintain some nerve fibers, or axons, that cross the site of injury. However, these surviving axons are often damaged and lose their myelin. In multiple sclerosis, the myelin is damaged by the body's own immune system, rather than by physical trauma. When an axon is demyelinated after injury, large numbers of the specialized potassium channels on the surface of axons that are normally hidden or covered by the myelin sheath are exposed and leak potassium ions, causing the axon to short circuit its electrical impulses. Fampridine appears to be able to block these exposed channels, thereby permitting the axon to transmit nerve impulses again, even in a demyelinated state. Fampridine may also serve to amplify electrical signals at sites of contact or synapses between nerve cells by blocking the same channels in the tips of the nerve fiber, thereby improving the function of surviving tissue in the injured nervous system. Fampridine does not repair damaged nerve fibers or axons, but appears to improve impulse conduction and must be given continuously to maintain its effects.

Fampridine-SR was developed by and is manufactured for us by Elan. We have a worldwide exclusive license from Elan to its patent for the sustained release formulation of aminopyridines, which includes fampridine, for the rights to, among other things, develop, promote, distribute, use and sell Fampridine-SR in all human clinical indications, and to develop, promote, distribute, use and sell other patented sustained-release formulations of the drug. We hold an exclusive license from the Canadian Spinal Research Organization to a patent for the use of fampridine in the treatment of neuropathic pain and spasticity in spinal cord injury, as well as an exclusive license from Cornell University to a patent for the use of fampridine in the treatment of anterior horn cell diseases, which include amyotrophic lateral sclerosis, known as Lou

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Gehrig's disease. We have obtained Orphan Drug designations from the FDA for Fampridine-SR in both incomplete spinal cord injury and multiple sclerosis.

We have performed a series of clinical trials of Fampridine-SR in chronic spinal cord injury and multiple sclerosis to establish the pharmacokinetics, safety, and optimal dosing of the drug, as well as to assess its efficacy. Our Phase 2 clinical trials have indicated that people with chronic and incomplete spinal cord injury experienced benefits with Fampridine-SR on a range of measures including improvements in spasticity, bowel and bladder function, and sexual function. We are currently sponsoring two independent Phase 3 clinical trials of Fampridine-SR in spinal cord injury, each designed to establish a significant clinical benefit of the drug on spasticity, which is marked by muscle stiffness, and we are preparing a regulatory filing based on this specific indication. These clinical trials also include secondary endpoints related to bowel, bladder and sexual function.

We believe there are several compelling reasons for the development of Fampridine-SR with a primary indication of spasticity:

approximately 75% of people with spinal cord injury suffer from spasticity;

clinical trials with Fampridine-SR in spinal cord injury patients have shown a statistically significant reduction in spasticity;

Fampridine-SR has not shown frequent adverse effects of sedation, weakness and flaccidity associated with muscle relaxants which are currently used to treat spasticity; and

dosing of Fampridine-SR is twice daily, rather than the inconvenient 3 to 4 times per day required for muscle relaxants.

We believe there are compelling reasons for the development of Fampridine-SR as a new therapy for multiple sclerosis, with a primary indication of lower extremity motor function:

most people with multiple sclerosis eventually experience a decline in their ability to walk, which is one of the most limiting aspects of the disease;

clinical trials with Fampridine-SR in multiple sclerosis patients have shown a statistically significant improvement in walking speed and leg strength; and

there are no current therapies that improve leg strength or walking ability in people with multiple sclerosis.

#### *Clinical Trials of Fampridine-SR*

In cooperation with 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 all the Phase 2 clinical trials, treatment with Fampridine-SR has been associated with a variety of neurological benefits in people with spinal cord injury and multiple sclerosis.

#### Fampridine-SR in Spinal Cord Injury

*Phase 3 Clinical Trials.* We are currently conducting two parallel Phase 3 clinical trials of Fampridine-SR in spinal cord injury, designated as SCI-F301 and SCI-F302. The protocols for these two clinical trials are identical. They are designed to provide evidence of efficacy of Fampridine-SR sufficient to allow submission of an NDA to the FDA in 2004. Each double-blinded clinical trial enrolled approximately 200 subjects with chronic and incomplete spinal cord injury at approximately 40 clinical centers in North America. Subjects entering the clinical trials were randomly assigned to receive a stable dose of either 25 mg of Fampridine-SR or placebo twice a day for 12 weeks. During the 12-week study period, subjects visit the clinic for evaluation once every four weeks. We anticipate that the data produced by these clinical trials

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should be unblinded and analyzed by the end of March 2004 for SCI-F302, and by the end of May 2004 for SCI-F301.

The primary endpoints for these two clinical trials are improvement in spasticity in the legs of the subjects, which is measured by a reduction in the Ashworth score, and improvement in the subject's rating of the effect of treatment, which is measured by a test called the Subject Global Impression. The Ashworth score is assigned by a clinician who measures the stiffness of the affected leg muscles by attempting to move the subject's relaxed leg around the knee joint. The stiffness is rated on a scale of 1, indicating no resistance and no spasticity, to 5, indicating stiffness so complete that the leg cannot be moved around the joint. Spasticity associated with an Ashworth score of 3 or greater is considered to have significantly negative effects on a person's quality of life. Our current Phase 3 clinical trials have required subjects to have average Ashworth scores greater than 2 both at their initial screening visit and after two weeks of placebo treatment. The Subject Global Impression, SGI, is a standard seven-point scale on which subjects rate how they feel about the overall effect of the study drug. In two previous double-blind Phase 2 clinical trials of Fampridine-SR in subjects with chronic spinal cord injury, the improvement registered by the SGI was statistically significant, even with relatively small study groups of 30 people or less.

We discussed the primary endpoints and the other aspects of the design of these clinical trials with the FDA during development of the protocols in order to determine the expected requirements for submission of an NDA. The FDA is familiar with the Ashworth score as a measure of spasticity and has approved two other drugs using it as a primary outcome measure. We have also agreed to use SGI, in addition to the Ashworth score, to avoid potential uncertainty about the degree of change in score that represents a clinically meaningful effect.

*Phase 2 Clinical Trials.* We conducted two double-blind Phase 2 clinical trials, SCI-200 and SCI-F201, and Elan sponsored a double-blind Phase 2 clinical trial, ELN 0295-001US, which was published in the *Journal of Neurotrauma* in October 1998. These clinical trials involved a total of 177 subjects with spinal cord injury. In these three clinical trials there was evidence of benefit across a broad spectrum of neurological functions in subjects treated with Fampridine-SR at doses ranging from 17.5 mg to 25 mg twice per day, compared to placebo. These benefits included improvements in sensory, motor, bowel, bladder and sexual function. The most consistent finding across the clinical trials was a reduction in spasticity in Fampridine-SR treated subjects.

Unlike the design of our Phase 3 clinical trials, our Phase 2 clinical trials did not require a minimum spasticity level for enrollment. The average Ashworth score at baseline was approximately 2, the mildest level of spasticity on the scale. Therefore in study SCI-F201, for example, although we saw improvement in the entire group treated with 25 mg twice a day, the difference was not quite statistically significant, as shown in Figure 1. A much clearer assessment of effects on spasticity was produced by separately analyzing the measurements for those subjects who had more than minimal spasticity before treatment, with average Ashworth scores greater than 2 at their initial baseline examination. The average improvement for those treated with Fampridine-SR, compared to those treated with placebo, was then both statistically significant and clinically meaningful, at more than half a point improvement to the average Ashworth score. Moreover, subjects whose spasticity at the beginning of the study registered as greater than 3 on the Ashworth scale, showed even larger mean improvements, at more than a full point on the scale, although statistical significance was reduced by the smaller number of subjects that could be included, as shown in Figure 1.

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**Figure 1: SCI-F201 Phase 2 Ashworth Scores  
Post-Treatment with Placebo or Fampridine-SR Treatment vs. Baseline**

*The illustration depicts Ashworth scores for the placebo group, shown on left, as compared to the Fampridine-SR treatment group, shown on right. The arrows highlight the differences in Ashworth scores between the placebo and Fampridine-SR treatment groups. The Ashworth scores were averaged over four muscle groups in each subject and compared against baseline for the four weekly clinic visits during the stable treatment period. Statistical significance for this clinical trial was established at  $p < 0.025$ .*

Similar results were derived from our earlier clinical trial, SCI-200, which examined a dose of 20 mg twice a day for one week, compared to placebo. A statistically significant improvement in Ashworth score was also seen in the published Elan-sponsored clinical trial for subjects receiving 17.5 mg of Fampridine-SR twice a day for one week.

Subjects treated with the 25 mg dose twice daily experienced side effects that were not significantly different from those experienced by subjects receiving the placebo. The number of subjects who discontinued the clinical trial because of side effects was similar between the 25 mg twice a day and placebo groups at approximately 10% and 8%, respectively. Side effects included dizziness, tingling, nervousness, insomnia and pain. This experience was similar to the earlier clinical trials that used lower doses of Fampridine-SR. Side effects were more severe and more frequent in the group treated with 40 mg of Fampridine-SR twice a day, including nausea, tremor, and abnormal thinking. These side effects led 11 of the 30 subjects in this group to discontinue the study, most during the stage of increasing doses at the beginning of the clinical trial. One subject in the 40 mg group experienced a seizure near the end of the designated treatment period. This subject had a prior history of traumatic brain injury and amnesia, combined with spinal cord injury two years earlier, and had been treated with Dilantin for three weeks following possible post-traumatic seizure activity that could not be thoroughly investigated at the time.

*Phase I Clinical Trials.* A series of earlier clinical trials, called SCI-101, SCI-102 and SCI-103, were designed to measure the concentration of drug achieved in the blood with a wide range of doses, and to relate those levels to side effects and possible clinical benefits. These clinical trials showed that a dose of 25 mg every 12 hours produced peak concentrations of Fampridine-SR in the subjects' blood that were usually in the target effective range of 50 to 100 ng/ml.

Overall, subject and clinician reports and clinical measures in these non-blinded clinical trials indicated that there was evidence of increasing dose-response through the range of 10 to 25 mg twice a day, but that evidence of increasing efficacy at doses higher than 25 mg twice a day was limited, possibly being offset by increased side effects.

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*Safety Studies.* As part of our evaluation of safety, we have established extension studies that allow subjects in earlier clinical trials to receive Fampridine-SR on an unblinded, or open-label basis, with their progress followed for at least a year, but with the potential for continuing treatment until the drug is approved. By their open-label design, these studies will allow us to gain some additional knowledge of the longer term efficacy and safety of the drug, albeit limited by the lack of a placebo control group. These studies are intended primarily to gain sufficient subject experience to satisfy the regulatory guidelines for long-term and overall safety assessments. As of September 2003, approximately 90

subjects from Phase 1 and Phase 2 spinal cord injury clinical trials have been enrolled in ongoing extension trials. A separate extension study for subjects of the current Phase 3 clinical trials is expected to enroll a total of approximately 350 subjects, beginning in the third quarter of 2003.

Only limited data are yet available from these ongoing safety studies, since no interim analysis of the data is planned, but there have been three incidences of seizures in subjects enrolled in the SCI-F201 extension. Two of these occurred in subjects taking more than 25 mg twice per day (70 mg/day for nine months and 80 mg/day for two months, respectively). Overall, including the subject in study SCI-F201, this represents 3 seizures in the 115 subjects (2.6%) exposed to doses greater than 50 mg daily, and 1 seizure in the 308 subjects (0.3%) exposed to doses less than or equal to 50 mg daily, the proposed commercial dose for Fampridine-SR in spinal cord injury applications. Some currently marketed drugs cite incidence of seizures in clinical trials of 3% or greater. We are carefully monitoring the potential for seizure as a side effect, including the possibility of interaction with other drugs that are known to lower the threshold for seizure in susceptible subjects.

#### Fampridine-SR in Multiple Sclerosis

*Phase 2 Clinical Trial.* The current late Phase 2 clinical trial, MS-F202, was designed, after extensive consultation with a panel of expert multiple sclerosis neurologists and with the FDA, so that it may provide pivotal data for support of an NDA for the use of Fampridine-SR in multiple sclerosis. The clinical trial is also designed to compare three doses of 10, 15 and 20 mg, twice per day, and to assess their relative safety and efficacy over a treatment period of 12 weeks. The primary endpoint of the study is an improvement in average walking speed using the Timed 25 Foot Walk. The Timed 25 Foot Walk is part of a standardized set of neurological tests, called the Multiple Sclerosis Functional Composite Score, MSFC, and involves timing the subject completing a 25 foot walk as fast as they can. We plan to use these measurements to support an indication for the treatment of lower extremity motor dysfunction, characterized by weakness and walking impairment.

The clinical trial was initiated early in 2003 and completed enrollment of approximately 200 subjects in 24 major multiple sclerosis centers in July 2003. We expect the data from this clinical trial to be available by the end of March 2004. If the clinical trial is successful, we plan to sponsor a second clinical trial as soon as possible to provide the necessary confirmation. It is also possible that the clinical trial may not provide statistical significance on the primary endpoint but give us a clear indication of dose and group size to inform the design of two subsequent Phase 3 clinical trials that should provide sufficient pivotal data for submission of the multiple sclerosis NDA.

In 2001, we completed a double-blind Phase 2 clinical trial of Fampridine-SR in Multiple Sclerosis, MS-F201. The clinical trial was designed to determine the optimal dose level of Fampridine-SR and to evaluate possible ways in which to measure the effect of the drug on symptoms of the disease, including motor strength, timed walking, and self-reported fatigue. The clinical trial involved a total of 36 multiple sclerosis subjects in four major academic multiple sclerosis research centers. A total of 25 subjects received Fampridine-SR in doses increasing from 10 mg to 40 mg twice per day over eight weeks of treatment, and 11 subjects were given placebo over the same period. This treatment period was preceded by a series of baseline evaluations over the course of four weeks to allow the subjects to become adjusted to the clinic visits and allow the various measurements to stabilize. A one week blinded treatment with placebo preceded the first drug administration to look for potential placebo effects on the various outcome measures.

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The clinical trial demonstrated that doses up to 25 mg twice a day were well tolerated, and were associated with statistically significant improvements in walking speed and leg muscle strength. Most of the improvement in strength and walking speed was apparent within the first three weeks of the Fampridine-SR treatment, at doses from 10 to 25 mg twice a day.

When we examined the measurements from individual subjects, and looked at the improvement in walking speed between the baseline period and the average over the first four treatment weeks, we found clear differences in the pattern of response between Fampridine-SR and placebo-treated subjects, as shown in Figure 2. The placebo-treated subjects showed some tendency to improve or worsen slightly in walking speed, mostly within 20% of their baseline average. However, the Fampridine-SR treated group showed a marked tendency for improvement in speed, with 9 of 25 subjects improving more than 20% from baseline, and 2 with greater than 50% improvement. These findings were consistent with the results of a small crossover study sponsored by Elan, using doses of 17.5 mg, twice a day for one week, which was published in the journal *Neurology* in 1997.

**Figure 2: Change in Walking Speed During the First Four Weeks of Treatment**



*The subjects (25 Fampridine-treated and 11 placebo-treated) were placed in order of degree of improvement, from top to bottom. The Fampridine-SR treated group showed a significantly greater improvement in walking speed during the treatment period.*

The side effects experienced by subjects in MS-F201 given Fampridine-SR up to 25 mg twice a day were similar to those in our spinal cord injury clinical trials. Two subjects experienced seizures while on doses of 30 and 35 mg twice a day, respectively. This was consistent with previous experience and the

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expected greater susceptibility of people with multiple sclerosis to seizure, which is thought to be related to the presence of demyelinating damage in the brain.

*Phase 1 Clinical Trials.* Two earlier Phase 1 clinical trials, AN751-101 and AN751-102, sponsored by Elan, addressed the pharmacokinetics of Fampridine-SR in subjects with multiple sclerosis in a manner equivalent to our SCI-101 and SCI-102 clinical trials. The pharmacokinetic characteristics of Fampridine-SR measured in these clinical trials were similar to those established in normal subjects and in people with spinal cord injury.

#### ***Valrocemide for Epilepsy***

Valrocemide is a new chemical entity derived from valproic acid which is a commonly used AED. Valrocemide was discovered as part of a program to identify a compound with similar or better efficacy than valproic acid, but with a more favorable side effect profile. Valrocemide has been studied by Teva both in animal models and in clinical trials in Europe.

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Based on responses in preclinical models of epilepsy and neuropathic pain and on the close relation between valrocecide and valproic acid, we believe this drug may be effective in epilepsy and bipolar disorder, and potentially in neuropathic pain, for which valproic acid is frequently prescribed.

In preclinical studies and clinical trials carried out by Teva, valrocecide appears to have minimal interactions with other drugs, unlike valproic acid which significantly affects liver enzymes that are used to metabolize many compounds. Valrocecide also shows less affinity for binding to proteins in the blood compared to valproic acid, which should simplify dosing. Based on animal toxicology studies, the side effects of valrocecide appear to be potentially less significant than those of valproic acid.

Studies in human volunteers have indicated that the maximum tolerated dose is in the range of 4 grams per day. Teva has completed a 13-week, early Phase 2 clinical trial in Europe involving 22 people with refractory epilepsy, using valrocecide as an add-on therapy with doses increasing up to four grams per day. Side effects were considered mild to moderate. However, one patient reported severe loss of strength, which may have been related to the treatment. All but one subject completed the study, with one leaving the study because of the requirement for multiple blood samples. This was an open-label study and was not designed to demonstrate safety or efficacy, although there were indications of clinical benefit that were consistent with the expectations for the drug. Larger scale clinical trials have yet to be conducted to demonstrate safety and efficacy.

Together with Teva, we plan to develop valrocecide initially for the treatment of epilepsy, for a number of reasons:

the development path is well known;

animal studies support efficacy in epilepsy;

an initial Phase 2 study in epilepsy has been completed in Europe; and

many of the studies needed for an epilepsy development program will also be required for other indications.

We also plan to initiate a clinical program to explore the potential for efficacy in bipolar disorder in 2004. We may also pursue clinical development of valrocecide for neuropathic pain in the future.

### ***Other Research and Development Programs***

#### *Remyelination Programs*

We believe that if the myelin sheath can be repaired, we can expect greater improvements in neurological function than those achieved with Fampridine-SR, which is intended to address a single, although crucial,

consequence of demyelination. We licensed two separate groups of patents, one group relating to the neuregulin growth factors and another group relating to a family of remyelinating antibodies, that may provide access to remyelinating therapies via different and potentially complementary routes.

#### Neuregulins/GGF-2

We are conducting a research and development program directed towards applying a neuregulin growth factor, GGF-2, to stimulate the cells that normally form the myelin sheath. GGF-2 was the subject of a comprehensive discovery program by CeNeS Pharmaceuticals, PLC, previously Cambridge Neuroscience, Inc. In 2002, we obtained an exclusive worldwide license to the neuregulin technology, including GGF-2, from CeNeS. In addition, we licensed cell lines for the production of the molecule from both CeNeS and Bayer AG, which had earlier partnered

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with CeNeS on the GGF-2 program. We have entered into an agreement with Lonza Biologics, plc for the manufacturing and process development for GGF-2. If our preclinical testing is successful, we intend to advance GGF-2 to clinical development by early 2005.

### Remyelinating Antibody Program

Our remyelinating antibody program is based on an exclusive license to patents derived from more than 15 years of research performed at the Mayo Clinic. Our remyelinating antibody program is designed to promote remyelination of affected areas in the brain and spinal cord. In particular, these remyelinating antibodies were found to react with molecules on the surface of the cells that make myelin, and stimulate them in a number of ways, leading to increased activity and remyelination.

In addition, we are continuing to support preclinical studies at the Mayo Clinic to learn more about the ways the antibodies act to stimulate the myelin-forming cells. The development costs of this program will be partially offset by a small business grant of \$1.0 million awarded to us in September of 2002 by the NIH.

### *Regeneration and Plasticity Programs*

#### Matrix Modification Program

We have developed a matrix modification program around the concept of breaking down part of the matrix of scar tissues that develops as a result of an injury. We believe this scar tissue is partly responsible for limiting the regeneration of nerve fibers in the central nervous system and restricting the ability to modify their existing connections, a process known as plasticity. It may also inhibit the repair of the myelin sheath, by restricting the movements of the myelinating cells into the area of damage. We believe that some of the molecular components of the scarring reaction are particularly inhibitory to nerve fiber growth.

Chondroitin sulfate proteoglycans, CSPGs, are a group of large molecules that form a major component of the scar matrix. Proteoglycans are composed of a combination of protein and sugar molecules, producing essentially a sugar-coated protein. Cell culture studies and animal studies have shown that these CSPGs inhibit the growth of nerve fibers and are likely to be key factors in the failure of the spinal cord to regenerate and repair. Cell culture studies have shown that it is possible to reduce the inhibitory activity of CSPG molecules by breaking them down with bacterial enzymes. These enzymes clip off surface sugar molecules from the protein core of the CSPG that are responsible for much of the inhibitory action.

#### Regenerative Antibodies

During the course of our remyelinating antibody program, for which we evaluated a range of antibodies that react with central nervous system tissues, we identified another family of antibodies that appear to stimulate growth of nerve fibers. Studies are under way to determine whether these antibodies are effective in promoting regeneration in animal models of spinal cord injury.

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## **R&D and Product Collaborations, Alliances and License Agreements**

### *Elan Corporation plc*

In January 1997, we licensed from Elan exclusive worldwide rights to Elan's sustained release formulation of fampridine, Fampridine-SR, for the treatment of spinal cord injury. In April 1998, we formed MS Research & Development Corporation, or MSRD, with Elan's subsidiary, Elan International Services, Ltd., or EIS, to develop Fampridine-SR for treatment of multiple sclerosis. At that time, MSRD licensed from Elan exclusive worldwide rights to Fampridine-SR for the treatment of multiple sclerosis. The upfront license fees paid under the two agreements were \$5.0 million and \$15.0 million, respectively.

#### Termination and Assignment Agreement

In September 2003, we entered into a termination and assignment agreement with Elan, EIS and MSRD pursuant to which MSRD assigned to us its assets, including the license from Elan for Fampridine-SR for multiple sclerosis. We paid MSRD approximately \$11.5 million for all the assets and assumed liabilities of MSRD. MSRD will distribute the purchase price to its shareholders according to their equity ownership interest. We will receive a distribution of approximately \$9.5 million as a result of this distribution. We also purchased EIS's shares at par value, and own approximately 88% of MSRD, which now has no assets or liabilities and is inactive.

Amended and Restated License

In September 2003, we entered into an amended and restated license with Elan, which replaced the two prior licenses for Fampridine-SR in oral sustained release dosage form. Under this agreement, Elan granted us exclusive worldwide rights to Fampridine-SR for all indications, including spinal cord injury, multiple sclerosis and all other indications. We agreed to pay Elan milestone payments of up to \$15.0 million over the life of the contract and royalties based on net sales of the product.

Elan may terminate our license in the US, the major European markets or Japan if we do not file to obtain regulatory approval or launch the product after regulatory approval in the applicable country within specified periods. If Elan terminates our license in any applicable country, Elan is entitled to license from us our patent rights and know-how relating to the product and to market the product in the applicable country, subject to royalty payments to us.

Elan is responsible for completing the chemistry, manufacturing and controls section of our NDA and equivalent regulatory applications outside the US. Elan is also supplying us with product for our clinical trials under this agreement.

Subject to early termination provisions, the Elan license terminates on a country by country basis on the last to occur of fifteen years from the date of the agreement, the expiration of the last to expire Elan patent or the existence of competition in that country.

Supply Agreement

In September 2003, we entered into a supply agreement with Elan relating to the manufacture and supply of Fampridine-SR by Elan. We agreed to purchase at least 75% of our annual requirements of product from Elan, unless Elan is unable or unwilling to meet our requirements, for a purchase price based on a specified percentage of net sales. In those circumstances where we elect to purchase less than 100% of our requirements from Elan, we agreed to make certain compensatory payments to Elan. Elan agreed to assist us in qualifying a second manufacturer to manufacture and supply us with Fampridine-SR subject to our obligations to Elan.

***Teva Pharmaceutical Industries Ltd.***

In September 2003, we entered into a collaboration agreement with Teva under which we were granted a co-exclusive license with Teva to jointly develop and promote in the United States products containing valroceamide as an active ingredient in any formulation and dosage form for any indication for human use, except multiple sclerosis. However, in the event that Teva seeks to develop and promote products containing valroceamide for multiple sclerosis it must provide us with notice and negotiate with us an amendment to the agreement. The agreement provides that Teva will own all right, title and interest in and to all intellectual property jointly developed by the parties while Teva has the sole right and obligation to defend against any infringement claims.

The agreement further provides that Teva is responsible for seeking and maintaining regulatory approval from the FDA upon the completion of any co-developed product and that Teva will consult with us in preparing the filings to obtain regulatory approval. Teva is also solely responsible for commercializing, manufacturing and supplying all co-developed products.

We made an initial payment to Teva of \$2.0 million upon execution of the collaboration agreement and are obligated to make payments to Teva of up to \$14.0 million over the life of the agreement upon achieving certain milestones. We are also responsible for the cost and conduct of the next clinical trial in epilepsy and a toxicology study for valroceamide. We will use commercially reasonable efforts to complete the next clinical trial by the first quarter of 2006 and, if further clinical trials are required after the completion of the next clinical trial, we will share the costs of such trials with Teva. Following the completion of the next clinical trial in epilepsy, we will share in 50% of co-development expenses and co-development profits. We are entitled to receive a royalty, on a country by country basis, on net sales by Teva of valroceamide outside of the United States if the clinical data used to obtain regulatory approval for sale of the product in such country was jointly developed, or independently developed by us, under this Agreement.

Unless earlier terminated under provisions of the Teva agreement, the agreement will expire on the earlier to occur of (i) September 23, 2009, if the parties have not achieved a statistically significant primary endpoint that is accepted by the FDA for the first pivotal trial in connection with any product, (ii) six months after the first generic version of any product is launched in the United States, or (iii) September 23, 2012, if the parties have not commenced the promotion and/or commercialization of any product under the Teva agreement.

In addition, if we seek a co-promotion partner for our products containing Fampridine-SR, Teva has a right of first negotiation for the co-development and co-promotion of these products in the United States. Teva's right of first negotiation terminates 60 days after we deliver to

Teva the summary results of the completed SCI-F301, SCI-F302 and MS-F202 clinical trials for Fampridine-SR.

***Rush-Presbyterian St. Luke's Medical Center***

In 1990, Elan licensed from Rush know-how relating to fampridine for the treatment of multiple sclerosis. We subsequently licensed this know-how from Elan. In September 2003, we entered into an agreement with Rush and Elan terminating the Rush license to Elan and providing for mutual releases. We also entered into a license agreement with Rush in which Rush granted us an exclusive worldwide license to their know-how relating to fampridine for the treatment of multiple sclerosis. Rush has also assigned to us their Orphan Drug Designation for fampridine for the relief of symptoms of multiple sclerosis.

We agreed to pay Rush a license fee of \$200,000, and milestone payments of up to \$1.15 million over the life of the agreement and royalties based on net sales of the product for neurological indications. We also entered into an agreement with Elan relating to the allocation of payments between us and Elan of certain payments to Rush under the Rush license.

Subject to early termination provisions, the Rush license terminates upon expiration of the royalty obligations, which expire fifteen years from the date of the agreement.

***Canadian Spinal Research Organization***

In August 2003, we entered into an Amended and Restated License Agreement with the Canadian Spinal Research Organization, CSRO. Under this agreement we were granted an exclusive and worldwide license under certain patent assets and know-how of CSRO relating to the use of fampridine in the reduction of chronic pain and spasticity in a spinal cord injured patient.

We are required to pay to CSRO royalties based on a percentage of net sales of any product incorporating the licensed rights, including royalties on the sale of Fampridine-SR for any indication.

Subject to early termination provisions, the CSRO agreement will expire upon the termination of all royalty or other payment obligations on a country-by-country basis, which will be no longer than the earlier of the expiration of the last to expire licensed patent in such country or ten years from the date of the first commercial sale of the product in such country.

***Cornell Research Foundation, Inc.***

In February 2003, we entered into a license agreement with Cornell Research Foundation, Inc., pursuant to which we were granted an exclusive license under a patent for the use of fampridine in the treatment of anterior horn cell diseases. In consideration for the license, we paid Cornell an upfront license fee and are required to make payments to Cornell upon the achievement of certain milestones relating to the successful reissuance or reexamination of the patents licensed to us and, the completion of a clinical trial testing the use of Fampridine-SR in amyotrophic lateral sclerosis. We are also obligated to pay Cornell royalties on net sales of Fampridine-SR in any and all indications.

Under the Cornell agreement, Cornell is responsible for all patent prosecution and maintenance activities relating to the licensed patent, and we are responsible for paying all fees incurred by Cornell in connection therewith. We have the right under this agreement to enforce any patent rights within the licensed patents against infringement by third parties at our own expense.

Subject to early termination by either of us, the term of the Cornell agreement will continue until the expiration of the last to expire valid claim under the licensed patent.

***Mayo Clinic Foundation***

In September 2000, we entered into a license agreement with The Mayo Foundation for Education and Research, or the Mayo Clinic, pursuant to which we were granted an exclusive worldwide license to its patents on remyelinating antibodies. Under this agreement, we have the right to develop, make, use and sell the remyelinating antibody products for the prevention, mitigation and treatment of central nervous system disorders. We have worked closely with the Mayo Clinic research group on developing and patenting this emerging technology in connection with the therapeutic use of these antibodies, specifically myelination and re-myelination in spinal cord injury and multiple sclerosis. The Mayo Clinic has the right to continue researching the antibodies and, in the event it develops other applications related to the licensed patent, which are outside of the scope of our current license, the Mayo Clinic is required to offer rights in these new applications to us before it offers such rights

to a third party.

Under the Mayo Clinic agreement, we are obligated to make milestone payments of up to \$1.875 million over the life of the agreement and pay royalties based on net sales. This license agreement will terminate upon the expiration of the last licensed patent in any such licensed product.

#### ***CeNeS Pharmaceuticals plc***

In November 2002, we entered into two license agreements with CeNeS Pharmaceuticals plc. The first agreement relates to an exclusive worldwide sublicense under certain patents, patent applications and know-how to make, have made, use, import, offer for sale and sell protein products composed of GGF-2 and

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non-protein products developed through the use of material covered by a valid claim in the patents. The license to these patents and the right to sub-license these patents were granted to CeNeS by the Ludwig Institute for Cancer Research.

Our payment obligations to CeNeS include payment of an upfront license fee, royalties based on annual net sales of the product, if any, as well as payments of up to \$8.5 million over the life of the agreement upon achieving certain milestones in connection with the development, testing and regulatory approval of any protein products. We are obligated to make minimum royalty payments commencing on the third calendar year following the first commercial sale of any licensed product. If we fail to pay any minimum royalty, CeNeS will have the option to convert our license or any sublicense to a non-exclusive license.

This agreement with CeNeS is effective until the later of November 12, 2017 or the expiration of the last-to-expire valid claim in the licensed patents.

The second agreement relates to an exclusive worldwide sublicense to us under certain patents, patent applications and know-how to make and have made, use and have used, sell, offer for sale, have sold and import protein products composed of one or more proteins encoded by the growth factor gene *nrg-2* and non-protein products developed through the use of material covered by a valid claim of the patents. The license to this patent and the right to sub-license this patent was granted to CeNeS by the President and Fellows of Harvard College.

We have agreed to a timeline to achieve certain milestones relating to the research and development and the clinical testing and filing of regulatory approvals for the products. We are also required to make milestone payments of up to \$5.93 million over the life of the agreement. If we are unable to meet a milestone, CeNeS has agreed to negotiate in good faith with us to agree for a reasonable extension of the time to achieve the milestone up to one year. We are obligated to pay CeNeS a license fee and royalties based on a percentage of net sales of protein products and non-protein products covered under the agreement.

Subject to early termination provisions, this agreement remains effective until the last patent, patent application or claim included in the licensed patents has expired, been abandoned or been held finally rejected or invalid.

#### ***Aeres Biomedical Limited***

In February 2002, we entered into a research collaboration and commercialization agreement with Aeres Biomedical Limited, pursuant to which Aeres will modify our Lym22 and Lym46 antibodies to switch their class from IgM to IgG and create a stable cell line expressing each antibody. We will have all right, title and interest in the DNA and RNA sequences expressing our antibodies, any and all cell lines, and all inventions and all patents and patent applications arising out of the research under this agreement.

We will pay Aeres for the costs of its research and will make payments to Aeres upon completion of each research milestone. We will also pay Aeres a royalty on our net sales of any product incorporating or derived from an antibody that is produced by Aeres' stable cell line under this agreement for a period of 12 years after commercial introduction of the product in a particular country.

Unless earlier terminated, the Aeres agreement will expire on a country by country basis until no further payments are due by us to Aeres in such country.

#### **Sales and Marketing**

We plan to market Fampridine-SR for both spinal cord injury and multiple sclerosis in the United States and Canada. We believe marketing synergies exist between the planned initial indication of spinal cord injury and the follow-on indication of multiple sclerosis. Spinal cord injury and multiple sclerosis have several symptoms in common, and these symptoms are treated with similar medications prescribed by similar physicians. This concentrated group of physicians may be targeted with a relatively small sales force. We do not intend to build commercial capabilities outside North America at this time, but intend to secure those capabilities through a partner or partners.

Our sales and marketing efforts in North America will focus on spinal cord injury specialists, physiatrists, neurologists, physical therapists and nurse practitioners involved in the treatment of spinal cord injury and multiple sclerosis. These health care professionals form a small group, and are located at major medical centers in the U.S. and Canada. We have existing relationships with a majority of these centers already, as a result of extensive interaction throughout the Fampridine-SR clinical testing process.

We believe that, in general, people with spinal cord injury and multiple sclerosis are knowledgeable about their condition, actively seek new treatments, and directly influence their prescriber's evaluation of treatment options. We have existing relationships with the major advocacy groups that focus on spinal cord injury and multiple sclerosis. We provide regular updates regarding our development programs, and sponsor or support several spinal cord injury and multiple sclerosis educational initiatives.

We have developed the following three-part strategy for the development and commercialization of our product candidates:

*Market development and education.* We are increasing awareness of Fampridine-SR for spinal cord injury and multiple sclerosis within the concentrated network of neurologists and physiatrists who prescribe the majority of therapies to treat these conditions. We plan initially to target those neurologists and physiatrists who prescribe the highest volume of prescriptions and who also are early adopters of new therapeutics. We believe there is considerable overlap between these prescriber groups, such that we will be able to leverage the introduction of Fampridine-SR for spinal cord injury into additional indications in multiple sclerosis. In addition, we plan to build on the unusually large role that people with spinal cord injury and multiple sclerosis play in the development of their own treatment. This will involve a variety of advocacy initiatives, including consumer education, professional medical seminars, continuing medical education programs, advisory boards and publications. To date, we have presented clinical results at most major medical conferences for physical medicine and rehabilitation as well as neurology.

*Agreements with Cardinal Health PTS, Inc. and inChord Communications, Inc.* We have entered into agreements with subsidiaries of Cardinal Health and inChord Communications to use the product commercialization services available through their RxPedit program to launch Fampridine-SR in spinal cord injury. Cardinal Health and inChord have developed the RxPedit program to provide marketing, selling and distribution capabilities to enhance commercialization of their clients' pharmaceutical products. We plan to manage strategic and tactical planning for launching Fampridine-SR in spinal cord injury. Under the agreement, Cardinal Health is responsible for providing medical education services, as well as recruiting, hiring and training sales representatives in the United States to target Fampridine-SR to the highly concentrated network of neurologists and physiatrists most active in prescribing therapies for spinal cord injury. inChord is responsible for providing marketing communications services, including creating and preparing sales promotion material and other advertising, marketing, and promotional programs for Fampridine-SR, web site development, product branding and data analysis. Under the agreement, we have the right to offer employment to all or any selected member of Cardinal Health's sales force in the RxPedit program. Cardinal will help us transition those members of their sales force who accept our offer to work for us as part of our own direct sales force.

*Co-development and co-promotion alliances.* We intend to develop product candidates jointly with other companies as a means to leverage our sales capabilities, as well as to gain incremental revenues from the expansion of our products into areas beyond our therapeutic focus. In these arrangements, we would expect to pay a share of the research and development costs, retain rights to co-promote or co-market the potential products, and share in the profits from sales. Our criteria for selecting product candidates for co-development include strategic fit, size of the market opportunity, our level of internal expertise related to the field, manufacturing requirements, clinical trial size and complexity, and investment considerations. In cases where we determine that it is worthwhile to invest our capital

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in a development program for a product candidate, but we do not believe that we can internally meet the development requirements, we will seek a co-development partner.

Part of our ability to market any products we may successfully develop may depend on the extent to which government health administration authorities, private health insurers and other third party payors will reimburse consumers for the cost of these products. Third party payors are increasingly challenging both the need for and the price of novel therapeutic drugs and uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third party reimbursement may not be available for our drug products to enable us to maintain price levels sufficient to realize an appropriate return on our investments in research and product development.

### **Manufacturing**

Under our supply agreement with Elan, Elan will manufacture and supply Fampridine-SR to us. We agreed to purchase at least 75% of our annual requirements of product from Elan, unless Elan is unable or unwilling to meet our requirements, for a purchase price based on a specified percentage of net sales. Except in those circumstances, if we elect to purchase less than 100% of our requirements from Elan, we agreed to make certain additional compensatory payments to Elan. Elan agreed to assist us in qualifying a second manufacturer and supply us with Fampridine-SR subject to our obligations to Elan.

We have entered into a technical transfer program agreement with Patheon, Inc., pursuant to which Patheon will perform certain manufacturing and analytical services on Fampridine-SR in connection with the contemplated transfer of Elan's Fampridine-SR technology to Patheon. Elan is supporting the technology transfer to Patheon, and if it is successful, we intend to pursue qualifying Patheon as an alternate manufacturer of Fampridine-SR in our NDA filing.

Fampridine Active Pharmaceutical Ingredient, API, is supplied by third parties directly under contract to Elan. Acorda may or may not have future direct contracts with these API suppliers. We currently participate in quality audits of these API suppliers, and have met with the FDA regarding our plans to submit two alternate suppliers of API.

Teva and its affiliates have the exclusive right to manufacture valroceamide. Commercially reasonable efforts, consistent with good pharmaceutical industry practices, shall be used to manufacture and supply valroceamide.

We have established the internal capability to manufacture research quantities of antibody and protein drug candidates. In April 2003, we entered into an agreement with Lonza Biologics, pursuant to which it will perform testing and manufacturing development activities for GGF-2. We have also retained the services of Aeres Biomedical for antibody engineering support. As NDA holder we plan to have quality assurance agreements with all manufacturing parties to ensure compliance with regulatory requirements.

### **Intellectual Property**

We have in-licensed, or are the assignee, of 24 U.S. patents, 40 U.S. patent applications and their numerous foreign counterparts. There are four major families of patents in our portfolio, corresponding to our four current major programs of research and development, i.e., fampridine, remyelinating antibodies, Neuregulins, including GGF-2, and the matrix modification program.

#### ***Fampridine***

We hold an exclusive, worldwide license from CSRO for a Canadian patent application and its foreign counterparts for the use of fampridine in the treatment of spasticity and neuropathic pain in chronic spinal cord injury. Foreign counterpart patents have been granted in the U.S. and in a number of other countries worldwide. The U.S. patent expires in 2013.

We hold an exclusive, worldwide license to three issued U.S. patents from Elan relating to timed delivery formulations of a family of aminopyridine compounds, including fampridine, and which also claim methods of administration and treatment for relevant neurological conditions. Foreign counterparts of these patents are also covered by the license. One of the three U.S. patents expires in 2011 and the other two U.S. patents expire in 2013.

We also hold an exclusive license from Cornell University for an issued U.S. patent that relates to the use of aminopyridine compositions, including fampridine, for the treatment of diseases of anterior horn cells, including amyotrophic lateral sclerosis, which is known as Lou Gehrig's disease. This patent expires in 2016.



### ***Valroceמיד***

Teva owns, has in-licensed or is the assignee of patents related to valroceמיד. The U.S. patent for valroceמיד expires in 2013.

### ***Remyelinating Antibodies***

We are the exclusive licensee of a portfolio of patents and patent applications related to a series of remyelinating monoclonal antibodies discovered in the laboratory of Dr. Moses Rodriguez at the Mayo Clinic in Minnesota. One U.S. patent has issued. Foreign counterparts of this patent are also issued in Australia, Mexico, and New Zealand, and applications are pending elsewhere, including Europe, Canada, Japan and Korea.

### ***Neuregulins***

We are the exclusive licensee of a worldwide portfolio of patents and patent applications related to products of neuregulin genes, including glial growth factors. These patents claim the use of particular neuregulins to treat various pathophysiological conditions, particularly stimulating myelinating cells in order to treat demyelinating conditions of the central and peripheral nervous system. These patents also claim a number of additional potential applications of neuregulins, including stimulation of growth in mammalian muscle cells and treating peripheral neuropathy and nerve injury.

### ***Matrix Modification***

We have filed patent applications related to our own research and development program in matrix modification.

### **Competition**

A number of biotechnology and pharmaceutical companies are engaged in development of therapeutics for a broad range of central nervous system conditions, though none of them have focused on the spinal cord as a point of access to this field. The current therapies for people with spinal cord injury and multiple sclerosis focus on treating symptoms associated with these diseases. Current approaches to symptom management include the use of compounds such as baclofen for spasticity, tricyclic antidepressants for neurological pain, fluoxetine for depression, amantadine or modafinil for fatigue, and oxybutinin for bladder contraction. Although our approach to the treatment of spinal cord injury and multiple sclerosis does not focus on treating symptoms, but rather on improving neurological function, our products will compete for market acceptance with these current treatments because they have been accepted and regularly prescribed to people with spinal cord injury and multiple sclerosis by health care providers.

Several biotechnology and pharmaceutical companies, as well as academic laboratories, are involved in research and/or product development for various neurological diseases, including spinal cord injury. However, to our knowledge, none has a comprehensive, multi-disciplinary approach for spinal cord injury therapeutic product development that is comparable to ours. 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 substantially greater financial, research and development, human and other resources than we do. Furthermore, large pharmaceutical companies have significantly more experience than we do in preclinical testing, human clinical trials and regulatory approval procedures.

Commercially available therapies for multiple sclerosis are centered on immunomodulatory compounds. These treatments reduce the frequency and severity of exacerbations or slow the accumulation of physical disability for people with certain types of multiple sclerosis, though their precise mechanisms of action are not known. Several biotechnology and pharmaceutical companies are engaged in developing products that include novel immunomodulator and cell transplant approaches to remyelination for the treatment of people with multiple sclerosis.

There are also numerous drugs used to treat epilepsy and bipolar disorder with which our valroceמיד product as well as other products we develop in collaboration with Teva may compete.

### **Government Regulation**

***FDA Regulation and Product Approval***

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

Our fampridine and valroceamide products are classified by FDA as drugs for regulatory purposes. GGF-2, and products that may be developed out of our Remyelinating Antibody, Matrix Modification and Regenerative Antibody programs, may be classified by FDA as biological products. While the regulatory standards and approval processes for drugs and biological products are similar, they generally proceed under different statutory authority which can affect the procedures and timing by which potential competing versions of the products may be approved for marketing by competitors.

The process required by the FDA before a new drug or biological product may be marketed in the United States generally involves the following:

preclinical laboratory and animal tests;

submission to the FDA of an Investigational New Drug, or IND, application which must become effective before clinical trials may begin;

performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug or biological product in our intended use; and

submission to the FDA of a New Drug Application or a biological license application that must be approved.

The testing and approval process requires substantial time, effort, and financial resources and we cannot be certain that any approval we seek will be granted on a timely basis, if at all.

Preclinical studies generally include laboratory evaluation of the product candidate, its chemistry, formulation and stability, as well as animal studies to assess potential safety and efficacy or activity. We submit the results of the preclinical studies, together with manufacturing information and analytical data, to the FDA as part of an IND application, which must become effective before we may begin human clinical trials. The IND automatically becomes effective 30 days after the FDA acknowledges that the filing is complete, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the preclinical trials or the design of the proposed clinical trials as outlined in the IND. In such a case, the

IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Further, one or more responsible independent Institutional Review Board must review, approve, and periodically monitor the conduct of clinical studies at each study site.

Human clinical trials are typically conducted in three sequential phases which may overlap:

Phase 1: The drug is initially administered into healthy human subjects or subjects with the target condition and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.

Phase 2: The drug is administered to a limited subject population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. In some cases, a company may decide to run what is referred to in the industry as a "Phase 2b"

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evaluation, which is a subsequent, confirmatory Phase 2 trial that could, if positive, provide efficacy data that may be considered in the potential approval of a drug. Throughout this prospectus, we have used the phrase "late Phase 2 trials" to refer to these Phase 2b trials, while all other Phase 2 trials are referred to herein as "early Phase 2 trials."

Phase 3: When Phase 2 evaluations demonstrate that a dosage range of the drug is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken to further evaluate dosage, clinical efficacy and to further test for safety in an expanded population, often at geographically dispersed clinical study sites.

In the case of product candidates for severe or life-threatening diseases such as multiple sclerosis, the initial human testing is often conducted in affected subjects rather than in healthy volunteers. Since these subjects already have the target condition, these clinical trials may provide initial evidence of efficacy traditionally obtained in Phase 2 clinical trials and thus these clinical trials are frequently referred to as Phase 1b clinical trials.

The orphan designation process is the mechanism by which sponsors of drugs and biological products for rare diseases qualify for a tax credit and seven-year marketing exclusivity incentives of the Orphan Drug Act. Orphan Drug designations are specific to a product and its FDA-approved indication. Market exclusivity begins at the time of FDA approval of a product for its designated use and during this time potential competitors will be unable to obtain FDA approval of their own version of that same drug or biological product for that indication unless the competitor can show that the original sponsor is unable to produce an adequate supply of the approved product or that the competitor's product is clinically superior to the approved product. We are the holders of two separate Orphan Drug designations for Fampridine-SR in the treatment of chronic, incomplete spinal cord injury and for the relief of symptoms of multiple sclerosis.

We cannot be certain that we will successfully complete Phase 1, Phase 2 or Phase 3 testing of our product candidates within any specific time period, if at all. Furthermore, the FDA or the Institutional Review Boards or the sponsor may suspend clinical trials at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk.

The results of product development, preclinical studies and clinical trials are submitted to the FDA as part of a new drug application or biological license application for approval of the marketing and commercial shipment of the product candidate. Applications for FDA approval must also contain information relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling and quality control. The FDA may deny a new drug application or biological license application if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if such data is submitted, the FDA may ultimately decide that the new drug application or biological license application does not satisfy the criteria for approval. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products which have been

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commercialized, and the agency has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Satisfaction of the above FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially, based upon the type, complexity and novelty of the pharmaceutical product candidate. Government regulation may delay or prevent marketing of potential products for a considerable period of time and to impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approval for any of our product candidates on a timely basis, if at all. Success in preclinical or early stage clinical trials does not assure success in later stage clinical trials. Data obtained from preclinical and clinical activities is not always conclusive and may be susceptible to varying interpretations which could delay, limit or prevent regulatory approval. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific indications or may impose significant limitations on use in the form of contraindications, warnings or precautions. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business. Marketing our product candidates abroad will require similar regulatory approvals and is subject to similar risks. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

Any drug or biological products manufactured or distributed by us pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug and biological product manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with current Good Manufacturing

Practices, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the current Good Manufacturing Practices and other FDA regulatory requirements. Failure to obtain or maintain approvals for the manufacture of our products at facilities that comply with current good manufacturing practice or to comply with other regulatory requirements imposed by the FDA may delay or interrupt the marketing of our products, may result in civil or criminal sanctions being imposed on us, may necessitate recalls of marketed products, and may lead to the withdrawal of approvals, withholding approvals of pending products and/or the refusal to review pending applications.

The FDA strictly regulates the promotional claims that may be made about prescription drug products. Although physicians are permitted to use approved products for uses that are not covered in their approved labeling, promotion of approved drugs for uses that are not covered by the FDA-approved labeling is prohibited. In addition, the FDA requires substantiation of any promotional claims that may be made about a product, including, in many cases, requirements that such claims be proven by adequate and well controlled clinical trials.

The Federal Food, Drug, and Cosmetic Act provides the opportunity for certain periods of market exclusivity against generic companies obtaining effective approval under abbreviated types of applications to market competitive products. These exclusivities potentially are applicable for new chemical entities, orphan drugs, certain patents, and for the NDA holder performing required clinical studies and/or pediatric studies. However, these exclusivities are limited in time and can be subject to challenge as being inappropriate or not applicable resulting in the loss of market exclusivity and thus competition from generics at earlier time frames than predicted. The timing and degree in which our products face generic competition could potentially have a material impact upon their profitability.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government

regulations which could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation which might arise from future legislative or administrative action, either in the United States or abroad.

We and our product candidates are also subject to a variety of state laws and regulations in those states or localities where they are or will be marketed. Any applicable state or local regulations may hinder our ability to market our product candidates in those states or localities.

#### ***Foreign Regulation and Product Approval***

Outside the United States, our ability to market a product candidate is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Community, or EC, registration procedures are available to companies wishing to market a product in more than one EC member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization will be granted. This foreign regulatory approval process involves all of the risks associated with FDA clearance discussed above.

#### ***Other Regulations***

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

#### **Employees**

As of September 30, 2003, we had 70 employees. Of the 70 employees, 41 perform scientific and research activities and 27 hold advanced degrees.

#### **Facilities**

Our principal executive offices are located in an approximately 30,000 square foot facility in Hawthorne, NY, which houses offices and laboratory space. The current annual rent for this facility is \$642,000. We believe that our facility is currently adequate for our purposes and that it will continue to be so for the foreseeable future. The lease for this facility expires in January 2008.

**Legal Proceedings**

We are not currently a party to any material legal proceedings.

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**MANAGEMENT****Executive Officers and Directors**

The following table sets forth information about our directors and executive officers.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Ron Cohen, M.D.	47	President, Chief Executive Officer and Director
Andrew R. Blight, Ph.D.	52	Executive Vice President, Research and Development
Mary Fisher	42	Vice President, Commercial Operations
Elliott A. Gruskin, Ph.D.	41	Vice President, Research and Development
Mitchell Katz, Ph.D.	48	Vice President, Clinical Programs
David Lawrence, M.B.A.	47	Vice President, Finance
Mark R.E. Pinney, M.B.A., C.F.A.	49	Chief Financial Officer and Director
Harold Safferstein, Ph.D., J.D.	38	Vice President, Business Development
John Friedman(1)(2)(3)	50	Director
Sandra Panem, Ph.D.(1)(2)(3)	57	Director
Michael Steinmetz, Ph.D.(2)	56	Director
Wise Young, Ph.D., M.D.(3)	53	Director

- (1) Member of Governance Committee
- (2) Member of Compensation Committee
- (3) Member of Audit Committee

**Ron Cohen, M.D.** has served as our President and Chief Executive Officer and a director since he founded Acorda in 1995. Dr. Cohen previously was a principal in the startup of Advanced Tissue Sciences, Inc., a biotechnology company engaged in the growth of human organ tissues for transplantation uses. Dr. Cohen serves as the Chairman of the Board of the New York Biotechnology Association and on the Board of Directors of Ceregene, Inc. He also serves on the Advisory Editorial Board of BioPeople magazine, and as a member of the Columbia-Presbyterian Health Sciences Council. Dr. Cohen received his B.A. degree with honors in Psychology from Princeton University, and his M.D. from the Columbia College of Physicians & Surgeons. He completed a residency in Internal Medicine at the University of Virginia Medical Center, and is Board Certified in Internal Medicine.

**Andrew R. Blight, Ph.D.** has served as our Executive Vice President, Research and Development since 2000 and was Vice President from 1998 to 2000. Prior to joining Acorda, Dr. Blight spent approximately 6 years as Professor and Director of the Neurosurgery Research Laboratory at the University of North Carolina at Chapel Hill. Dr. Blight held prior academic positions at Purdue University and New York University. Dr. Blight is a leader in spinal cord injury pathophysiology research and has made several important contributions to the field, particularly on the role of demyelination in spinal cord injury. He also pioneered the therapeutic application of 4-AP in spinal cord injury animal models and in human clinical trials. Dr. Blight is a member of the editorial board of the Journal of Neurotrauma and has served as a member of the NIH NSDA review committee. He was previously Secretary, Treasurer and Vice President of the National Neurotrauma Society. Dr. Blight received his B.S. in Zoology and his Ph.D. in Zoology/Neurobiology from the University of Bristol, U.K.

**Mary Fisher** has served as our Vice President, Commercial Operations since September 2003 and was Vice President, Marketing and Strategic Planning since 2000 to 2003. From 1999 to 2000, Ms. Fisher was an independent consultant to various pharmaceutical companies. From 1994 to 1999, Ms. Fisher was Vice President, Strategic Healthcare and Commercial Operations for Cephalon, Inc. In that capacity she had responsibility for the company's corporate sales, managed care marketing, pricing, reimbursement, health economics, patient support programs, product planning, commercial manufacturing, distribution and customer service. From 1990 until joining Cephalon, Ms. Fisher was Corporate Communications Manager for Immunex Corporation. Previously, she spent nine years in a variety of line and staff positions, including production

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planning, purchasing, accounting, and public affairs at Boehringer Ingelheim Pharmaceuticals, Inc. Ms. Fisher currently serves as a director of PharmaMetrics.

**Elliott A. Gruskin, Ph.D.** has served as our Vice President, Research & Development since 2001. From November 1990 until joining Acorda, Dr. Gruskin served as Senior Director of the Life Sciences Division of United States Surgical Corporation where he was responsible for all operations including strategic planning, budgets, corporate development, contracts, external research agreements, intellectual property, research, development and transfer of products to manufacturing. Dr. Gruskin was responsible for two approved wound healing products, has been issued 8 U.S. patents and has published scientific papers in DNA repair enzymology biomaterials, wound healing and tissue engineering. Dr. Gruskin received his B.S. Degree in Biochemistry from the University of Rochester and his Ph.D. in Biochemistry from Vanderbilt University as a Harold Sterling Vanderbilt Scholar and completed his postdoctoral training at MIT in Biophysics.

**Mitchell Katz, Ph.D.** has served as our Vice President, Clinical Programs since 2000. Prior to joining Acorda, he served as the Director of Clinical Operations at SCP Communications from 1998 to 2000. He also supported clinical and preclinical operations at several start-up biotechnology companies, and held management positions at R.W. Johnson Pharmaceutical Research Institute, and Schering-Plough. In these prior positions, he participated in four successful NDA applications. He received a B.A. in Biology from CUNY Brooklyn and a Ph.D. in microbiology from Rutgers University Graduate School and served as a postdoctoral research fellow in the Department of Microbiology and Immunology at Downstate Medical Center, Brooklyn, New York. Dr. Katz has also published scientific papers in numerous peer-review journals.

**David Lawrence, M.B.A.** joined us as Vice President, Finance in 1999. From 1991 to 1999, Mr. Lawrence held several positions for Tel-Air Communications, Inc. including Vice President and Controller. Prior to Tel-Air, he held financial management positions of Controller and Finance Manager for Southwestern Bell and Metromedia Telecommunications respectively. Mr. Lawrence received his undergraduate degree in Accounting from Roger Williams College in Rhode Island, and an M.B.A. in Finance from Iona College in New York. Mr. Lawrence is a founding member and currently serves on the Board of Directors as Treasurer of The Brian Ahearn Children's Fund.

**Mark R. E. Pinney, M.B.A., C.F.A., M.S.** has served as our Chief Financial Officer since 2001 and has been a member of the board of directors since the founding of the company in 1995. Prior to joining Acorda, from 2000 to 2001, Mr. Pinney was Chairman of CanDo, Inc., an Internet company that offered product and service solutions to people with disabilities. In 1998, he co-founded and was Chief Executive Officer of LifeWire, Inc., a company developing community-based destination web sites for the disability population. LifeWire merged with CanDo in 2000. Mr. Pinney also co-founded Real Media, Inc., an Internet advertising software and services firm, in 1996, and participated in the start-up of Acorda. From 1984 to 1988, he was Vice President, Corporate Finance for Merrill Lynch Capital Markets and from 1988 to 1992, he was Vice President, Private Transactions at Dillon Read & Co., Inc. Mr. Pinney serves as a Trustee of the Christopher Reeve Paralysis Foundation and currently serves as a director of Healthlink Systems, Inc. He received an undergraduate degree in engineering at the University of Exeter, England, an M.B.A. from the University of Chicago Graduate School of Business, and a masters degree in engineering from Columbia University. He is a Chartered Financial Analyst.

**Harold Safferstein, Ph.D., J.D.** has served as our Vice President, Business Development since 2001. From 1997 to 2001, Dr. Safferstein spent approximately 5 years at Bristol-Myers Squibb, most recently as Director, Lifecycle Management, Business Development and Strategic Planning for the Diabetes Franchise. Prior to joining Bristol-Myers Squibb, Dr. Safferstein was Director, Technology Transfer at the National Heart, Lung and Blood Institute, Cooperative Venture Manager for the National Institute of Allergy and Infectious Diseases and Chair, PHS Technology Development Coordinators Committee at the National Institutes of Health. Dr. Safferstein was a NIH Post-Doctoral Fellow and Fellow of the Multiple Sclerosis Society. Dr. Safferstein received a B.A. in biochemistry from Rutgers University, a Ph.D. in neurobiology

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from the University of Louisville, a J.D. from The American University, Washington College of Law and an M.B.A. from Columbia University.

**John Friedman** has served as a director of Acorda since May 2003. Mr. Friedman is the founder and principal of Easton Hunt Capital Partners which he founded in 1998. Prior to founding Easton Hunt Capital Partners he was managing director of Easton Capital Corp. from 1993 to 1998, which he also founded. Mr. Friedman was also the founder and Managing General Partner of Security Pacific Capital Investors, a \$200-million private equity fund geared towards expansion financings and recapitalizations. Prior to joining Security Pacific, he spent more than eight years at E.M. Warburg, Pincus & Co., Inc., serving last as a Managing Director and Partner. Before joining Warburg, Mr. Friedman was an attorney with Sullivan and Cromwell LLP. He holds a J.D. from Yale Law School and a B.A. degree from Yale College. He currently serves on

the boards of directors of Transave, Inc., Renovis, Inc., Conor Med Systems, Comverse Technology Inc., Trellis Bioscience, Assistive Technology, Inc., and ModelWire, Inc., and is on the President's Council at the Cold Spring Harbor Laboratory.

**Sandra Panem, Ph.D.** has served as a director of Acorda since 1998. She is currently a partner at Cross Atlantic Partners which she joined in 2000. From 1994 to 1999, Dr. Panem was President of Vector Fund Management, the asset management affiliate of Vector Securities International. Prior thereto, Dr. Panem served as Vice President and Portfolio Manager for the Oppenheimer Global BioTech Fund, a mutual fund that invested in public and private biotechnology companies. Previously, she was Vice President at Salomon Brothers Venture Capital, a fund focused on early and later-stage life sciences and technology investments. Dr. Panem was also a Science and Public Policy Fellow in economic studies at the Brookings Institution, and an Assistant Professor of Pathology at the University of Chicago. She received a B.S. in biochemistry and Ph.D. in microbiology from the University of Chicago. Dr. Panem currently serves on the boards of directors of Martek Biosciences Corp., Bioject Medical Technologies, Inc., AirLogix, Inc. and Confluent Surgical, Inc.

**Michael Steinmetz, Ph.D.** joined our board of directors in 1998. Dr. Michael Steinmetz currently serves as a General Partner of MPM Capital, which he joined in 1997. Prior to MPM, he held positions at various academic institutions, including the California Institute of Technology and the Basel Institute for Immunology where he was a permanent member. In 1986, he joined Hoffmann-La Roche and held various leadership positions in R&D, initially in Switzerland and subsequently in the U.S.A. where, as Vice President of Preclinical Research and Development, he was responsible for Roche's drug discovery activities in the U.S.A. and Roche's global biotechnology efforts. Dr. Steinmetz was trained as a chemist and holds a Ph.D. from the University of Munich. He did academic research in the areas of Biochemistry, Molecular Biology and Immunology and published over 130 manuscripts in leading scientific journals. He is currently Chairman of the Board at BioXcell SpA and the ISB Accelerator Corporation and a director of Amphora Discovery Corporation, atugen AG, Biovitrum AB, Cellular Genomics, Inc., Epigenomics AG, Intracel Resources, LLC, MacroGenics Inc., and TaiGen Bioscience Corporation.

**Wise Young, Ph.D., M.D.** has been a member of the board of directors and of our scientific advisory board since the founding of the company in 1995. Dr. Young has been at Rutgers University since 1997, where he serves as Professor and Chair of the Department of Cell Biology and Neuroscience, Professor II and Director of the Neuroscience Center and founder of the W.M. Keck Center for Neuroscience. Dr. Young is one of the preeminent scientists in the fields of spinal cord injury and neurotrauma, spinal cord injury animal models, and the pharmacological therapy of spinal cord injury. He was the Principal Investigator for the Multicenter Animal Spinal Cord Injury Study, funded by the National Institutes of Health; is editor-in-chief of *Current Concepts in Critical Care and Trauma*; and serves on numerous editorial boards, including those of *Experimental Neurology*, *Journal of Neurotrauma*, *Brain Research* and *Stroke*. Dr. Young has received the Wakeman Award for Research in Neurosciences, and a Jacob Javits Neuroscience Award from the National Institute of Neurological Disorder and Stroke. He is also a member of the Scientific Advisory Council of the American Paralysis Association and of the National Acute Spinal Cord Injury Study executive committee. Dr. Young received a B.A. in biology and chemistry from Reed College, a Ph.D. in physiology and biophysics from the University of Iowa and an M.D. from Stanford University.

## Scientific Advisory Board

Our Scientific Advisory Board is composed of the following individuals who are well recognized scientists and academic leaders in the spinal cord injury and multiple sclerosis fields, representing multiple areas of expertise, including neuropharmacology, cellular and molecular neurobiology, clinical neurology, spinal cord injury animal models, and spinal cord pathophysiology. They provide us with advance access to information and technology within the spinal cord injury and multiple sclerosis fields, as well as advise us on particular project needs, perform experiments and write grants that help to support in-house research.

**Michael S. Beattie, Ph.D.** holds the Brumbaugh Chair in Brain Research and Teaching, and is Professor of and Chair of the Department of Neuroscience at Ohio State University. In collaboration with Dr. Jacqueline Bresnahan, Dr. Beattie has contributed seminal work in the areas of spinal cord injury mechanisms and regeneration, most recently in elucidating the role of programmed cell death in spinal cord injury, and he is co-developer of the Beattie-Bresnahan-Basso, or BBB, scale that is now a standard for measurement of behavioral recovery in animals after spinal cord injury. He has served on the editorial board of *Journal of Neurotrauma*, *NIH study sections*, and has chaired international symposia on neural transplantation and neurotrauma. Dr. Beattie received his B.S. in psychology from the University of California, and his M.A. and Ph.D. in neuropsychology from Ohio State University.

**Jacqueline C. Bresnahan, Ph.D.** is Professor of Neuroscience at Ohio State University. In collaboration with Dr. Michael Beattie, Dr. Bresnahan has contributed seminal work in the areas of spinal cord injury mechanisms and regeneration, most recently in elucidating the role of apoptosis in spinal cord injury, and she is co-developer of the BBB scale that is now a standard for measurement of behavioral recovery in animals after spinal cord injury. She is a past President of the Neurotrauma Society, serves on the editorial boards of the *Journal of Neurotrauma* and the *Neurotrauma Society Newsletter*, and is a member of the Scientific Advisory Council of the American Paralysis

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Association. Dr. Bresnahan received her B.A. in psychology and biology from Kent State University, and her M.A. and Ph.D. in physiological psychology from Ohio State University.

**Mary B. Bunge, Ph.D.** is Professor of Cell Biology and Anatomy, Neurological Surgery and Neurology at the University of Miami School of Medicine. Dr. Bunge's research focuses on the development and repair of neural tissue, particularly by the application of cultured Schwann cell grafts and various nerve growth factors. She has served on the editorial boards of the *Journal of Cell Biology* and *Journal of Neurocytology*. She is the first winner of the Mika Salpeter Women in Neuroscience Lifetime Achievement Award and the recipient of the 1996 Wakeman Award for her seminal contributions to the field of spinal cord injury repair. Dr. Bunge received her B.S. in biology from Simmons College, her M.S. in medical physiology and Ph.D. in zoology/cytology from the University of Wisconsin Medical School, and her Post-Doctoral Fellowship in developmental neurobiology at the Columbia College of Physicians and Surgeons.

**Carl W. Cotman, Ph.D.** is Professor of Psychobiology and Neurology at the University of California, Irvine. His research focus is on programmed cell death in the central nervous system, and on beta amyloid-associated neurotoxicity. Among other honors, Dr. Cotman has received the Bristol Myers Neuroscience Research Award, the Pattison Prize in Neuroscience, and the Camhi Research Award of the American Paralysis Association, or APA. He has published nearly 500 papers in the field of neuroscience and serves on several editorial boards, including the *Journal of Neurochemical Research*, *Journal of Biological Chemistry* and *Central Nervous System Trauma*. Dr. Cotman also is past Chairman of the Scientific Advisory Council of the APA, and continues to serve as a Scientific Advisor. He received his B.A. in chemistry from Wooster College, and his Ph.D. in biochemistry from Indiana University.

**James W. Fawcett, Ph.D.** is Merck Company Professor of Experimental Neurology, Cambridge University, and Chairman of the MRC Cambridge Centre for Brain Repair. He is a world authority on regeneration in the nervous system, has published extensively in the field of neural development and repair. He is also edited of a number of books, including the recent *Brain Damage and Brain Repair*.

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**Martin Grumet, Ph.D.** is Professor of Cell Biology and Neuroscience in the Division of Life Sciences at Rutgers University and he is Director of the W.M. Keck Center for Neuroscience. He is the discoverer of the Ng-CAM protein, a chick homologue of L1. He is a leading researcher of cell adhesion molecules in the nervous system and their roles in central nervous system development and regeneration. Dr. Grumet received his B.Sc. in physics and biology from, respectively, The Cooper Union and New York University, his Ph.D. in biophysics at Johns Hopkins University, and did his Post-Doctoral Fellowship in developmental and molecular biology at The Rockefeller University.

**Eugene Johnson, Jr., Ph.D.** is Norman J. Stupp Professor of Neurology, and Professor of Molecular Biology and Pharmacology at Washington University School of Medicine, St. Louis. He is preeminent in the field of pharmacologic regulation of nerve growth factors, and in the mechanisms and prevention of programmed nerve cell death. Dr. Johnson has received both a Jacob Javits Neurosciences Investigator Award and a MERIT Award from the National Institutes of Health, and a Decade of the Brain Medal from the American Association of Neurological Surgeons. He serves as the Co-Director of the Washington University Alzheimer's Disease Research Center. His editorial board service includes *Neuron*, *Journal of Neuroscience*, *Synapse* and *Journal of Neurotrauma*. Dr. Johnson received his B.Sc. in pharmacy, and his Ph.D. in medicinal chemistry from the University of Maryland.

**Mark D. Noble, Ph.D.** is Professor of Genetics at the Center for Cancer Biology, University of Rochester Medical Center, Rochester, NY. Dr. Noble is a world leader in the areas of stem cell biology, central nervous system myelin repair, glial progenitor cells, and central nervous system regeneration. He is a recipient of the Jean Monnet Prize of the European Neurological Society, and serves on the editorial boards of, among others, *Developmental Neuroscience*, *International Journal of Developmental Neuroscience* and *Glia*. Dr. Noble received his B.A. in Biology and Philosophy from Franklin and Marshall College, and his Ph.D. in Genetics from Stanford University

**Melitta Schachner, Ph.D.** is Professor and Director of the Institute for Synthesis of Neural Structures at the University of Hamburg, in Germany. Dr. Schachner is the discoverer of the L1 protein, a promoter of axonal outgrowth, and the L2/HNK-1 carbohydrate, a critical motor neuron guidance factor. Her research focus is on cell adhesion molecules in the nervous system, and their role in nerve cell regeneration. She serves on the editorial boards of numerous scientific journals, including the *Journal of Neurobiology*, *Brain Research*, *Molecular Brain Research*, *Journal of Neuroscience* and the *Journal of Neuroimmunology*. Dr. Schachner received her undergraduate degree in biochemistry at the University of Tubingen, and her Ph.D. in biochemistry from the Max-Planck Institute in Munich.

**Jerry Silver, Ph.D.** is Professor of Neurosciences at Case Western Reserve University. Dr. Silver is a world authority on neuroglial cells, extracellular matrix and nerve regeneration, particularly in relation to spinal cord injury. He is associate editor of *Experimental Neurology*, and serves on the editorial boards of *Glia*, *The Journal of Neurobiology*, and *Restorative Neurobiology and Neuroscience*. He is a member of the



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Scientific Committee of the International Spinal Research Trust and the Daniel Heumann Fund. He has served as Chairman of the Workshop on New Developments in Spinal Cord Injury: Acute Interventions and Neural Grafts, sponsored by the U.S. Congress. Dr. Silver received his B.S. in biology from Cleveland State University, and his Ph.D. in anatomy from Case Western Reserve University.

**Patrick A. Tresco, Ph.D.** is Associate Professor of Bioengineering at the University of Utah. He has performed groundbreaking research in the development of cell encapsulation systems as sustained delivery devices for treatment for central nervous system disorders. Dr. Tresco holds 11 issued and pending patents relating to this and other bioengineering areas. Dr. Tresco is a regular peer reviewer for *Experimental Neurology* and *Bioengineering and Biotechnology*. He received his B.A. in biology from Susquehanna University, his M.S. in pharmacology and toxicology from the University of Rhode Island, and his Ph.D. in medical sciences from Brown University.

**Mark H. Tuszynski, M.D., Ph.D.** is Professor of Neurosciences, Director of the Center for Neural Repair, and Attending Neurologist at the University of California, San Diego, or UCSD. Dr. Tuszynski has

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performed pioneering research in the regeneration of central nervous system axons by use of genetically modified cell grafts, notably in the areas of spinal cord injury and Alzheimer's disease. He holds a Physician Scientist Award from the University of Minnesota, and in 1995 was the first recipient of the Silvio O. Conte Neuroscience Research Award from the American Academy of Neurology. He serves as a reviewer for, among others, the *Journal of Neuroscience*, *Experimental Neurology*, *Cell Transplantation*, and the *Journal of Neuroscience Methods*. Dr. Tuszynski received his B.A. in biology and his M.D. from the University of Minnesota, and his Ph.D. in neurosciences from UCSD. He completed his neurology residency at Cornell University Medical Center.

**Stephen G. Waxman, M.D., Ph.D.** is Chairman of the Department of Neurology, Yale University School of Medicine, and Neurologist-in-Chief, Yale-New Haven Hospital. He also is founder and Director of the PVA/EPVA Neuroscience Research Center. Dr. Waxman is internationally recognized for elucidating the molecular architecture of nerve fibers and glial cells, and mechanisms of injury to nerve fibers in the spinal cord and brain. He has published over 400 scientific papers and has authored three books on neuroscience. He is editor of *The Neuroscientist*, associate editor of the *Journal of Neurological Sciences* and *Muscle and Nerve*, and serves on the editorial boards of numerous other journals. Dr. Waxman is a member of the Institute of Medicine of the National Academy of Sciences; and has served on the Advisory Boards of the American Paralysis Association and the Spinal Cord Research Foundation. A graduate of Harvard College, his honors include the Wartenburg Award of the American Academy of Neurology and the Distinguished Alumnus Award of the Albert Einstein College of Medicine, where he received his MD and Ph.D. degrees.

**Wise Young, Ph.D., M.D.** See "Executive Officers and Directors" above.

### Board Composition

Following this offering, our board of directors will consist of six directors divided into three classes, with each class serving for a term of three years. At each annual meeting of stockholders, directors will be elected for a three-year term to succeed the directors whose terms are expiring. Mr. Pinney and Dr. Young will be Class I directors whose terms will expire in 2004; Drs. Panem and Steinmetz will be Class II directors whose terms will expire in 2005 and Dr. Cohen and Mr. Friedman will be Class III directors whose terms will expire in 2006.

### Director Compensation

In connection with this offering, each of our non-employee directors will receive non-qualified stock options to purchase 20,000 shares at the initial public offering price per share, which options will vest in 12 equal quarterly installments commencing 180 days after the date of grant.

In connection with this offering, each of our non-employee directors will receive an annual retainer in the form of an option grant on the date of our annual stockholder meeting to purchase 10,000 shares. In addition, directors will receive an annual grant of 5,000 options exercisable to purchase shares for each committee on which they serve. Directors will also be reimbursed for expenses incurred in attending meetings.

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### Board Committees

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The board of directors has an audit committee, a compensation committee and a governance committee.

Our audit committee is responsible for the following functions:

- approve and retain the independent auditors to conduct the annual audit of our books and records;
- review the proposed scope and results of the audit;
- review and pre-approve the independent auditors' audit and non-audit services rendered;
- approve the audit fees to be paid;
- review accounting and financial controls with the independent auditors and our financial and accounting staff;
- review and approve transactions between us and our directors, officers and affiliates;
- recognize and prevent prohibited non-audit services;
- establish procedures for complaints received by us regarding accounting matters; and
- oversee internal audit functions.

Our compensation committee is responsible for the following functions:

- review and recommend the compensation arrangements for executives, including the compensation for our president and chief executive officer;
- establish and review general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals; and
- administer our stock incentive plan and annual bonus pool.

The governance committee is responsible for identifying potential candidates to serve on our board.

### **Compensation Committee Interlocks and Insider Participation**

Our Compensation Committee is composed of three members, Mr. John Friedman and Drs. Sandra Panem and Michael Steinmetz. No member of our Compensation Committee has at any time been an officer or employee of ours, or our subsidiary. No interlocking relationship exists between our board of directors or compensation committee and the board of directors or compensation committee of any other company, nor has any interlocking relationship existed in the past.

Mr. Friedman, Dr. Panem and Dr. Steinmetz are affiliated with Easton Hunt Capital Partners, Cross Atlantic Partners and MPM/BB Bioventure group, respectively, each of which participated in the sale of our Series J preferred stock in a private placement consummated in May 2003, and MPM/BB Bioventure group also participated in our Series I preferred stock a private placement consummated in March 2001. Pursuant to an amended and restated registration rights agreement among us and certain of our stockholders, including entities affiliated with Mr. Friedman and Drs. Panem and Steinmetz, the parties to the registration rights agreement have demand and piggy-back registration rights.

See "Certain Relationships and Related Transactions."

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## Executive Compensation

The following summary compensation table sets forth the aggregate compensation awarded to, earned by, or paid to the Chief Executive Officer and to our four most highly compensated executive officers whose annual compensation exceeded \$100,000 for the fiscal year ended June 30, 2003, for services during the fiscal year ended June 30, 2003:

**Summary Compensation Table**

Name and Principal Position	Year	Annual Compensation			Long-Term Compensation	
		Salary	Bonus(1)	Other Annual Compensation	Securities Underlying Options	All Other Compensation
Ron Cohen, M.D. President and Chief Executive Officer	2003	\$ 285,000	\$ 60,000			
Andrew R. Blight, Ph.D. Executive Vice President, Research and Development	2003	\$ 179,500	\$ 28,915			
Mary Fisher Vice President, Marketing	2003	\$ 176,000	\$ 28,263			
Mitchell Katz, Ph.D. Vice President, Clinical Programs	2003	\$ 187,292	\$ 20,161			
Mark Pinney, M.B.A., C.F.A.(2) Chief Financial Officer	2003	\$ 191,250	\$ 33,306			

(1) These bonuses were earned in calendar year 2002 and paid out in fiscal year 2003. The amount of bonuses for calendar year 2003 has not yet been determined by the Board of Directors.

(2) A portion of Mr. Pinney's salary in the amount of \$91,250 was deferred and paid in September 2003.

## Option Grants in Last Fiscal Year

During the fiscal year ended June 30, 2003, no stock option grants were made to the named executive officers. No stock appreciation rights were granted to these individuals during such year.

## Aggregate Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values

The following table sets forth information concerning option exercises and option holdings for the fiscal year ended June 30, 2003 with respect to the named executive officers. No stock appreciation rights were exercised during such year or were outstanding at the end of that year.

Name	Shares Acquired on Exercise	Value Realized (\$)	Number of Securities Underlying Unexercised Options at June 30, 2003		Value of Unexercised In-the-Money Options at June 30, 2003(1)		Value of Unexercised In-the-Money Options at Public Offering Price(2)	
			Exercisable	Unexercisable	Exercisable	Unexercisable	Exercisable	Unexercisable

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		Number of Securities Underlying Unexercised Options at		Value of Unexercised In-the-Money Options at		Value of Unexercised In-the-Money Options at	
		June 30, 2003	19,618	June 30, 2003(1)	178,915	Public Offering Price(2)	39,679
Ron Cohen	0	39,063	19,618	\$ 36,253	\$ 178,915	178,915	39,679
Andrew Blight	0	18,438	2,813	215,300	25,650	178,425	20,025
Mary Fisher	0	4,896	3,437	48,851	32,749	39,059	25,874
Mitchell Katz	0	4,531	2,552	45,873	24,327	36,811	19,222
Mark Pinney	0	16,111	12,854	150,832	117,232	118,610	91,523

(1) Based on the estimated fair market value of our common stock at June 30, 2003 of \$15.00 which was based on the estimated per share valuation of our company at the time the accompanying financial statements were prepared, less the exercise price payable for such shares. Such options are exercisable at \$1.20, \$4.20 and \$5.88 (the last reflecting a subsequent repricing).

(2) Based on \$13.00, the midpoint of the current estimated IPO price range.

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The following table sets forth the number of shares underlying options that have been issued in fiscal year 2004 to each of the named executive officers and directors and the additional number of stock options repriced in September 2003:

Name	Number of Shares Underlying Stock Options Granted in Fiscal Year 2004	Additional Number of Stock Options Repriced(1)
Ron Cohen	790,100	58,681
Andrew Blight	102,411	5,833
Mary Fisher	39,621	5,000
Mitchell Katz	32,570	3,750
Mark Pinney	204,508	28,132

(1) See disclosure under "1999 Employee Stock Option Plan."

### 1999 Employee Stock Option Plan

In June 1999, our board of directors adopted the 1999 Employee Stock Option Plan. We obtained stockholder approval of the plan in August 1999. The plan allows us to issue awards of incentive or nonstatutory stock options for shares of our common stock and stock appreciation rights. Our compensation committee administers the plan, selects those persons who are to be granted awards under the plan and determines the terms and conditions of those awards. Our directors, key employees, officers, independent contractors, agents and consultants are eligible to receive awards under our plan, but only employees and officers may receive incentive stock options. As of June 30, 2003 we reserved a total of 1,653,130 shares of common stock for issuance and have granted options to purchase 188,291 shares under the plan. In September 2003, our board of directors adopted an amendment to the plan, which is subject to approval by our stockholders. The amendment to the plan, which will become effective upon consummation of this offering, provides for automatic annual increases to the share reserve on the first day of each fiscal year by a number of shares equal to the lesser of:

2.5% of our then outstanding shares of common stock;

647,151 shares; or

a number determined by our board of directors.

The exercise price per share of the incentive stock options awarded under the plan must be at least equal to the fair market value of a share of our common stock on the date of grant. The exercise price per share of nonstatutory stock options awarded under the plan must be equal to the fair market value of a share of our common stock on the date of grant, or such other price that the compensation committee may determine is appropriate. The compensation committee determines the exercise period of the stock options, but in no event will the stock options expire later than ten years from the date of grant. Except as the compensation committee may otherwise determine, upon the voluntary termination or involuntary termination without cause of the option holder, the stock options may be exercised for a period of three months after such termination. In the case of termination of the option holder by reason of retirement or due to disability, the stock options may be exercised at any time to the extent that such stock option was vested, but only within one year of termination in the case of incentive stock options. In the case of termination by death, the option holder's estate, or any person who acquires the stock option by reason of the option holder's death, may exercise the stock option within a period of three years after the option holder's death.

The compensation committee has the authority to include with any stock option award a progressive stock option, which allows an option holder to exercise their stock option by surrendering shares of common stock and entitles them to receive additional shares of common stock equal to the number of shares surrendered. The compensation committee also has the authority to grant stock appreciation rights in connection with any stock option award, which may be paid in shares of common stock, cash or both, at the discretion of the compensation committee and subject to the requirements of the plan.

In the event of a tender offer by a person or persons other than us, for all or any part of the outstanding stock, which if upon consummation of the tender offer, the offeror or offerors would, own, beneficially or of

record, an aggregate of more than 25% of our outstanding common stock, or in the event of a change of control, the stock options will become immediately exercisable to the extent of the total number of shares subject to the stock options. The compensation committee may authorize payment of cash upon exercise of a stock appreciation right in the event of a tender offer as described above, or a change of control.

At June 30, 2003, options to purchase an aggregate of 188,291 shares at prices ranging from \$4.20 to \$24.00 were outstanding under the 1999 option plan. In September 2003, we unilaterally reduced the exercise price of 150,251 of such options to \$5.88, the effective common stock price per share at which we sold our Series J preferred stock. Also in September 2003, we granted stock options to purchase an aggregate of 1,374,997 shares of our common stock at \$5.88 per share to our officers and employees. These options had been authorized for issuance under the Plan by the board of directors at the closing of the Series J financing in May 2003.

#### **401(k) Plan**

Effective September 1, 1999, we adopted a defined contribution 401(k) savings plan covering all of our employees. Participants may elect to defer a percentage of their annual pre-tax compensation to the 401(k) plan, subject to defined limitations. Our board of directors has discretion to match contributions made by our employees. We did not make any matching contributions to the plan in fiscal years 2001, 2002 and 2003.

#### **Employment Contracts, Termination of Employment and Change-in-Control Arrangements**

We are a party to an employment agreement with Dr. Cohen which governs the terms and conditions of his employment as our President and Chief Executive Officer. The employment agreement provides for a base annual salary of \$280,000, subject to annual increases and bonuses at the discretion of the board of directors. Dr. Cohen is eligible to receive annual performance-based stock options to purchase common stock in an amount determined by the board of directors based on Dr. Cohen's individual performance and the achievement of our goals and objectives. Dr. Cohen's employment agreement expires in January 2004, but is subject to automatic successive one-year renewal periods unless either Dr. Cohen or we give the other written notice at least 60 days prior to the expiration date that Dr. Cohen or we do not intend to renew the contract. Dr. Cohen's employment agreement has been renewed effective January 2004 for a one-year period. In the event we terminate the agreement with Dr. Cohen without cause, or if Dr. Cohen voluntarily terminates the agreement with good reason, we are obligated to make severance payments equal to one year's base annual salary and COBRA premium payments for the severance period plus a bonus equal to his prior year's bonus pro rated for the number of days worked prior to termination. In such event, all of Dr. Cohen's options will become immediately exercisable and will remain exercisable for 48 months following termination. If Mr. Cohen's employment terminates for death or disability, we are obligated to pay his base salary for three months and COBRA premiums for the COBRA coverage period and 65% of his outstanding options will become immediately vested and remain exercisable for 48 months following such termination. In the event of a change in control, the vesting of Dr. Cohen's options will be governed by the terms of our stock option plan and his stock option agreement, but in no event will less than 65% of Dr. Cohen's then unvested stock options become immediately vested and exercisable. If Dr. Cohen voluntarily terminates his employment without good reason following a change in control, he is entitled to receive the same severance and bonus package described above, however, only 65% of his outstanding options will become immediately vested and remain exercisable for 48 months following

termination. Following his termination of employment, Mr. Cohen will remain subject to confidentiality, non-competition and non-solicitation covenants for one year in the case of non-competition and non-solicitation and five years in the case of confidentiality.

We are a party to an employment agreement with Mr. Pinney which governs the terms and conditions of his employment as our Chief Financial Officer. The employment agreement provides for a base annual salary of \$197,500. Mr. Pinney is eligible to receive an annual bonus and to receive annual performance-based stock options to purchase common stock in an amount to be determined by the board of directors based on Mr. Pinney's performance and, in the case of the stock options, upon the achievement of our goals and objectives. Mr. Pinney's employment agreement expires in September 2004, but is subject to automatic successive one-year renewal periods unless either Mr. Pinney or we give written notice to the other at least 60 days prior to the expiration date that either Mr. Pinney or we do not intend to renew the agreement. In the

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event we terminate the agreement with Mr. Pinney without cause, or if Mr. Pinney voluntarily terminates the agreement with good reason, we are obligated to make severance payments equal to six months base annual salary and COBRA premium payments for the severance period plus a bonus equal to his prior year's bonus pro rated for the number of days worked prior to termination. In such event, all of Mr. Pinney's options will become immediately exercisable and will remain exercisable for 48 months following termination. If Mr. Pinney's employment terminates for death or disability, we are obligated to pay his base salary for three months and COBRA premiums for the COBRA coverage period and 33% of his outstanding options will become immediately vested and remain exercisable for 48 months following such termination. In the event of a change in control, the vesting of Mr. Pinney's options will be governed by the terms of our stock option plan and his stock option agreements, but in no event will less than 33% of Mr. Pinney's then unvested stock options become immediately vested and exercisable. If Mr. Pinney voluntarily terminates his employment without good reason following a change in control, he is entitled to receive the same severance and bonus package described above. However, only 33% of his outstanding options will become immediately vested and remain exercisable for 48 months following termination. Following his termination of employment, Mr. Pinney will remain subject to confidentiality, non-competition and non-solicitation covenants for one year in the case of non-competition and non-solicitation and five years in the case of confidentiality.

#### **Indemnification of Directors and Executive Officers and Limitation on Liability**

Our bylaws currently provide and, upon the closing of this offering our amended and restated bylaws will provide, that we shall indemnify our directors and officers to the fullest extent permitted by Delaware law, provided that, with respect to proceedings initiated by our officers and directors, we are only required to indemnify these persons if the proceeding was authorized by our board of directors. Our bylaws permit us, by action of our board of directors, to indemnify our other employees and agents to the same extent as we are required to indemnify our officers and directors. We are also empowered under our bylaws to enter into indemnification agreements with our directors, officers, employees or agents and to purchase insurance on behalf of any of our director, officer, employee or agent whether or not we are required or permitted to indemnify such persons under Delaware law.

We have entered into indemnification agreements with certain of our directors and executive officers and intend to enter into indemnification agreements with all of our other directors and executive officers prior to the consummation of this offering. Under these agreements, we will indemnify our directors and executive officers against amounts actually and reasonably incurred in connection with actual or threatened proceedings if any of them may be made a party because of their role as one of our directors or officers. We are obligated to pay these amounts only if the officer or director acted in good faith and in a manner that he or she reasonably believed to be in or not opposed to our best interests. For any criminal proceedings, we are obligated to pay these amounts only if the officer or director had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth procedures that will apply in the event of a claim for indemnification thereunder.

In addition, our bylaws provide that our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability:

for any breach of the director's duty of loyalty to us or our stockholders;

for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

under Section 174 of the Delaware General Corporation Law; or

for any transaction from which the director derives an improper personal benefit.

There is no pending litigation or proceeding involving any of our directors or officers for which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

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### CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

#### Sale of Securities

In March 2001, we consummated a private placement of 10,204,047 shares of Series I preferred stock for an aggregate purchase price of approximately \$39,694,000. Except for Michael Steinmetz, who is affiliated with MPM/BB Bioventure, respectively, none of our executive officers or directors purchased any shares of the Series I preferred stock.

The following table sets forth, with respect to the Series I preferred stock transaction, the purchase price per share, the aggregate shares purchased and the total investment for MPM/BB Bioventure group.

Investor	Purchase Price per Share of Series I Preferred	Aggregate Shares of Series I Preferred Purchased	Total Investment in Series I Preferred
MPM/BB Bioventure group	\$ 3.89	639,359	\$ 2,487,107

In May 2003, we consummated a private placement of 112,790,233 shares of Series J preferred stock for an aggregate purchase price of approximately \$55,267,000. Except for Michael Steinmetz, John Friedman and Sandra Panem, who are affiliated with MPM/BB Bioventure group, Easton Hunt Capital Partners and Cross Atlantic Partners, respectively, none of our executive officers or directors purchased any shares of the Series J preferred stock.

The following table sets forth, with respect to the Series J preferred stock transaction, the purchase price per share, the aggregate shares purchased and the total investment for each of MPM/BB Bioventure group, Easton Hunt Capital Partners and Cross Atlantic Partners:

Investor	Purchase Price per Share of Series J Preferred	Aggregate Shares of Series J Preferred Purchased	Total Investment in Series J Preferred
MPM/BB Bioventure group	\$ 0.49	15,306,121	\$ 7,500,000
Easton Hunt Capital Partners	\$ 0.49	11,224,490	\$ 5,500,000
Cross Atlantic Partners	\$ 0.49	8,506,256	\$ 4,168,065

#### Board Representation and Registration Rights

Pursuant to an amended and restated registration rights agreement, the above parties have demand and piggy-back registration rights; provided that the board of directors has the right to postpone a demand registration in certain circumstances. However, under the amended and restated registration rights agreement, we are not obligated to register the registrable securities prior to the date that is six months after the effective date of our registration statement for this offering. We have agreed to pay for all expenses in connection with the registration. See "Description of Capital Stock Registration Rights".

In addition, if we propose to register any of our securities under the Securities Act, including in this offering, certain of our other stockholders are entitled to notice of the registration and to include their registrable shares in the offering. If the managing underwriter determines that marketing factors require a limitation on the number of shares to be underwritten, the managing underwriters may limit or exclude from such underwriting the registrable securities and other securities of the holders to be so distributed. If we are so advised by the managing underwriter, then all securities other than registrable securities shall first be excluded from the registration. We are required to bear substantially all costs incurred in these registrations, other than underwriting discounts and commissions.

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### Indemnification agreements

For a description of our indemnification arrangements with our directors and executive officers, see "Management Indemnification of Directors and Executive Officers and Limitation on Liability".

### Agreements with Elan

In September 2003, we entered into the following agreements with Elan, which holds more than 5% of our outstanding common stock:

We entered into a termination and assignment agreement with Elan. Pursuant to the terms of this agreement, we purchased all of the assets of MS Research and Development Corp., our jointly owned subsidiary. See "Business R&D and Product Collaborations, Alliances and License Agreements".

We entered into an amended and restated license agreement with Elan. Pursuant to the terms of the license agreement we were granted an exclusive worldwide license to develop, use and sell Fampridine-SR. We are obligated under the license to make milestone and royalty payments to Elan. See "Business R&D and Product Collaborations, Alliances and License Agreements".

We entered into a supply agreement with Elan. Subject to certain exceptions in the supply agreement, Elan will be our exclusive supplier of Fampridine-SR. See "Business R&D and Product Collaborations, Alliances and License Agreements".

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### PRINCIPAL STOCKHOLDERS

The following table contains information about the beneficial ownership of our common stock before and after the consummation of this offering for:

each person, or group of persons, who beneficially owns more than 5% of our capital stock;

each of our directors;

each executive officer named in the summary compensation table; and

all directors and executive officers as a group.

Unless otherwise indicated, the address for each person or entity named below is c/o Acorda Therapeutics, Inc., 15 Skyline Drive, Hawthorne, New York 10532.

Beneficial ownership is determined in accordance with the rules and regulations of the Securities and Exchange Commission. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options held by that person that are currently exercisable or exercisable within 60 days of the date hereof are deemed outstanding. Such shares, however, are not deemed outstanding for the purposes of computing the percentage ownership of any other person. Except as indicated in the footnotes to the following table or pursuant to applicable community property laws, each stockholder named in the table has sole voting and investment power with respect to the shares set forth opposite such stockholder's name. The percentage of beneficial ownership is based on 16,059,779 shares of common stock outstanding on November 25, 2003.



Beneficial Owner	Number of Shares(1)	Percentage of Common Stock Outstanding	
		Before Offering	After Offering(2)
<b>Five Percent Stockholders</b>			
MPM/BB Bioventure group(3)	2,132,189	13.3%	10.2%
Elan group(4)	1,297,115	7.9%	6.2%
Forward Ventures group(5)	1,136,061	7.1%	5.4%
Easton Hunt Capital Partners, LP(6)	935,374	5.8%	4.5%
MDS/Neuroscience Partners Healthcare(7)	876,597	5.5%	4.2%
TVM Life Sciences(8)	850,340	5.3%	4.1%
ABN AMRO(9)	850,340	5.3%	4.1%
J.P. Morgan(10)	850,340	5.3%	4.1%
Cross Atlantic Partners(11)	850,339	5.3%	4.1%
<b>Directors and Executive Officers:</b>			
Ron Cohen, M.D.(12)	793,724	4.8%	3.7%
Andrew R. Blight, Ph.D.(13)	116,687	*	*
Mary Fisher(14)	31,636	*	*
Elliott A. Gruskin, Ph.D.(15)	22,209	*	*
Mitchell Katz, Ph.D.(16)	28,144	*	*
David Lawrence, M.B.A.(17)	24,728	*	*
Mark R.E. Pinney, M.B.A., C.F.A.(18)	161,471	1.0%	*
Harold Safferstein, Ph.D., J.D.(19)	16,972	*	*
John Friedman(20)	935,374	5.8%	4.5%
Sandra Panem, Ph.D.(21)	856,105	5.3%	4.1%
Michael Steinmetz, Ph.D.(22)	2,132,189	13.3%	10.2%
Wise Young, Ph.D., M.D.(23)	24,167	*	*
All directors and executive officers as a group (12 persons)(24)	5,143,406	30.1%	22.5%

\* Represents beneficial ownership of less than one percent of the outstanding shares of our common stock.

(1) Reflects preferred stock on an as converted basis.

(2) Assumes no shares are purchased in this offering by the listed persons.

(3) Includes 1,906,058 shares beneficially owned by BB Bioventures LP, 201,610 shares beneficially owned by MPM Bioventures Parallel Fund, L.P., and 24,521 shares beneficially owned by MPM Asset Management

Investors 1998 LLC. The address of MPM/BB Bioventures group is c/o MPM Capital Asset Management, 111 Huntington Avenue, 31st Floor, Boston, Massachusetts 02199.

(4) Includes 361,842 shares of common stock issuable to EIS, upon conversion of convertible promissory notes and 21,930 shares of common stock issuable upon exercise of a warrant to purchase common stock. The address of Elan group is c/o Elan Pharmaceuticals,

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345 Park Avenue, New York, NY 10154.

- (5) Includes 1,047,278 shares beneficially owned by Forward Ventures IV, L.P. and 88,783 shares beneficially owned by Forward Ventures IV B. L.P. The address of Forward Ventures group is c/o Forward Ventures, 9393 Towne Center Drive, Suite 200, San Diego, California 92121.
- (6) The address of Easton Hunt Capital Partners, L.P. is 641 Lexington Avenue, 21st Floor, New York, New York 10022.
- (7) Includes 211,002 shares beneficially owned by MDS Life Sciences Technology Fund Limited Partnership, 49,889 shares beneficially owned by MDS Life Sciences Technology Fund USA, L.P., 36,617 shares beneficially owned by MDS Life Sciences Technology Barbados Investment Trust, 473,608 shares beneficially owned by Neuroscience Partners Limited Partnership, 47,090 shares beneficially owned by The Health Care and Biotechnology Venture Fund and 58,391 shares beneficially owned by SC Biotechnology Development Fund. The address for MDS/Neuroscience Partners Healthcare is c/o MDS Capital Corp., 100 International Blvd., Toronto, Ontario M9W6J6.
- (8) The address of TVM Life Sciences is c/o TVM Management Corporation, 101 Arch Street, Boston, MA 02110.
- (9) The address for ABN AMRO is c/o ABN-AMRO Participaties, B.V., Gustav Mahler Loan 10, 1082 PP Amsterdam, The Netherlands.
- (10) The address of JPMorgan is c/o JP Morgan Fleming Investment, 522 Fifth Ave., New York, NY 10036.
- (11) The address of Cross Atlantic is c/o Cross Atlantic Partners, Inc., 551 Madison Ave., New York, NY 10022.
- (12) Includes 653,850 shares of common stock issuable upon exercise of stock options.
- (13) Includes 114,604 shares of common stock issuable upon exercise of stock options.
- (14) Includes 31,636 shares of common stock issuable upon exercise of stock options.
- (15) Includes 22,209 shares of common stock issuable upon exercise of stock options.
- (16) Includes 28,144 shares of common stock issuable upon exercise of stock options.
- (17) Includes 24,728 shares of common stock issuable upon exercise of stock options.
- (18) Includes 147,471 shares of common stock issuable upon exercise of stock options.
- (19) Includes 16,972 shares of common stock issuable upon exercise of stock options.
- (20) Includes 935,374 shares beneficially owned by Easton Hunt Capital Partners, L.P. Mr. Friedman is a founder and principal of Easton Hunt Capital Partners, L.P. and exercises investment and voting power over these shares. Mr. Friedman disclaims beneficial ownership of these shares.
- (21) Includes 3,646 shares of common stock issuable upon exercise of stock options, and 708,854 shares beneficially owned by Cross Atlantic Partners and 141,485 shares beneficially owned by Nordea Bank Delaware A/S. Cross Atlantic Partners has voting and

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dispository authority over the shares owned by Nordea Bank. Dr. Panem is a partner of Cross Atlantic Partners IV, K/S and exercises investment and voting power over these shares. Dr. Panem disclaims beneficial ownership of these shares.

(22)

Includes 1,906,058 shares beneficially owned by BB Bioventures LP, 201,610 shares beneficially owned by MPM Bioventures Parallel Fund, L.P. and 24,521 shares beneficially owned by MPM Asset Management Investors 1998 LLC. Dr. Steinmetz is a general partner of MPM Capital Asset Management and exercises investment and voting power over these shares. Dr. Steinmetz disclaims beneficial ownership of these shares.

(23)

Includes 7,500 shares of common stock issuable upon exercise of stock options.

(24)

Includes 1,050,760 shares of common stock issuable upon exercise of stock options.

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### DESCRIPTION OF CAPITAL STOCK

Prior to the consummation of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock consists of 260,000,000 shares of common stock, \$0.001 par value per share, and 140,221,535 shares of preferred stock, \$0.001 par value per share. Immediately following the consummation of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock will consist of 75,000,000 shares of common stock, \$0.001 par value per share, and 1,000,000 shares of preferred stock, \$0.001 par value per share. As of November 25, 2003, there were outstanding:

253,167 shares of common stock, held of record by 39 stockholders; and

136,881,522 shares of preferred stock, held of record by 74 stockholders.

As of the consummation of this offering, all of the outstanding shares of preferred stock will automatically convert into common stock. After giving effect to the conversion, we will have outstanding 16,059,779 shares of common stock based on common stock outstanding as of November 25, 2003 and no shares of preferred stock.

#### Common stock

Under our amended and restated certificate of incorporation, the holders of common stock are entitled to one vote per share on all matters to be voted on by the stockholders. After payment of any dividends due and owing to the holders of preferred stock, holders of common stock are entitled to receive dividends declared by the board of directors out of funds legally available for dividends. In the event of our liquidation, dissolution or winding up, holders of common stock are entitled to share in all assets remaining after payment of liabilities and liquidation preferences of outstanding shares of preferred stock. Holders of common stock have no preemptive, conversion, subscription or other rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are, and all shares of common stock to be outstanding upon completion of this offering will be, fully paid and nonassessable.

#### Preferred stock

In accordance with our amended and restated certificate of incorporation, our board of directors has the authority, without further action by the stockholders, to issue up to 1,000,000 shares of preferred stock. Our board of directors may issue preferred stock in one or more series and may determine the rights, preferences, privileges, qualifications and restrictions granted to or imposed upon the preferred stock, including dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preferences and sinking fund terms, any or all of which may be greater than the rights of the common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and reduce the likelihood that common stockholders will receive dividend payments and payments upon liquidation. The issuance of preferred stock could also have the effect of decreasing the market price of the common stock and could delay, deter or prevent a change in control of our company. We have no present plans to issue any shares of preferred stock.

#### Warrants

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As of November 25, 2003, we have outstanding warrants to purchase 41,758 shares of common stock at a weighted average exercise price of \$1.47 per share.

### **Stock options**

As of November 25, 2003, 1,708,509 shares of common stock are issuable upon the exercise of outstanding stock options to purchase our common stock. After this offering, we intend to file a registration statement on Form S-8 to register the shares of common stock reserved for issuance upon exercise of

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outstanding options. The registration statement is expected to be filed and become effective approximately six months after the closing of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market without restriction, except with respect to Rule 144 volume limitations that apply to our affiliates.

### **Convertible Promissory Notes**

In January 1997, EIS loaned us an aggregate of \$7.5 million pursuant to two promissory notes that are convertible into 361,842 shares of our common stock.

### **Classified Board of Directors**

Our amended and restated certificate of incorporation provides for our board of directors to be divided into three classes, with each class serving for a term of three years. At each annual meeting of stockholders, directors will be elected for a three-year term to succeed the directors whose terms are expiring. Mr. Pinney and Dr. Young will be class I directors whose terms will expire in 2004; Drs. Panem and Steinmetz will be class II directors whose terms will expire in 2005 and Dr. Cohen and Mr. Friedman will be class III directors whose terms will expire in 2006. There will be no cumulative voting with respect to the election of directors.

### **Registration rights**

Pursuant to an amended and restated registration rights agreement between us and certain of our stockholders, commencing six months after the effective date of our registration statement for this offering, holders of an aggregate of shares of our common stock have demand and piggy-back registration rights. The demand rights may be exercised by holders of 30% of the registrable securities. Additionally, if at any time we propose to register our common stock under the Securities Act for our own account or the account of any of our stockholders or both, the stockholders party to the registration rights agreement are entitled to notice of the registration and to include registrable shares in the offering, provided that the underwriters of that offering do not limit the number of shares included in the registration. We are required to bear substantially all costs incurred in these registrations, other than underwriting discounts and commissions. The registration rights described above could result in substantial future expenses for us and adversely affect any future equity or debt offerings.

### **Anti-takeover provisions**

We are governed by the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a public Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A business combination includes mergers, asset sales or other transactions resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns, or within three years, did own 15.0% or more of the company's voting stock. The statute could delay, defer or prevent a change in control of our company.

### **Listing**

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

### **Transfer agent and registrar**

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company.

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### SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our common stock. Upon completion of this offering, we will have outstanding an aggregate of 20,859,779 shares of common stock, and if the underwriters exercise their over-allotment option in full, we will have outstanding an aggregate of 21,579,779 shares of our common stock. Of these shares, the shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except that any shares purchased by our affiliates, as that term is defined in Rule 144 of the Securities Act, may generally only be sold in compliance with the limitations of Rule 144 described below. Persons who may be deemed to be affiliates generally include individuals or entities that control, are controlled by, or are under common control with, us and may include our directors and officers.

Sales of substantial amounts of our common stock in the public market could adversely affect the market price of our common stock. We cannot estimate the number of shares of common stock that may be sold by third parties in the future because such sales will depend on market prices, the circumstances of sellers and other factors.

#### Sales of restricted shares

16,059,779 shares of our common stock held by existing stockholders as of November 25, 2003 are restricted securities under Rule 144. The number of these shares of common stock available for sale in the public market is limited by restrictions under the Securities Act.

In general, under Rule 144 as currently in effect, beginning 90 days after the date of this prospectus, a person (or persons whose shares are aggregated), including any of our affiliates, who has beneficially owned restricted shares for at least one year (including the holding period of any prior owner, except if the prior owner was an affiliate) will be entitled to sell, within any three-month period a number of shares that does not exceed the greater of: (a) one percent of the number of shares of common stock then outstanding (which will equal approximately 208,556 shares upon completion of this offering); or (b) the average weekly trading volume of our common stock on the Nasdaq National Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale. Sales of restricted securities pursuant to Rule 144 are also subject to requirements relating to manner of sale notice and the availability of current public information about us. Under Rule 144(k), a person who is not deemed to have been an affiliate of ours at any time during the three months preceding a sale, and who has beneficially owned the shares proposed to be sold for at least two years (including the holding period of any prior owners except a prior owner who was an affiliate), is entitled to sell its shares without complying with the volume limitation or the manner of sale, notice or current public information provisions of Rule 144. Therefore, unless otherwise restricted, 144(k) shares could be sold immediately upon the completion of this offering. As of the date of this prospectus, an aggregate of approximately 5,649,379 shares qualified as 144(k) shares which are not otherwise restricted.

#### Lock-up Agreements

We and our directors, officers and substantially all of our existing stockholders and option holders have entered into lock-up agreements with the underwriters or us pursuant to which we and those holders of stock and options have agreed not to, directly or indirectly, sell, dispose of or hedge any shares of our common stock or securities convertible into or exchangeable for shares of our common stock without the prior written consent of Banc of America Securities LLC for a period of 180 days after the date of this prospectus. This consent may be given at any time without public notice. In addition, during this 180 day period, we have also agreed not to file any registration for, and each of our officers has agreed not to make any demand for, or exercise any right of, the registration of, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock without the prior written consent of Banc of America Securities LLC.

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#### Registration rights

Commencing six months after the effective date of our registration statement for this offering, holders of 15,806,616 shares of our common stock will be entitled to certain rights with respect to the registration of their shares under the Securities Act.

See "Description of Capital Stock Registration Rights." Except for shares purchased by affiliates, registration of their shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. These stockholders are not permitted to exercise their registration rights for at least six months following this

offering.

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### UNDERWRITING

We are offering the shares of common stock described in this prospectus through a number of underwriters. Banc of America Securities LLC, Lazard Frères & Co. LLC, U.S. Bancorp Piper Jaffray Inc. and RBC Dain Rauscher, Inc. are the representatives of the underwriters. We have entered into a underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has agreed to purchase, the number of shares of common stock listed next to its name in the following table:

Underwriter	Number of Shares
Banc of America Securities LLC	
Lazard Frères & Co. LLC	
U.S. Bancorp Piper Jaffray Inc.	
RBC Dain Rauscher, Inc.	
<b>Total</b>	<b>4,800,000</b>

The underwriting agreement is subject to a number of terms and conditions and provides that the underwriters must buy all of the shares if they buy any of them. The underwriters will sell the shares to the public when and if the underwriters buy the shares from us.

The underwriters initially will offer the shares to the public at the price specified on the cover page of this prospectus. The underwriters may allow to selected dealers a concession of not more than \$ \_\_\_\_\_ per share. The underwriters may also allow, and any dealers may reallocate, a concession of not more than \$ \_\_\_\_\_ per share to some other dealers. If all the shares of common stock are not sold at the public offering price, the underwriters may change the public offering price and the other selling terms. Our common stock is offered subject to a number of conditions, including:

receipt and acceptance of the common stock by the underwriters; and

the underwriters' right to reject orders in whole or in part.

We have granted the underwriters an option to purchase up to 720,000 additional shares of our common stock at the public offering price less the underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering any over-allotments made in connection with this offering. The underwriters have 30 days from the date of this prospectus to exercise this option. If the underwriters exercise this option, they will each purchase additional shares approximately in proportion to the amounts specified in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Paid by Us	
	No Exercise	Full Exercise
Per share	\$ _____	\$ _____
Total	\$ _____	\$ _____

We estimate that the total expenses of this offering to be paid by us, not including the underwriting discounts and commissions, will be approximately \$1,400,000.

We, our executive officers and directors and substantially all of our stockholders have entered into lock-up agreements with the underwriters or us. Under these agreements, we and each of these persons may

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not, without the prior written approval of Banc of America Securities LLC, offer, sell, contact to sell or otherwise dispose of or hedge our common stock or securities convertible into or exchangeable for our common stock. These restrictions will be in effect for a period of 180 days after the date of this prospectus. At any time and without notice, Banc of America Securities LLC may, in its sole discretion, release all or some of the securities from these lock-up agreements.

We will indemnify the underwriters against various liabilities, including liabilities under the Securities Act. If we are unable to provide this indemnification, we will contribute to payments the underwriters may be required to make in respect of those liabilities.

We have applied to have our common stock included for quotation on the Nasdaq National Market under the symbol "ACRD."

In connection with this offering, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our common stock, including:

stabilizing transactions;

short sales;

syndicate covering transactions;

imposition of penalty bids; and

purchases to cover positions created by short sales.

Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of our common stock while this offering is in progress. Stabilizing transactions may include making short sales of our common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock from us or in the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' over-allotment option referred to above, or may be "naked" shorts, which are short positions in excess of that amount.

The underwriters may close out any covered short position either by exercising their over-allotment option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares pursuant to the over-allotment option.

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 common stock in the open market that could adversely affect investors who purchased in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The representatives also may impose a penalty bid on underwriters and selling group members. This means that if the representatives purchase shares in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters or selling group members that sold those shares as part of this offering to repay the selling concession received by them.

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As a result of these activities, the price of our common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdaq National Market, in the over-the-counter market or otherwise.

The underwriters do not expect sales to accounts over which they exercise discretionary authority to exceed 5% of the total number of shares of common stock offered by this prospectus.

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Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations among us and the representatives of the underwriters. The primary factors to be considered in determining the initial public offering price include:

the economic conditions in and future prospects for the industry in which we compete;

our past and present operating performance and financial condition;

our prospects for future earnings;

an assessment of our management;

the present state of our development;

the prevailing conditions of the equity securities markets at the time of this offering; and

current market valuations of publicly traded companies considered comparable to our company.

At our request, the underwriters have reserved up to 5% of the common stock being offered by this prospectus for sale to our directors, employees, business associates and related persons at the public offering price. The sales will be made by Banc of America Securities LLC through a directed share program. We do not know if these persons will choose to purchase all or any portion of these reserved shares, but any purchases they do make will reduce the number of shares available to the general public. These persons must commit to purchase no later than the close of business on the day following the date of this prospectus. Any directors, employees or other persons purchasing such reserved shares will be prohibited from disposing of or hedging such shares for a period of at least 180 days after the date of this prospectus.

A prospectus in electronic form may be made available on the websites maintained by one or more of the underwriters participating in this offering. Other than the prospectus in electronic format, the information on any such website, is not part of the prospectus.

The underwriters and their affiliates may from time to time engage in future transactions with us and our affiliates and provide services to us and our affiliates in the ordinary course of their business.

### LEGAL MATTERS

The validity of the shares of common stock offered in this prospectus will be passed upon for us by Loeb & Loeb LLP, New York, New York. Shearman & Sterling LLP New York, New York, will pass upon certain legal matters in connection with this offering for the underwriters.

### EXPERTS



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The consolidated financial statements of Acorda Therapeutics, Inc. and subsidiary as of June 30, 2002 and 2003, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the years in the three-year period ended June 30, 2003, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent accountants, appearing elsewhere herein and upon the authority of said firm as experts in accounting and auditing.

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### WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the common stock offered by this prospectus. As permitted by the rules and regulations of the SEC, this prospectus, which is a part of the registration statement, omits various information, exhibits, schedules and undertakings included in the registration statement. For further information pertaining to us and the common stock offered under this prospectus, reference is made to the registration statement and the attached exhibits and schedules. Although required material information has been presented in this prospectus, statements contained in this prospectus as to the contents or provisions of any contract or other document referred to in this prospectus may be summary in nature, and in each instance reference is made to the copy of this contract or other document filed as an exhibit to the registration statement, and each statement is qualified in all respects by this reference.

A copy of the registration statement may be inspected without charge at the public reference facilities maintained by the SEC at the Public Reference Room, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of all or any part of the registration statement may be obtained from the SEC's offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference facilities. In addition, registration statements and certain other filings made with the commission through its Electronic Data Gathering, Analysis and Retrieval system, including our registration statement and all exhibits and amendments to our registration statement, are publicly available through the SEC's website at [www.sec.gov](http://www.sec.gov). After this offering, we will have to provide the information and reports required by the Securities Exchange Act of 1934, as amended, and we will file periodic reports, proxy statements and other information with the Securities and Exchange Commission.

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### ACORDA THERAPEUTICS, INC. AND SUBSIDIARY (A Development Stage Enterprise)

#### INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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#### Independent Auditors' Report

The Board of Directors and Stockholders  
Acorda Therapeutics, Inc.:

We have audited the accompanying consolidated balance sheets of Acorda Therapeutics, Inc. and subsidiary (a development stage enterprise) as of June 30, 2002 and 2003, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for

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each of the years in the three-year period ended June 30, 2003. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Acorda Therapeutics, Inc. and subsidiary (a development stage enterprise) as of June 30, 2002 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended June 30, 2003, in conformity with accounting principles generally accepted in the United States of America.

KPMG LLP

September 26, 2003, except as to Note 13  
which is as of December 15, 2003

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### ACORDA THERAPEUTICS, INC. AND SUBSIDIARY (A Development Stage Enterprise)

#### Consolidated Balance Sheets

	June 30,		September 30,	Pro Forma September 30,
	2002	2003	2003	2003
			(Unaudited)	(Unaudited)
<b>Assets</b>				
Current assets:				
Cash and cash equivalents	\$ 27,012,412	\$ 48,319,175	\$ 8,032,578	\$ 8,032,578
Restricted cash	249,502	252,997	253,566	253,566
Short-term investments	2,835,526	12,250,449	43,835,503	43,835,503
Grant receivable	147,721	361,607	163,674	163,674
Prepaid expenses	74,128	244,982	606,488	606,488
Deferred offering costs			807,037	807,037
Other current assets	87,324	318,176	212,902	212,902
	30,406,613	61,747,386	53,911,748	53,911,748
Property and equipment, net of accumulated depreciation	2,939,968	2,947,747	3,000,954	3,000,954
Minority interest Related party	110,374			
Other assets	139,816	111,516	111,516	111,516
	\$ 33,596,771	\$ 64,806,649	\$ 57,024,218	\$ 57,024,218
<b>Liabilities, Mandatorily Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>				
Current liabilities:				
Accounts payable	\$ 1,454,636	\$ 787,980	\$ 1,045,754	\$ 1,045,754
Accounts payable to Related party	965,435	173,668	2,555,758	2,555,758
Accrued expenses and other current liabilities	825,192	1,291,774	2,731,361	2,731,361

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	June 30,	September 30,	Pro Forma September 30,
Due to Related party	64,394	113,260	129,229
Deferred revenue		95,462	57,251
Current portion of notes payable		310,233	317,027
<b>Total current liabilities</b>	<b>3,309,657</b>	<b>2,772,377</b>	<b>6,836,380</b>
Long-term portion of notes payable		612,087	530,236
Long-term convertible notes payable principal amount, plus accrued interest less unamortized debt discount of \$636,749 and \$417,814 as of June 30, 2002 and 2003, respectively and \$373,594 as of September 30, 2003 (unaudited) Related party	7,538,251	7,907,186	7,995,236
<b>Mandatorily Redeemable Convertible Preferred Stock:</b>			
Series E convertible preferred stock \$0.001 par value. Authorized, issued, and outstanding 7,472,612 shares as of June 30, 2002 and 2003 and September 30, 2003 (unaudited) (Redemption and liquidation value of \$20,176,052 at June 30, 2003 and September 30, 2003 (Unaudited))	20,066,835	476,478	1,463,067
Series I convertible preferred stock \$0.001 par value. Authorized 10,282,777, 10,204,047 shares and 10,204,047 shares as of June 30, 2002 and 2003, and September 30, 2003 (unaudited) respectively; issued and outstanding, 10,204,047 shares as of June 30, 2002 and 2003 and September 30, 2003 (unaudited) (Redemption and liquidation value of \$39,693,743 at June 30, 2003 and September 30, 2003 (Unaudited))	39,591,760	1,024,149	2,960,797
Series J convertible preferred stock \$0.001 par value. Authorized, issued, and outstanding 112,790,233 shares as of June 30, 2003 and September 30, 2003 (unaudited) (Redemption and liquidation value of \$56,003,896 at June 30, 2003 and \$57,109,240 at September 30, 2003 (Unaudited))		16,685,902	19,754,999
<b>Commitments and contingencies</b>			
<b>Stockholders' equity (deficit):</b>			
Series A convertible preferred stock, \$0.001 par value. Authorized 1,656,000, 1,646,068 and 1,646,068 shares as of June 30, 2002 and 2003, and September 30, 2003 (unaudited) respectively; issued and outstanding 1,306,068 shares as of June 30, 2002 and 2003 (liquidation value of \$1,306,068 at June 30, 2003 and September 30, 2003 (Unaudited))	1,306	1,306	1,306
Series B convertible preferred stock, \$0.001 par value. Authorized 2,250,000 shares as of June 30, 2002 and 2003; and September 30, 2003 (unaudited) issued and outstanding 900,000 shares as of June 30, 2002 and 2003 and September 30, 2003 (liquidation value of \$1,800,000 at June 30, 2003 and September 30, 2003 (Unaudited))	900	900	900
Series C convertible preferred stock \$0.001. Authorized, issued, and outstanding 333,333 shares as of June 30, 2002 and 2003 and September 30, 2003 (unaudited) (liquidation value of \$999,999 at June 30, 2003 and September 30, 2003 (Unaudited))	333	333	333
Series D convertible preferred stock, \$0.001. Authorized 400,000 shares as of June 30, 2002 and 2003, and September 30, 2003 (unaudited); issued and outstanding none			
Series F convertible preferred stock, \$0.001 par value. Authorized, issued, and outstanding 2,300,000 shares as of June 30, 2002 and 2003 and September 30, 2003 (unaudited) (liquidation value of \$11,999,100 at June 30, 2003 and at September 30, 2003 (Unaudited))	2,300	2,300	2,300
Series G convertible preferred stock, \$0.001. Authorized 1,250,000 shares as of June 30, 2002 and 2003, and at September 30, 2003 (Unaudited) issued, and outstanding none			
Series H convertible preferred stock, \$0.001 par value. Authorized, issued, and outstanding 1,575,229 shares as of June 30, 2002 and 2003 and September 30, 2003 (unaudited) (liquidation value of \$5,119,494 as of June 30, 2003 and as of September 30, 2003 (Unaudited))	1,575	1,575	1,575
Common stock, \$0.001 par value. Authorized 33,670,451, 260,000,000 and 260,000,000 shares as of June 30, 2002 and 2003 and September 30, 2003 (Unaudited), respectively; issued and outstanding 248,994 shares as of June 30, 2002 and 2003 respectively and 248,995 at September 30, 2003 (Unaudited)	249	249	249
Additional paid-in capital	28,408,252	126,386,834	131,783,252
Deficit accumulated during the development stage	(65,324,647)	(91,058,949)	(114,282,541)

	June 30,		September 30,		Pro Forma September 30,
Other comprehensive loss		(6,078)		(23,871)	(23,871)
Total stockholders' equity (deficit)	(36,909,732)	35,328,470	17,483,503	41,662,366	
Total liabilities, mandatorily redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 33,596,771	\$ 64,806,649	\$ 57,024,218	\$ 57,024,218	

See accompanying Notes to Consolidated Financial Statements

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**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**  
(A Development Stage Enterprise)

**Consolidated Statements of Operations**

	Year ended June 30			Three months ended September 30,		Period From March 17, 1995 (inception) to September 30, 2003
	2001	2002	2003	2002	2003	
				(unaudited)	(unaudited)	(unaudited)
Grant revenue	\$ 462,407	\$ 131,592	\$ 473,588	\$ 201,704	\$ 3,838,821	
Operating expenses incurred in the development stage:						
Research and development	6,141,705	11,146,415	17,526,656	3,498,491	9,874,329	56,049,772
Research and development Related party	2,223,407	4,686,671	2,265,233	668,557	2,798,626	35,149,584
General and administrative	3,489,509	6,636,306	6,387,999	1,767,977	10,801,871	33,656,664
Total operating expenses	11,854,621	22,469,392	26,179,888	5,935,025	23,474,826	124,856,020
Operating loss	(11,392,214)	(22,337,800)	(25,706,300)	(5,935,025)	(23,273,122)	(121,017,199)
Other income (expense):						
Interest expense			(77,712)	(11,933)	(19,645)	(97,357)
Interest expense Related party	(443,400)	(407,686)	(368,935)	(92,234)	(88,050)	(2,668,463)
Interest income	1,824,050	983,876	392,742	128,122	157,225	5,195,214
Other income			25,903	25,903		25,903
Total other income (expense)	1,380,650	576,190	(28,002)	49,858	49,530	2,455,297
	698,894	580,467				4,279,361

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Minority interest Related party	Three months ended September 30,					Period From March 17, 1995 (inception) to September 30, 2005
Net loss	(9,312,670)	(21,181,143)	(25,734,302)	(5,885,167)	(23,223,592)	(114,282,541)
Beneficial conversion feature, accretion of issuance costs, preferred dividends, and fair value of warrants issued to convertible preferred stockholders	(35,897)	(54,973)	(24,320,031)	(13,743)	(5,992,334)	(30,945,726)
Net loss allocable to common stockholders	\$ (9,348,567)	\$ (21,236,116)	\$ (50,054,333)	\$ (5,898,910)	\$ (29,215,926)	\$ (145,228,267)
Net loss per share allocable to common stockholders basic and diluted	\$ (39.08)	\$ (86.05)	\$ (201.03)	\$ (23.69)	\$ (117.34)	
Weighted average common shares outstanding used in computing net loss per share allocable to common stockholders basic and diluted	239,207	246,778	248,994	248,994	248,995	

See accompanying Notes to Consolidated Financial Statements.

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**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**  
**(A Development Stage Enterprise)**  
**Consolidated Statements of Changes in Stockholders' Equity (Deficit)**

**Stockholders' Equity (Deficit)**

	Series A convertible preferred stock		Series B convertible preferred stock		Series C convertible preferred stock		Series F convertible preferred stock		Series H convertible preferred stock		Common Stock		Additional paid-in capital	Stock subscriptions receivable	Deficit accumulated during development stage	Accumulated other comprehensive income (Loss)
	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value				
Issuance of common stock in March 1995, \$0.12 per share		\$		\$		\$		\$		\$	216,875	\$ 2,603	\$ 23,422	\$ (24,750)		\$
One-for twelve reverse stock split																
Issuance of Series A convertible	610,000	610														

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Stockholders' Equity (Deficit)

preferred stock in May 1995, \$1.00 per share									
Contribution of services								125,000	
Issuance of detachable warrants with Series A convertible preferred stock								44,971	
Amortization of Series A warrants								(44,971)	
Net loss									(276,998)

Balance at June 30, 1995	610,000	610			216,875	217	760,198	(24,750)	(276,998)
Issuance of common stock in February through March and June 1996, \$1.20 per share					4,333	52	5,148	(4,800)	
Exercise of stock warrants					7,500	90	810		
One-for twelve reverse stock split						(130)	130		
Issuance of Series A convertible preferred stock in December 1995 and April 1996, \$1.00 per share	450,000	450					449,550		
Contribution of services							125,000		
Research and development expense for issuance of stock options to non-employees							155,189		
Net loss									(1,116,738)

Balance at June 30, 1996	1,060,000	1,060			228,708	229	1,496,025	(29,550)	(1,393,736)
Issuance of Series A convertible preferred stock in January 1997, \$1.00 per share	195,000	195					194,805		
Issuance of Series B convertible preferred stock, net in January 1997, \$2.00 per share			750,000	750			1,499,250		
Discount on below-market interest rate convertible notes							2,173,127		







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Stockholders' Equity (Deficit)

	Series A convertible preferred stock		Series B convertible preferred stock		Series C convertible preferred stock		Series F convertible preferred stock		Series H convertible preferred stock		Common Stock		Additional paid-in capital	Stock sub- scriptions receivable	Deficit accumulated during development stage	Accumulated other comprehensive income (Loss)
	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value				
Issuance of common stock in January and June 2001, \$0.84 per share		\$		\$		\$		\$		\$	6,307	\$ 75	\$ 5,115	\$		\$
Payment received on notes due from shareholders												(68)	68	3,000		
Research and development expense for issuance of stock options to non-employees													94,397			
Compensation expense for issuance of stock options to employees													643,028			
Accretion of issuance costs related to Series E mandatorily redeemable convertible preferred stock													(27,337)			
Accretion of issuance costs related to Series I mandatorily redeemable convertible preferred stock													(8,560)			
Net loss																(9,312,670)
Balance at June 30, 2001	1,255,000	1,255	750,000	750			2,300,000	2,300	1,575,229	1,575	244,598	245	25,096,144			(44,143,504)
Issuance of Series A convertible preferred stock in May 2002, \$1.00 per share	51,068	51											22,749			
Issuance of Series B convertible preferred stock in January 2002, \$2.00 per share			150,000	150									299,850			
Issuance of Series C convertible preferred stock					333,333	333							999,666			

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Stockholders' Equity (Deficit)

in															
February 2002, \$3.00 per share															
Issuance of common stock in September and October 2001 and February 2002, \$4.68 per share								4,396	53					20,566	
One-for-twelve reverse stock split									(49)					49	
Research and development expense for issuance of stock options to non-employees														74,624	
Compensation expense for issuance of stock options to employees														1,331,911	
Accretion of issuance costs related to Series E mandatorily redeemable convertible preferred stock														(27,337)	
Accretion of issuance costs related to Series I mandatorily redeemable convertible preferred stock														(27,636)	
Research and development expense for issuance of warrants and Series C preferred stock on obtaining Phase II clinical trial approval														617,666	
Net loss															(21,181,143)
Balance at June 30, 2002	1,306,068	1,306	900,000	900	333,333	333	2,300,000	2,300	1,575,229	1,575	248,994	249	28,408,252	(65,324,647)	
Research and development expense for issuance of stock options to non-employees														(6,539)	
Compensation expense for issuance of stock options to employees														1,580,054	
Accretion of issuance costs														(27,337)	

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Stockholders' Equity (Deficit)

related to Series E mandatorily redeemable convertible preferred stock		
Accretion of issuance costs related to Series I mandatorily redeemable convertible preferred stock	(27,636)	
Accretion of issuance costs related to Series J mandatorily redeemable convertible preferred stock	(10,990)	
Accrual of preferred dividend on Series J mandatorily redeemable convertible preferred stock	(629,895)	
Beneficial conversion feature for reduction in conversion price	80,730,286	
Deemed dividends on preferred stock for reduction in conversion price	(20,860,491)	
Deemed dividends on preferred stock for reduction in conversion price	(1,656,854)	
Issuance of preferred stock with beneficial conversion feature	39,994,812	
Deemed dividends on preferred stock for issuance of preferred stock with beneficial conversion feature	(1,106,828)	
<i>Comprehensive loss</i>		
Unrealized loss on investment securities		(6,078)
Net loss	(25,734,302)	

Stockholders' Equity (Deficit)

Total  
Comprehensive  
loss

Balance at June 30, 2003	1,306,068	\$ 1,306	900,000	\$ 900	333,333	\$ 333	2,300,000	\$ 2,300	1,575,229	\$ 1,575	248,994	\$ 249	\$ 126,386,834	\$ (91,058,949)	\$ (6,078)
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See accompanying Notes to Consolidated Financial Statements.

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**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**  
(A Development Stage Enterprise)  
Consolidated Statements of Changes in Stockholders' Equity (Deficit)

Stockholders' Equity (deficit)

	Series A convertible preferred stock		Series B convertible preferred stock		Series C convertible preferred stock		Series F convertible preferred stock		Series H convertible preferred stock		Common Stock		Additional paid-in capital	Subscriptions receivable	Deficit accumulated during the development stage	Accumulated Comprehensive Income (Loss)
	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value				
Balance at June 30, 2003	1,306,068	1,306	900,000	900	333,333	333	2,300,000	2,300	1,575,229	1,575	248,994	249	126,386,834		(91,058,949)	(6,078)
Research and development expense for issuance of stock options to nonemployees (unaudited)													4,285			
Compensation expense for issuance of stock options to employees (unaudited)													11,384,457			
Exercise of stock options (unaudited)											1			10		
Accretion of issuance costs related to Series E mandatorily redeemable convertible preferred stock (unaudited)																(4,094)
Accretion of issuance costs related to Series I mandatorily redeemable convertible preferred stock (unaudited)																(3,717)
																(16,161)



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	Three months ended September 30, (unaudited)					Period from March 17, (unaudited) (inception) to September 30, 2003
<b>Cash flows from operating activities:</b>						
Net loss	\$ (9,312,670)	\$ (21,181,143)	\$ (25,734,302)	\$ (5,885,156)	\$ (23,223,592)	\$ (114,282,541)
Adjustments to reconcile net loss to net cash used in operating activities:						
Stock compensation expense	737,425	1,406,535	1,573,514	399,296	11,388,742	17,460,200
Expensing of warrants and beneficial conversion feature on completing Phase II clinical trial		617,666				617,666
Amortization of note discount	293,400	257,686	218,935	54,733	44,220	1,799,533
Depreciation and amortization expense	123,449	417,479	740,201	168,718	195,617	1,573,963
Minority interest - Related party	(698,894)	(580,467)				(4,279,361)
Changes in assets and liabilities						
Decrease (increase) in grant receivables	143,263	50,993	(213,886)	53,906	197,933	(163,674)
(Increase) decrease in prepaid expenses and other current assets	(119,353)	84,917	(401,706)	(73,733)	(256,232)	(819,390)
(Increase) decrease in other assets	(110,200)	23,639	28,300	15,000		(111,516)
Increase (decrease) in accounts payable and accrued expenses and other current liabilities	56,720	223,984	(200,072)	(414,395)	1,697,361	3,777,117
Increase (decrease) in amounts due to Related party	749,846	579,983	(592,901)	(195,242)	2,441,889	3,553,817
Deferred revenue			95,462		(38,211)	57,251
Restricted cash	(11,901)	(6,015)	(3,495)	(985)	(569)	(253,566)
<b>Net cash used in operating activities</b>	<b>(8,148,915)</b>	<b>(18,104,743)</b>	<b>(24,489,950)</b>	<b>(5,877,858)</b>	<b>(7,552,842)</b>	<b>(91,070,501)</b>
<b>Cash flows from investing activities:</b>						
Purchases of property and equipment	(936,510)	(2,230,916)	(747,981)	(269,418)	(248,824)	(4,574,918)
Purchases of short-term investments		(2,835,526)	(18,669,923)	(1,952,431)	(36,600,338)	(58,105,787)
Proceeds from maturities of short-term investments			9,248,922		4,997,491	14,246,413
<b>Net cash used in investing activities</b>	<b>(936,510)</b>	<b>(5,066,442)</b>	<b>(10,168,982)</b>	<b>(2,221,849)</b>	<b>(31,851,671)</b>	<b>(48,434,292)</b>
<b>Cash flows from financing activities:</b>						
Proceeds from issuance of preferred stock, net of issuance costs	39,555,564	1,322,799	54,933,001			135,652,640
Proceeds from sale of interest in subsidiary						3,000,000
Funding received from minority owner	411,421	757,566	110,374	110,374		1,279,361
Proceeds received on notes due from shareholders	3,000					29,550
Proceeds from issuance of common stock	5,190	20,619			10	35,594
Deferred offering costs					(807,037)	(807,037)
Proceeds from issuance of notes payable			1,163,511	1,163,511		1,163,511
Repayments of notes payable			(241,191)	(33,161)	(75,057)	(316,248)
Proceeds from issuance of long-term convertible notes payable						7,500,000
<b>Net cash provided by (used in) financing activities</b>	<b>39,975,175</b>	<b>2,100,984</b>	<b>55,965,695</b>	<b>1,240,724</b>	<b>(882,084)</b>	<b>147,537,371</b>

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	Three months ended September 30,				Period from March 17, 1995, (inception) to September 30, 2003	
Net increase (decrease) in cash and cash equivalents	30,889,750	(21,070,201)	21,306,763	<del>(6,838,983)</del>	<del>(40,280,397)</del>	8,032,578
Cash and cash equivalents at beginning of period	17,192,863	48,082,613	27,012,412	27,012,412	48,319,175	
Cash and cash equivalents at end of period	\$ 48,082,613	\$ 27,012,412	\$ 48,319,175	\$ 20,153,429	\$ 8,032,578	\$ 8,032,578
Supplemental disclosure:						
Issuance of common stock for notes receivable	\$	\$	\$	\$	\$	\$ 29,550
Discount on below-market interest rate convertible notes	\$	\$	\$	\$	\$	\$ 2,173,127
Cash paid for interest	\$	\$	\$ 77,712	\$ 11,933	\$ 19,645	\$ 97,357

See accompanying Notes to Consolidated Financial Statements.

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**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**  
(A Development Stage Enterprise)

**Notes to Consolidated Financial Statements**

**(1) Organization and Business Activities**

Acorda Therapeutics, Inc. ("Acorda" or the "Company") was incorporated in Delaware on March 17, 1995. The Company is a development stage biopharmaceutical company engaged in the identification, development and commercialization of therapies that improve neurological function in people with spinal cord injury, multiple sclerosis and related disorders of the central nervous system.

The Company is devoting substantially all of its efforts toward conducting pharmaceutical development, conducting clinical trials, pursuing regulatory approval for products under development and raising needed capital. In the course of its activities the Company has sustained operating losses and expects such losses to continue for the foreseeable future.

The Company has not generated product revenues and has not achieved profitable operations or positive cash flows from operations. There is no assurance that profitable operations, if ever achieved, could be sustained on a continuing basis. The Company's deficit accumulated during the development stage aggregated \$91,058,949, through June 30, 2003, and \$114,282,541 through September 30, 2003 (unaudited) and it expects to incur substantial and increasing losses in future periods. Further, the Company's future operations are dependent on the success of the Company's research and commercialization efforts and, ultimately, upon regulatory approval and market acceptance of the Company's products.

The Company plans to finance its operations with a combination of public and/or private placement of equity securities, grants, payments from strategic research and development arrangements, and revenues from future product sales. There are no assurances that the Company will be successful in obtaining an adequate level of financing needed for the long-term development and commercialization of its planned products. The Company believes that its current financial resources and sources of liquidity should be adequate to fund operations through December 31, 2004, based on the Company's current projected spending levels.

**(2) Summary of Significant Accounting Policies**

***Principles of Consolidation***

The accompanying consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States of America include the results of operations of the Company and its majority owned subsidiary (see Notes 7 and 14). All intercompany accounts and transactions have been eliminated in consolidation.

***Interim Financial Information***

The consolidated financial information and information in the notes to consolidated financial statements as of September 30, 2003 and for the three months ended September 30, 2002 and 2003, are unaudited but in management's opinion, include all adjustments, consisting of normal

and recurring adjustments, that the Company considers necessary for a fair presentation, in all material respects, of its consolidated financial position, operating results, and cash flows for the interim date and periods presented. The results of operations for the three months ended September 30, 2003 are not necessarily indicative of the results to be expected for the full year or future periods.

#### ***Use of Estimates***

The preparation of the consolidated financial statements requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the

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reported amounts of revenues and expenses during the period. Significant items subject to such estimates and assumptions include research and development, income taxes, beneficial conversion charge and stock warrants and option accounting. Actual results could differ from those estimates.

#### ***Cash and Cash Equivalents***

The Company considers all highly liquid debt instruments with original maturities of three months or less to be cash equivalents. All cash and cash equivalents are held in United States financial institutions and money market funds, which are unrestricted as to withdrawal or use. To date, the Company has not experienced any losses on its cash and cash equivalents. The carrying amount of cash and cash equivalents approximates its fair value due to its short-term and liquid nature.

#### ***Restricted Cash***

Restricted cash represents a certificate of deposit placed by the Company with a bank for issuance of a letter of credit in the amount of \$226,825 to the Company's lessor for office space.

#### ***Short-Term Investments***

Short-term investments consist of corporate debt securities with original maturities greater than three months. In accordance with Statement of Financial Accounting Standards ("SFAS") No. 115 ("SFAS 115"), *Accounting for Certain Investments in Debt and Equity Securities*, the Company classifies its short-term investments as available-for-sale. Available-for-sale securities are recorded at fair value of the investments based on quoted market prices. The Company considered all of these investments to be available-for-sale.

Unrealized holding gains and losses, which are determined to be temporary, on available-for-sale securities are excluded from earnings and are reported as a separate component of other comprehensive loss.

Premiums and discounts on investments are amortized over the life of the related available-for-sale security as an adjustment to yield using the effective-interest method. Dividend and interest income are recognized when earned. Realized gains and losses are determined on the average cost method. Amortized premiums and discounts, dividend and interest income and realized gains and losses are included in interest income.

#### ***Property and Equipment***

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed on the straight-line basis over the estimated useful lives of the various assets, which range from three to seven years. Leasehold improvements are recorded at cost, less accumulated amortization, which is computed on the straight-line basis over the shorter of the useful lives of the asset or the remaining lease term. Expenditures for maintenance and repairs are charged to expense as incurred.

#### ***Patent Costs***

Patent application and maintenance costs are expensed as incurred.

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### ***Research and Development***

Research and development expenses include the costs associated with internal research and development by the Company and research and development conducted on behalf of the Company by outside advisors, sponsored university-based research agreements, and clinical study vendors. All research and development costs are expensed as incurred. Costs incurred in obtaining technology licenses are charged immediately to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future uses.

### ***Long-Lived Assets***

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, which the Company adopted on July 1, 2002, the Company monitors events or changes in circumstances that may indicate carrying amounts of its long-lived assets may not be recoverable. When such events or changes in circumstances are present, the Company assesses the recoverability of its assets by determining whether the carrying amount of its assets will be recovered through undiscounted, expected future cash flows. Should the Company determine that the carrying values of specific long-lived assets are not recoverable, the Company would record a charge to operations to reduce the carrying value of such assets to their fair values. The Company considers various valuation factors, principally discounted cash flows, to assess the fair values of long-lived assets.

Prior to the adoption of SFAS No. 144, the Company accounted for long-lived assets in accordance with SFAS No. 121, *Accounting for Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of*.

### ***Accounting for Income Taxes***

Income taxes are accounted for under the asset and liability method with deferred tax assets and liabilities recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be reversed or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance for the amounts of any tax benefits which, more likely than not, will not be realized.

### ***Revenue Recognition Grants***

Revenue related to research and development grants is recognized when the related research expenses are incurred and the Company's specific performance obligations under the terms of the respective contract are satisfied. To the extent expended, grant funding related to purchases of equipment is deferred and amortized over the shorter of the equipment's useful life or the life of the related contract. Revenue recognized in the accompanying consolidated financial statements is not subject to repayment. Payments, if any, received in advance of performance under the contract are deferred and recognized as revenue when earned. Since inception through June 30, 2003, the Company has recognized \$3,637,117 in grant revenue, of which \$3,370,972 has been received by the Company.

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### ***Concentration of Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of investments in cash and cash equivalents, restricted cash and debt securities. The Company maintains such financial instruments with approved financial institutions. The Company is exposed to credit risks in the event of default by the financial institutions or issuers of investments in excess of FDIC insured limits. The Company performs periodic evaluations of the relative credit standing of these financial institutions and limits the amount of credit exposure with any institution.

The Company is substantially dependent upon Elan Corporation plc ("Elan") for several activities related to the development and commercialization of Fampridine-SR. The Company will rely on Elan to complete the chemistry, manufacturing and controls section of the New Drug Application ("NDA") for Fampridine-SR in spinal cord injury. If Elan fails to provide it in a complete and timely manner the Company could incur delays in filing of its NDA for Fampridine-SR in spinal cord injury.

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The Company relies upon Elan to manufacture at least 75% of its Fampridine-SR product requirements. In addition, the Company does not have direct contractual relationships with the suppliers of fampridine, the active pharmaceutical ingredient in Fampridine-SR, referred to as API. Currently, the Company is relying 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 by the Company. Although other suppliers of API are readily available, a change to a supplier, that was not previously approved in the Company's NDA may require formal approval by the Food and Drug Administration ("FDA") before the Company could use the new suppliers' API product. Any delays in obtaining API to manufacture Fampridine-SR would delay the commercialization of Fampridine-SR.

If Elan were to file for bankruptcy under the laws of Ireland the Company's rights to Fampridine-SR could be transferred, altered or terminated.

### ***Fair Value of Financial Instruments***

The fair value of a financial instrument represents the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced sale or liquidation. Significant differences can arise between the fair value and carrying amounts of financial instruments that are recognized at historical cost amounts.

The following methods are used to estimate the Company's financial instruments:

- (a) Cash and cash equivalents, grant receivables, accounts payable and accrued liabilities approximate their fair value due to the short-term nature of these instruments;
- (b) Available-for-sale securities are recorded based on quoted market prices;
- (c) Notes payable carrying value approximate fair value as the interest rates on these notes approximate market rate of interest; and

It is not practical for the Company to estimate the fair value of the convertible notes payable to Elan due to the specific provisions of these notes including the uncertainty of the timing of repayment which is tied to regulatory approval of certain products. The terms of these notes are disclosed at Note 10. In September 2003, the notes were restructured, see Note 14.

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### ***Net Loss Per Share***

Net loss per share is computed in accordance with SFAS No. 128, *Earnings Per Share*, by dividing the net loss allocable to common stockholders by the weighted average number of shares of common stock outstanding. The Company has certain options, warrants, convertible preferred stock and mandatorily redeemable convertible preferred stock (see Notes 3 and 7), which have not been used in the calculation of diluted net loss per share because to do so would be anti-dilutive. As such, the numerator and the denominator used in computing both basic and diluted net loss per share allocable to common stockholders for each year are equal. The Company has reflected the beneficial conversion feature of \$23,624,173, accretion of issuance costs of \$65,963, and preferred dividend of \$629,895 in the 2003 net loss allocable to common stockholders (See Notes 3 and 7). The 2001 and 2002 net loss allocable to common stockholders reflect accretion of issuance costs and the beneficial conversion feature on issuance of Series C convertible preferred stock in the net loss allocable to common stockholders (See Note 10).

### ***Stock-Based Compensation***

At June 30, 2003, the Company had various stock-based employee and non-employee compensation plans, which are described more fully in Note 8. The Company accounts for options granted to employees and directors in accordance with the fair value method of SFAS No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123* and related interpretations. As such, compensation expense is recorded on stock option grants based on the fair value of the options granted, which is estimated on the date of grant using the Black-Scholes option-pricing model and it is recognized on a straight-line basis over the vesting period. The Company accounts for stock options granted to non-employees on a fair-value basis in accordance with SFAS No. 123, Emerging Issues Task Force Issue ("EITF") No. 96-18, *Accounting for Equity Instruments That Are*

*Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, and FASB Interpretation No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans an Interpretation of APB Opinion No. 15 and 25.* As a result, the non-cash charge to operations for non-employee options with vesting or other performance criteria is affected each reporting period by changes in the estimated fair value of the Company's common stock. All the stock option grants made by the Company since fiscal 1996 are in the money. The two factors which most affect charges or credits to operations related to stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded and the volatility of such fair value. If the Company's estimates of the fair value of these equity instruments changes, it would have the effect of changing compensation expense. Because shares of the Company's common stock have not been publicly traded, the Company estimates the fair value of its common stock based on the most recent previous sale of convertible preferred stock (convertible on a one-for-one basis (one-for-twelve post reverse split) into common stock). The Company does not discount the issuance price of its preferred stock in estimating the fair value of its common stock.

### ***Segment Information***

The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer. The Company does not operate separate lines of business with respect to any of its product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate product candidates or by location and does not have separately

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reportable segments as defined by SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*.

### ***Derivatives***

On July 1, 2001, the Company adopted SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. This Statement requires the recognition of all derivative instruments as either assets or liabilities in the consolidated balance sheet, and the periodic adjustment of those instruments to fair value. The classification of gains and losses resulting from changes in the fair values of derivatives is dependent on the intended use of the derivative and its resultant designation.

During the first quarter of fiscal 2003, the Company entered into a foreign currency option transaction to sell (put option) U.S. dollars to British Pounds amounting to \$294,739, with a strike price of \$1.4280. The option expiration date was January 31, 2003. The Company's primary purpose for entering into this transaction was to cover an exchange gain or loss on a British Pound denominated contract to be entered into with a foreign company. This contract was not entered into by the Company. During fiscal 2003, the Company recorded a gain of \$25,903 related to this option transaction, which is classified as other income in the consolidated statement of operations.

### ***Comprehensive income (loss)***

SFAS No. 130, *Reporting Comprehensive Income* ("SFAS No. 130") establishes standards for the reporting and display of comprehensive income (loss) and its components in a full set of financial statements. SFAS No. 130 requires that unrealized losses from the Company's investment securities be included in other comprehensive income (loss).

### ***Pro Forma Consolidated Balance Sheet (Unaudited)***

Upon the consummation of the initial public offering contemplated herein, all of the outstanding shares of convertible preferred stock and mandatorily redeemable convertible preferred stock at September 30, 2003 automatically convert into 15,806,617 shares of common stock (see Note 7). The September 30, 2003 unaudited pro forma consolidated balance sheet has been prepared assuming the conversion of the convertible preferred stock and the mandatorily redeemable convertible preferred stock outstanding as of September 30, 2003, into common stock as of September 30, 2003.

### ***Pro Forma Net Loss Per Share (Unaudited)***

The following pro forma basic and diluted net loss per share allocable to common stockholders and shares used in computing pro forma basic and diluted net loss per share allocable to common stockholders have been presented reflecting the assumed automatic conversion into shares of common stock of the convertible preferred stock and mandatorily redeemable convertible preferred stock upon completion of the initial public offering contemplated herein (see Note 7), using the as converted method from the beginning of the year ended June 30, 2003 or their respective dates of issuance if later. Pro forma adjustments have been computed assuming the initial public offering was consummated at the beginning of the fiscal year ended June 30, 2003. The pro-forma adjustments to the historical net loss allocable to common stockholders for the

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three month period ended September 30, 2003 reflect the reversal of the accrued preferred dividend,

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amortized beneficial conversion charge and amortized issuance costs given the assumption that the automatic conversion occurred in the fiscal year ended June 30, 2003. Pro forma adjustments are as follows:

	Year Ended June 30, 2003	Three Months Period Ended September 30, 2003
Net loss allocable to common stockholders, as reported	\$ (50,054,333)	\$ (29,215,926)
Unamortized portion of beneficial conversion charge(1)	(97,100,925)	
Unamortized portion of issuance cost(2)	(479,457)	
Reversal of accrued preferred dividend(3)	629,895	1,105,344
Reversal of amortized beneficial conversion charge(4)		4,863,018
Reversal of amortized issuance costs(5)		23,972
<b>Pro forma net loss allocable to common stockholders</b>	<b>\$ (147,004,820)</b>	<b>\$ (23,223,592)</b>
 Pro forma net loss per share allocable to common stockholders basic and diluted	 \$ (17.67)	 \$ (1.45)
 Weighted average common shares outstanding used in computing pro forma net loss per share allocable to common stockholders basic and diluted(6)	 8,320,796	 16,055,613

- (1) Recognition of unamortized portion of beneficial conversion charge of \$97,100,925, which is calculated as follows: (x) beneficial conversion feature of \$80,730,286 for reset in conversion price (see Note 2), plus (y) beneficial conversion feature of \$39,994,812 on issuance of Series J mandatorily redeemable convertible preferred stock (see Note 3), less (z) beneficial conversion feature charged to additional paid-in capital (included in net loss allocable to common stockholders) for the year ended June 30, 2003 of \$23,624,173.
- (2) Recognition of unamortized portion of issuance cost relating to Series E, Series I and Series J preferred stock charge of \$479,457, which is calculated as follows: (x) total issuance costs relating to Series E, Series I and Series J of \$681,668 (See Note 7), less (y) accumulated amortization of issuance costs as of June 30, 2003 of \$202,211.
- (3) Reversal of accrued preferred dividend on Series J preferred stock in the amount of \$629,895 and \$1,105,344 for the year ended June 30, 2003 and for the three months period ended September 30, 2003 (see Note 7).
- (4) Reversal of beneficial conversion charge recognized for the three months period ended September 30, 2003 in the amount of \$4,863,018, which comprises of (x) beneficial conversion amortization charge of \$2,915,426 relating to Series E and Series I for reset in conversion price, plus (y) beneficial conversion amortization charge of \$1,947,592 relating to Series J for issuance of Series J mandatorily redeemable convertible preferred stock.
- (5) Reversal of amortized issuance costs for the three months period ended September 30, 2003 in the amount of \$23,972.

- (6) Weighted average common shares outstanding used in computing pro forma net less per share allocable to common stockholder is calculated based on (a) Series A through Series I equivalent common shares from the beginning of the fiscal year ended June 30, 2003, (b) additional equivalent common shares issuable for Series A through Series I, based on reset to conversion price from the date of reset; and (c) Series I equivalent common shares issuable from the May 2003 date of issuance of Series J preferred stock.

### **Recent Accounting Pronouncements**

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* ("SFAS No. 146"). SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity* (including Certain Costs Incurred in a Restructuring). The adoption of SFAS No. 146 did not impact the Company's consolidated financial statements for the fiscal year ended June 30, 2003.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* ("SFAS No. 150"). SFAS No. 150 revises the accounting for certain financial instruments that, under previous guidance, issuers could account for as equity. SFAS No. 150 requires that those instruments be classified as liabilities in statements of financial position. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective for interim periods beginning after June 15, 2003. The adoption of SFAS No. 150 did not impact the Company's consolidated financial statements for the fiscal year ended June 30, 2003.

### **(3) Beneficial Conversion Feature**

In May 2003, the Company completed a private placement of 112,790,233 shares of Series J mandatorily redeemable convertible preferred stock at \$0.49 per share for an aggregate purchase price of approximately \$55,267,000. The terms of the preferred stock are more fully described in Note 7.

As part of this financing, the original conversion price on the Series A through Series I preferred stock was reduced as a result of anti-dilution adjustments, which resulted in a beneficial conversion amounting to \$80,730,286 in accordance with EITF No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios* and EITF No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*. The beneficial conversion charge of \$20,860,491 related to Series A, Series B, Series C, Series F and Series H convertible preferred stock, which are not mandatorily redeemable and may be converted at any time at the option of the holders to common stock, has been recorded as an immediate charge to additional paid-in capital. The remaining beneficial conversion amount of \$59,869,795 related to Series E and Series I convertible preferred stock, which are mandatorily redeemable at any time on or after June 30, 2008, is being accreted ratably over the mandatory redemption period. Such accretion for the year ended June 30, 2003 and the three months ended September 30, 2003 amounted to \$1,656,854 and \$2,915,426 (unaudited), respectively, and is charged to additional paid-in capital.

In addition, the issuance of Series J mandatorily redeemable convertible preferred stock resulted in a beneficial conversion amounting to \$39,994,812 in accordance with EITF No. 98-5. The beneficial conversion is calculated based on the estimated fair value of the Company's common stock price per share at the date of issuance of Series J preferred stock of approximately \$10.14 per share of common stock, which was

calculated based on the estimated projected midpoint of the range of the Company's initial public offering price per common share at the date the accompanying consolidated financial statements were prepared and the stock price appreciation in comparable public companies from May 2003 to August 2003. The beneficial conversion feature is being accreted ratably over the mandatory redemption period, with a charge to additional paid-in capital of \$1,106,828 and \$1,947,592 (unaudited) for the year ended June 30, 2003 and the three months ended September 30, 2003, respectively.

### **(4) Short-Term Investments**

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The Company has accounted for its investments in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and determined that all of its short-term investments are classified as available-for-sale. Available-for-sale securities are carried at fair value with interest on these securities included in interest income. Available-for-sale securities consisted of the following:

	<u>Amortized Cost</u>	<u>Gross unrealized gains</u>	<u>Gross unrealized losses</u>	<u>Estimated fair value</u>
<b>Corporate debt securities</b>				
As of June 30, 2002	\$ 2,835,526			2,835,526
As of June 30, 2003	\$ 12,256,527	518,122	(524,200)	12,250,449

The contractual maturities of available-for-sale debt securities at June 30, 2003 are within one year.

Proceeds from sales and maturities of investment securities available-for-sale during fiscal 2001, 2002 and 2003 and for the period from March 17, 1995 (inception) to June 30, 2003, were \$0, \$0, \$9,255,000 and \$9,255,000, respectively. No gains/(losses) were realized on those sales during any of the periods presented. Purchases of investment securities during fiscal 2001, 2002 and 2003 and for the period March 17, 1995 (inception) to June 30, 2003, were \$0, \$2,835,526, \$18,669,923 and \$21,505,449, respectively. Short-term investments with original maturity of three months or less have been classified as cash and cash equivalents, and amounted to \$24,902,027 and \$46,638,611 as of June 30, 2002 and June 30, 2003, respectively.

### (5) Property and Equipment

Property and equipment consisted of the following as of June 30, 2003 and 2002:

	<u>2002</u>	<u>2003</u>	<u>Estimated useful lives</u>
Laboratory equipment	\$ 1,399,729	1,641,423	5 years
Furniture and fixtures	518,772	499,743	5 years
Computer equipment	315,197	474,239	3 years
Leasehold improvements	1,344,415	1,710,688	5 to 7 years
	<u>3,578,113</u>	<u>4,326,093</u>	
Less accumulated depreciation	638,145	1,378,346	
	<u>\$ 2,939,968</u>	<u>2,947,747</u>	

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Depreciation and amortization expense on property and equipment was \$123,449, \$417,479, \$740,201 and \$1,378,346 for the years ended June 30, 2001, 2002 and 2003 and for the period from March 17, 1995 (inception) to June 30, 2003, respectively.

### (6) Notes Payable

In 2003, the Company entered into two financing agreements with General Electric Capital Corporation in the aggregate amount of \$1,163,511, bearing annual fixed interest rates of 8.57% and 8.88%, to finance the purchase of certain property and equipment. Borrowings are secured by a security interest in certain property and equipment of the Company. The Company is required to pay monthly installments until October 2006. The aggregate maturities for each of the four years subsequent to June 30, 2003 are: \$310,233 in 2004, \$338,317 in 2005, \$231,937 in 2006 and \$41,833 in 2007.

For Long-term convertible notes payable to related party see Note 10.

### (7) Mandatorily Redeemable Convertible Preferred Stock and Convertible Preferred Stock

The board of directors of the Company has authorized 140,221,535 shares of convertible preferred stock, designated as Series A, B, C, D, E, F, G, H, I and J preferred stock (Series A, Series B, Series C, Series D, Series E, Series F, Series G, Series H, Series I and Series J;

collectively, the Preferred Stock). Series E, Series I and Series J are mandatorily redeemable convertible preferred stock (Redeemable Preferred Stock). The terms of the Preferred Stock are as follows:

(a)

***Dividends***

The Preferred Stock is entitled to noncumulative dividends prior to and in preference to dividends declared or paid on the common stock, at the rate of \$0.10 per share per annum for Series A through Series H and at the rate of \$0.39 per share per annum for Series I when and if declared by the board of directors. Dividends accrue on each share of Series J Preferred Stock commencing on the date of issuance, whether or not earned or declared at the rate of \$0.0392 per share per annum, based on the original issue price of Series J Preferred Stock, prior and in preference to any declaration or payment of any dividend on any other Series of Preferred Stock holders (Series A through Series I). Series J dividends are payable when declared by the Board of Directors or upon liquidation, as defined or upon redemption.

(b)

***Liquidation***

The preferred stockholders have liquidation preferences over common stockholders based on the series of Preferred Stock held. In the event of liquidation, dissolution, or winding up of the Company, each holder of shares of Series J Preferred Stock is entitled to be paid in preference to common stockholders and any other Series of Preferred Stock holders (Series A through Series I) an amount equal to the original issue price per share of \$0.49, plus all accrued or declared but unpaid dividend, as defined. After payment has been made to Series J Preferred Stock, Series I, Series E, Series F and Series H shall be entitled to receive out of the available assets, on a pro rata basis, an amount per share of \$3.89, \$1.31, \$1.07, \$1.09 and \$1.36, respectively, plus all declared but unpaid dividends on each such share issued. After payment of the above mentioned preferential amounts have been made by the Company, the holders of Series E, Series F and Series H Preferred Stock shall be entitled to be paid out of the remaining available assets an amount per share equal to

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\$0.26, \$0.21 and \$0.27, respectively, plus all declared but unpaid dividends. After payment of the above mentioned preferential amounts, the holders of Series A through Series H Preferred Stock shall be entitled to be paid out of remaining available assets an amount per share up to and including such amounts paid in accordance with as mentioned above, equal to \$1.00, \$2.00, \$3.00, \$12.50, \$3.13, \$5.22, the greater of \$2.00 and 80% of the closing price per share of the Institutional Financing, as defined, most recently completed by the Company prior to the issuance of the Series G Preferred Stock and \$3.25, respectively.

(c)

***Conversion***

The Preferred Stock is convertible into common stock at the option of the stockholder. The per share conversion price on preferred stock are Series A \$6.97, Series B \$9.12, Series C \$11.26, Series D \$9.12, Series E \$10.62, Series F \$10.62, Series G the product of (x) the number of Series G Preferred Stock surrendered and (y) the number determined by dividing (i) the greater of \$24.0 or 80% of the closing price per share of the most recently completed bona fide equity financing of the Company prior to the issuance of Series G Preferred Stock by (ii) the Series G conversion price in effect, Series H \$11.80, Series I \$13.16 and Series J \$5.88. The Preferred Stock will be automatically converted into common stock upon either the approval by written consent of the holders of a majority of the then outstanding shares of Series A, Series B, Series C, Series D, Series E, Series F, Series G, Series H and Series I voting together as a single class and upon approval by written consent of the holders of a majority of the then outstanding shares of Series J, or upon an Initial Public Offering, provided that (i) the price to the public is not less than \$14.76 per share and (ii) the aggregate proceeds are not less than approximately \$40 million (see Note 14 for modification of terms).

In the event the convertible promissory notes payable to Elan are converted into common stock, the per share conversion price on the Series I and Series J preferred stock would be adjusted to \$12.59 and \$5.48, respectively. In the event the Company issues common stock (or securities convertible into common stock) at an effective common stock issuance price of less than \$5.88 per share, the conversion price on all convertible preferred stock will be reduced based on anti-dilution provisions.

(d)

**Redemption**

Holders of Series E, Series I and Series J Preferred Stock may at any time on or after June 30, 2008, require the Company to redeem all or any portion of such Holders' Redeemable Preferred Stock at a redemption price, as specified below, provided, however, that no holder of Redeemable Preferred Stock may so require such redemption unless and until (i) the holders of not less than a majority of the Redeemable Preferred Stock then issued and outstanding make such election and (ii) the holders of a majority of the Series J Preferred Stock then issued and outstanding make such election prior to September 30, 2008. Redemption price for each share of Redeemable Preferred Stock shall be original issue price plus accrued but unpaid dividends. One half of such aggregate redemption price for all Redeemable Preferred Stock shall be payable in cash on the Redemption Date, as defined and the second half of such aggregate redemption price shall be payable in cash on the first anniversary of the Redemption Date, as defined. For the fiscal year ended June 30, 2003, the Company has accrued preferred dividends in the amount of \$629,895 for Series J Preferred Stockholders.

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(e)

**Voting**

Each holder of outstanding Preferred Stock (other than Series F) shall be entitled to the number of votes equal to the number of shares of common stock into which the shares of Preferred Stock so held could be converted. The holders of Series F Preferred Stock shall have no voting rights except as required by Delaware General Corporation Law. The board of directors consist of seven directors: (i) two directors elected by the holders of Series A, Series E and Series H Preferred Stock, voting as a single class; (ii) one director elected by Series I Preferred Stock; (iii) two directors elected by Series J Preferred Stock; (iv) one director elected by holders of common stock; and (v) one director elected by the holders of common stock and Preferred Stock, voting as a single class. The Company's certificate of incorporation includes provisions which restrict the Company from certain actions without the approval of a defined percentage of the preferred stockholders.

**Convertible Preferred Stock**

In May 1995, the Company issued 610,000 shares of Series A, at a per share price of \$1.00, for aggregate proceeds of \$610,000, and granted each purchaser a warrant to purchase one additional share of Series A for every ten Series A shares purchased, at an exercise price of \$1 per share. 51,068 of these warrants were exercised in fiscal 2002. The Company estimated the fair value of warrants at approximately \$44,971. Such value was determined by the Black-Scholes valuation method, using a risk free interest rate of 6.5%, its contractual life of seven years, an annual volatility of 73% and no expected dividends. Such amount was credited to additional paid-in capital and charged immediately to additional paid-in capital as the warrants were exercisable at any time at the option of the holder. Each warrant was exercised for one share of Series A. Through June 30, 2003, 22,800 of these warrants were exercised on a cash basis and 28,268 were exercised in a cashless exercise resulting in total proceeds of \$22,800. The remaining 9,932 of these warrants were not exercised and have expired.

In fiscal 1996 and 1997, the Company issued 450,000 and 195,000 shares of Series A, at a per share price of \$1.00, for aggregate proceeds of \$450,000 and \$195,000, respectively. In August 1996 and January 1997, the Company granted 340,000 warrants to purchase shares of Series A at an exercise price of \$1.00. These warrants expire in August 2003 and January 2004, respectively, and the number of Series A shares to be received upon exercise is one share for one warrant. The Company estimated the fair value of warrants at approximately \$254,110. Such value was determined by the Black-Scholes valuation method, using a risk free interest rate of 6.5%, the warrant's contractual life of seven years, an annual volatility of 75% and no expected dividends. Such amount was credited to additional paid-in capital and charged immediately to additional paid-in capital as the warrants were exercisable at any time at the option of the holder. In January 1997, the Company issued 750,000 shares of Series B, at a per share price of \$2.00, for aggregate proceeds of \$1,500,000. In January 2002, the Company issued 150,000 shares of Series B, at a per share price of \$2.00, for aggregate proceeds of \$300,000 (see Note 10).

In February 2002, the Company issued to Elan and affiliates 333,333 shares of Series C, at a per share price of \$3.00, for aggregate proceeds of \$999,999.

In April 1998, the Company issued to Elan 2,300,000 shares of Series F, at a per share price of approximately \$5.22, for aggregate proceeds of approximately \$12 million. Also, in April 1998, the Company

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entered into a joint venture agreement with Elan. The \$12 million proceeds from the sale of the Series F was then transferred to MS Research and Development Corp. ("MSRD"), a joint venture company of which the Company owned approximately 80% and Elan owned 20%, approximately. To purchase its approximate 20% interest, Elan invested an additional \$3 million into MSRD. The combined \$15 million was subsequently used to license research and development technology from Elan to develop Elan's proprietary oral sustained release formulation of fampridine for the treatment of multiple sclerosis. This purchase is recorded as a license payment expense in the consolidated financial statements for the fiscal year ended June 30, 1998. For the years ended June 30, 2001, 2002 and 2003, and the period from March 17, 1995 (inception) to June 30, 2003, MSRD incurred approximately \$2.2 million, \$2.9 million, \$3.2 million, and \$24.6 million, respectively, in research and development expenses, which is included as research and development expense in the accompanying statements of operations, of which Acorda funded 80% and Elan funded 20% until June 30, 2002, in accordance with the terms of the original development agreement. Elan's ownership interest in MSRD is reflected as minority interest in the accompanying statement of operations. The minority interest share of the MSRD losses were being funded by Elan, and through June 30, 2002 the Company received \$1,279,361 as a reimbursement of this funding. In fiscal 2003, Elan ceased funding its approximately 20% share of its minority interest in MSRD and the Company ceased recognizing the related minority interest benefit resulting in an increase in the Company's ownership interest to 83% pursuant to the original agreement.

In August 1999, the Company completed a private placement of 1,575,229 shares of Series H at \$3.25 per share, resulting in net proceeds to the Company of \$5,119,494 after payment of legal and certain other fees.

As of June 30, 2003, 340,000 Series A and 100,000 Series B warrants were outstanding with a weighted average exercise price per share of \$1.23. The warrants to acquire Series A and Series B Preferred Stock enable the holder to acquire 70,695 shares of common stock.

### ***Mandatorily Redeemable Convertible Preferred Stock***

The following convertible preferred stock are classified as free standing instruments based on the redemption rights and conversion option as discussed above under terms of the Preferred Stock.

In July and November 1998, the Company issued 7,472,612 shares of Series E, which are mandatorily redeemable at \$2.70 per share for an aggregate purchase price of approximately \$20,176,000. The Company incurred issuance costs of \$209,270. Such costs are netted against the proceeds of the Series E, and are being amortized over the mandatory redemption period.

In March 2001, the Company issued 10,204,047 shares of Series I which are mandatorily redeemable at \$3.89 per share for an aggregate purchase price of approximately \$39,694,000. The Company incurred issuance costs of \$138,179. Such costs are netted against the proceeds of the Series I, and are being amortized over the mandatory redemption period.

In May 2003, the Company issued 112,790,233 shares of Series J which are mandatorily redeemable at \$0.49 per share for an aggregate purchase price of approximately \$55,267,000. The Company incurred issuance costs of \$334,219. Such costs are netted against the proceeds of the Series J, and are being amortized over the mandatory redemption period.

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The changes in mandatorily redeemable convertible preferred stock since inception are as follows:

#### Mandatorily Redeemable Convertible Preferred Stock

	Series E mandatorily redeemable convertible preferred stock		Series I mandatorily redeemable convertible preferred stock		Series J mandatorily redeemable convertible preferred stock	
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount
Balance at June 30, 1998		\$		\$		\$
Issuance of Series E mandatorily redeemable convertible preferred stock	7,472,612	19,966,782				
Accretion of issuance costs		18,042				
Balance at June 30, 1999	7,472,612	19,984,824				

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Mandatorily Redeemable Convertible Preferred Stock

Accretion of issuance costs		27,337					
Balance at June 30, 2000	7,472,612	20,012,161					
Issuance of Series I mandatorily redeemable convertible preferred stock			10,204,047	39,555,564			
Accretion of issuance costs		27,337		8,560			
Balance at June 30, 2001	7,472,612	20,039,498	10,204,047	39,564,124			
Accretion of issuance costs		27,337		27,636			
Balance at June 30, 2002	7,472,612	20,066,835	10,204,047	39,591,760			
Issuance of Series J mandatorily redeemable convertible preferred stock					112,790,233	54,933,001	
Accretion of issuance costs		27,337		27,636		10,990	
Accrual of preferred dividend on Series J mandatorily redeemable convertible preferred stock							629,895
Beneficial conversion feature for reduction in conversion price		(20,176,052)		(39,693,743)			(39,994,812)
Deemed dividends on preferred stock for reduction in conversion price		558,358		1,098,496			
Deemed dividends on preferred stock for issuance of preferred stock with beneficial conversion feature							1,106,828
Balance at June 30, 2003	7,472,612	\$ 476,478	10,204,047	\$ 1,024,149	112,790,233	\$ 16,685,902	
Deemed dividends on preferred stock for reduction in conversion price (unaudited)		982,495		1,932,931			
Deemed dividends on preferred stock for issuance of preferred stock with beneficial conversion feature (unaudited)							1,947,592
Accretion of issuance costs (unaudited)		4,094		3,717		16,161	
Accrual of preferred dividend on Series J mandatorily redeemable convertible preferred stock (unaudited)							1,105,344
Balance at September 30, 2003 (unaudited)	7,472,612	1,463,067	10,204,047	\$ 2,960,797	112,790,233	\$ 19,754,999	

**(8) Common Stock and Common Stock Options and Warrants**

Upon inception of the Company in March 1995, the founders, directors, and certain employees purchased 216,875 shares of restricted common stock at a per share price of \$0.12. Full recourse promissory notes with interest rates of 7.75% were issued for the purchase price and have been received by the Company for 206,250 of these shares. The remaining amounts due were paid during 2001.

The Company's president began devoting substantial time to the formation and then-operation of the Company in November 1993. Compensation expense and additional paid in capital for the estimated value of his services has been recorded in the amount of \$125,000 in both fiscal 1995 and 1996 and \$70,000 in fiscal 1997,

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as his salary was not paid and has been forgiven. The amount recorded in fiscal 1995 includes an amount related to the period prior to incorporation. The Company's president has received a salary since 1997.

In fiscal 1996, the Company issued 4,000 shares of common stock at a per share price of \$1.20. Promissory notes due and received in fiscal 2001 were for 1,500 of these shares. The remaining promissory notes for 2,500 of these shares were paid in August 2000.

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On June 18, 1999, the Company's board of directors approved the adoption of the Acorda Therapeutics, Inc. 1999 Employee Stock Option Plan (the "Plan"). The Plan reserves 1.7 million shares for issuance through option grants (see Note 14 for changes to stock option plan). All employees of the Company are eligible to participate in the Plan, including executive officers, as well as directors, independent contractors, and agents of the Company. The Plan is administered by the Compensation Committee of the board of directors, which selects the individuals to be granted options and stock appreciation rights, determines the time or times at which options and stock appreciation rights shall be granted under the Plan, determines the number of shares to be granted subject to any option or stock appreciation right under the Plan and the duration of each option and stock appreciation right, and makes any other determinations necessary, advisable, and/or appropriate to administer the Plan. Under the Plan, each option granted expires no later than the tenth anniversary of the date of its grant. No option may be granted pursuant to the Plan more than ten years after the date on which the Plan was adopted by the board of directors and any option granted under the Plan shall, by its terms, not be exercisable more than ten years after the date of grant.

The effects of applying SFAS No. 123 in a particular year, may not be representative of the effects on reported net income or loss for future years. The fair value of each option granted is estimated on the date of grant using an option-pricing model with the following weighted average assumptions:

	Year ended June 30,			Three months ended September 30,	
	2001	2002	2003	2002	2003
					(unaudited)
<b>Employees and directors</b>					
Estimated volatility	104.4%	97.7%	94.0%	94.0%	89.81%
Expected life in years	5	5	5	5	5
Risk free interest rate	4.79%	4.41%	3.04%	3.27%	3.28%
<b>Dividend yield</b>					

The weighted average fair value per share of options granted to employees for the years ended June 30, 2001, 2002 and 2003 amounted to approximately \$33.96, \$39.96 and \$40.56, respectively. The weighted average fair value per share of options granted to employees for the three months period ended September 30, 2002 and 2003 amounted to approximately \$38.04 (unaudited) and \$12.48 (unaudited), respectively. The weighted average fair value per share of options granted to non-employees for the year ended June 30, 2001 amounted to approximately \$28.68. No options were granted to non-employees for the years ended June 30, 2002 and 2003. No options were granted to non-employees for the three months period ended September 30, 2003. The fair value of each option granted in 2001 to non-employees was calculated at the date of grant using an option-pricing model with the following weighted average assumptions (a) estimated volatility 104.5%; (b) expected life in years 10 years; (c) risk free interest rate 5.11%; and (d) dividend yield 0%.

The Company estimated volatility for purposes of computing compensation expense on its employee and non-employee options using the volatility of public companies that the Company considered comparable. The expected life used to estimate the fair value of non-employee options is equal to the contractual life of the option granted, which is 10 years.

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Common stock option and warrant activity from March 17, 1995 (inception) to June 30, 2003 is as follows (this table does not include Warrants to acquire Series A and Series B Preferred stock, which are discussed in Note 7.):

	Shares	Exercise Price per share
March 17, 1995 (inception)		\$
Granted	5,000	0.12
Exercised		
Balance at June 30, 1995	5,000	
Granted	29,583	0.12 1.20
Exercised	(7,500)	0.12

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	Shares	Exercise Price per share	
Balance at June 30, 1996	27,083		
Granted	45,417	1.20	2.40
Exercised			
Balance at June 30, 1997	72,500		
Granted	3,500	2.40	4.20
Forfeited	(500)	2.40	
Exercised	(2,209)	1.20	2.40
Balance at June 30, 1998	73,291		
Granted	24,833	4.20	
Exercised	(1,333)	1.20	4.20
Balance at June 30, 1999	96,791		
Granted	13,625	4.20	
Exercised	(6,041)	0.12	1.20
Balance at June 30, 2000	104,375		
Granted	95,709	4.20	18.00
Forfeited	(1,984)	4.20	18.00
Exercised	(6,308)	0.12	4.20
Balance at June 30, 2001	191,792		
Granted	56,720	18.0	24.00
Forfeited	(3,965)	4.20	18.00
Exercised	(4,395)	4.20	18.00
Balance at June 30, 2002	240,152		
Granted	14,521	9.60	24.00
Forfeited	(5,965)	4.20	24.00
Balance at June 30, 2003	248,708		

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Options and Warrants outstanding				Options and Warrants exercisable			
Range of exercise prices	Outstanding as of June 30, 2003	Weighted average remaining contractual life	Weighted average exercise price	Exercisable as of June 30, 2003	Weighted average exercise price		
\$0.12 2.40	58,333	3.19	\$ 1.20	58,333	\$ 1.20		
4.20 and 9.60	41,579	6.67	5.40	30,423	4.32		
18.0 and 24.0	148,796	7.93	18.36	79,846	18.12		
	248,708	6.61	\$ 12.12	168,602	\$ 9.72		

The Company has granted certain common stock options and warrants. These options and warrants are exercisable for a period of ten years and vest up to four years.

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Compensation expense for options granted to employees amounted to \$643,028, \$1,331,911 and \$1,580,054 for the years ended June 30, 2001, 2002 and 2003, respectively. Compensation expense for options granted to employees amounted to \$387,134 (unaudited), \$11,384,457 (unaudited) and \$15,215,359 (unaudited) for the three months ended September 30, 2002 and 2003 and for the period from March 17, 1995 (inception) to September 30, 2003, respectively. Compensation expense for options granted to employees are classified between research and development and general and administrative expense based on employee job function.

Options granted to non-employees vest immediately or over a one to four year period based upon future service requirements. Compensation expense for options granted to non-employees amounted to \$94,397, \$74,624 and (\$6,539) for the years ended June 30, 2001, 2002 and 2003, respectively. Compensation expense for options granted to non-employees amount to \$12,162 (unaudited), \$4,285 (unaudited) and \$1,923,960 (unaudited) for the three months ended September 30, 2002 and 2003 and for the period from March 17, 1995 (inception) to September 30, 2003, respectively. The amount of compensation expense to be recorded in the future for options granted to non-employees is subject to change each reporting period based upon changes in the fair value of the Company's common stock, estimated volatility and risk free interest rate until the non-employee completed performance under the option agreement. 1,770 options subject to this treatment remain unvested at June 30, 2003.

### (9) Income Taxes

As of June 30, 2003, the Company had available net operating loss carry-forwards ("NOL") of approximately \$75,591,000 for federal and state income tax purposes, which are available to offset future federal and state taxable income, if any, and expire between 2009 and 2023. The Company also has research and development tax credit carryforwards of approximately \$704,000 for federal income tax reporting purposes which are available to reduce federal income taxes, if any, and expire in future years through 2017.

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The tax effect of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities as of June 30, 2002 and 2003, are presented below:

	2002	2003
Net operating loss carryforwards	\$ 16,320,233	32,504,088
Research and development tax credit	503,000	703,500
Property and equipment	6,000	(270,300)
Intellectual property	6,521,667	5,948,334
Other temporary differences	35,482	42,061
	23,386,382	38,927,683
Less valuation allowance	(23,386,382)	(38,927,683)
	\$	

Changes in the valuation allowance for the years ended June 30, 2001, 2002 and 2003 amounted to approximately \$5,300,000, \$3,853,000 and \$15,541,000 respectively. Since inception the Company has incurred substantial losses and expects to incur substantial losses in future periods. The Tax Reform Act of 1986 (the "Act") provides for a limitation of the annual use of NOL and research and development tax credit carryforwards (following certain ownership changes, as defined by the Act) that could significantly limit the Company's ability to utilize these carryforwards. The Company has experienced various ownership changes, as defined by the Act, as a result of past financings. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, because U.S. tax laws limit the time during which these carryforwards may be applied against future taxes, the Company may not be able to take full advantage of these attributes for federal income tax purposes. Because of the above mentioned factors and the development stage nature of its operations (see Note 1), the Company has not recognized its net deferred tax assets as of and for all periods presented. Accordingly, the Company has provided a full valuation allowance against its deferred tax assets and no tax benefit has been recognized relative to its pretax losses.

### (10) License and Research Agreements

In January 1997, the Company entered into several agreements with Elan, including a License and Supply Agreement to develop Elan's proprietary oral, sustained-release formulation of Fampridine-SR for treatment of spinal cord injury. In return for this exclusive license granted by Elan, the Company paid a license fee of \$5 million which was expensed in fiscal 1997. The term of the agreement is equal to the greater of

20 years or the duration of relevant fampridine patent rights. Any mutually agreed to research conducted by Elan will be paid by the Company at cost plus 45%. The Company will be responsible for all clinical trials and regulatory approvals. Elan will have the right to manufacture, subject to certain exceptions, products for the Company upon regulatory approval at specified prices as a percentage of net selling price. In the event Elan does not manufacture the products, it is entitled to a royalty as a stated percentage of the products' net selling price. The Company may recover up to \$2.5 million of the license fee by reducing the royalty payable to Elan by stated percentages of the products' net selling price.

Concurrent with the License and Supply Agreement, the Company entered into a Preferred Stock, Convertible Note and Warrant Purchase Agreement (the "Agreement") with Elan. Under this Agreement, Elan purchased 750,000 shares of the Company's Series B at a per share price of \$2.00 and also agreed to purchase 333,333 shares of the Company's Series C at a per share price of \$3.00 within 30 days of the

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completion of Phase 2 clinical trials relating to products to be developed under the License and Supply Agreement. Concurrent with the purchase of Series B, the Company issued to Elan a warrant to purchase an additional 150,000 shares of Series B at a per share exercise price of \$2.00 for a period of five years. The Company estimated the fair value of warrants at approximately \$198,031. Such value was determined by the Black-Scholes valuation method, using a risk free interest rate of 6.4%, the warrant's contractual life of five years, an annual volatility of 75% and no expected dividends. Such amount was credited to additional paid-in capital and charged immediately to additional paid-in capital as the warrants were exercisable at any time at the option of the holder. Concurrent with the purchase of Series C, described below the Company issued to Elan a warrant to purchase 100,000 shares of Series B at a per share exercise price of \$2.00 for a period of five years from the date of issuance.

Phase 2 clinical trials relating to products to be developed under the License and Supply Agreement were completed in February 2002 and Elan purchased 333,333 shares of Series C at a per share price of \$3.00 resulting in total proceeds of \$999,999. Elan also exercised its Series B warrant and the Company issued 150,000 shares of Series B at a per share price of \$2.00 resulting in total proceeds of \$300,000. The Company also issued an additional five-year warrant to purchase 100,000 shares of Series B on January 4, 2002. The Company estimated the fair value of the five-year warrant to purchase 100,000 shares of Series B at approximately \$321,000. Such value was determined by the Black-Scholes valuation method, using a risk free interest rate of 4.3%, the warrant's contractual life of five years, an annual volatility of 102% and no expected dividends. Such amount was credited to additional paid-in capital and charged immediately to research and development expenses as these warrants were issued in connection with the Company completing Phase 2 clinical trials. In addition, the Company recognized \$296,666 as a beneficial conversion feature on issuance of Series C convertible preferred stock and charged this amount to research and development expenses as these shares were issued upon the Company completing Phase II clinical trials pursuant to a previous arrangement.

Under the Agreement, Elan also loaned to the Company an aggregate of \$7.5 million pursuant to two convertible promissory notes. One promissory note in the amount of \$5 million bears interest at a rate of 3% beginning on the first anniversary of the note. The unpaid principal is convertible into shares of the Company's Series D at a conversion price of \$12.50 per share. Principal and interest are repayable, if not converted, ratably over a seven-year period beginning one year after the Company receives certain regulatory approval for the products to be developed, subject to limitations related to gross margin on product sales. If it is determined by both parties that regulatory approval will not likely occur, all principal and interest shall not be repayable and the note will be cancellable after a defined notice period, if not earlier converted. If the License and Supply Agreement is otherwise terminated, the principal and interest is repayable ratably over 15 years.

The second promissory note in the amount of \$2.5 million is non-interest bearing. This promissory note is convertible after January 22, 1999 into either shares of Series B at a conversion price of \$2 per share or into an undesignated series of Preferred Stock at a conversion price equal to 80% of the-then most recently completed equity financing, as defined, whichever conversion price is greater. This promissory note is repayable by the Company, if not converted by Elan, ratably over a seven-year period beginning one year after the Company receives certain regulatory approval for the products to be developed. If it is determined by both parties that regulatory approval will not likely occur or if the License and Supply Agreement is otherwise terminated, the note is repayable ratably over 15 years from the date of determination. Interest on these convertible promissory notes has been imputed using 9% on 50% of the \$5 million note and 8% on the

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\$2.5 million note. In case of the \$5 million note, the Company did not impute interest on 50% of the \$5 million note based on the provision in the License and Supply Agreement which provided for a recovery of up to \$2.5 million of the license fee paid, which was dependent upon regulatory approval of the product. If regulatory approval of the product is received, the convertible note would be repayable and the Company would have been entitled to recovery of up to \$2.5 million based on the aforementioned provision. If the parties determine that regulatory approval will not likely occur, the note shall not be repayable and the Company would not receive recovery of up to \$2.5 million of the license

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fee, (see Note 14 for subsequent amendments of the license and supply agreements). The \$2,173,127 difference between the \$7.5 million principal amount of the notes and the discounted balance is being accreted to interest expense over the estimated term of the notes. Elan is considered to be a related party based on its ownership interest in the Company, significant license agreements entered into and involvement with research and development activities of the Company. In addition, Elan had a right to appoint a representative on the board of directors from January 22, 1997 through May 8, 2003. The aggregate amount of the \$7.5 million convertible notes payable are convertible into 361,842 shares of common stock.

In April 1998, the Company entered into an agreement with Elan to develop Elan's proprietary oral sustained release formulation of fampridine for the treatment of multiple sclerosis (see Note 7). Upon approval of a NDA for the product by the FDA in the United States the Company is obligated to pay \$2.5 million. In addition, the Company is obligated to pay an additional amount of \$2.5 million to Elan, upon the earlier occurrence of the following: (a) first anniversary from the date of approval of NDA approval in the United States, or (b) upon approval of the product by a regulatory authority in Japan, the United Kingdom, Germany, France or Italy.

The Company has entered into various other research and license agreements which, as of June 30, 2003, upon accomplishment of certain milestones, will require payments by the Company aggregating up to \$15.8 million. Approximately \$375,000 of these milestone payments can be taken as credits against earned royalties. Upon regulatory approval, these agreements also require the Company to make royalty payments as a percentage of product sales.

### (11) Employee Benefit Plan

Effective September 1, 1999, the Company adopted a defined contribution 401(k) savings plan (the "401(k) plan") covering all employees of the Company. Participants may elect to defer a percentage of their annual pretax compensation to the 401(k) plan, subject to defined limitations. No contributions were made by the Company for the years ended June 30, 2001, 2002 and 2003, respectively.

### (12) Commitments and Contingencies

During 1998, the Company entered into a lease agreement for its facility. During November, 2000 and May, 2001, the Company entered into amendments of the lease for its facility. Under the amendments, the Company increased the total leased space and extended the lease term for its original leased space. Future minimum commitments under the facility leases are as follows:

2004	\$	641,808
2005		641,808
2006		641,808
2007		641,808

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2008		374,388
	\$	2,941,620

Rent expense under these operating leases during the years ended June 30, 2001, 2002, and 2003 was \$309,442, \$468,309, and \$652,339, respectively.

Under the terms of the employment agreement with the Company's chief executive officer, the Company is obligated to pay severance under certain circumstances. If the employment agreement is terminated by the Company or by the Company's chief executive officer for reasons other than for cause, the Company must pay (i) an amount equal to the base salary for a period of one year following the date of termination, plus (ii) bonus equal to last annual bonus received by chief executive officer multiplied by a fraction, the numerator of which shall be the number of days in the calendar year elapsed as of the termination date and the denominator of which shall be 365.

The Company has entered into various clinical trial agreements which, as of June 30, 2003, upon accomplishment of certain milestones, will require payments by the Company aggregating up to \$5.1 million. Approximately \$2.5 million of these milestone payments have been made or accrued in the consolidated financial statements.

The Company is not a party to any material legal proceedings. It is the Company's policy to accrue for amounts related to legal matters if it is probable that a liability has been incurred and the amount is reasonably estimable.

### (13) Reverse Stock Split

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On September 25, 2003, the Company's stockholders approved a one-for-twelve reverse stock split of its common stock to be effective immediately prior to the effectiveness of the registration statement filed in connection with the initial public offering contemplated herein. On December 15, 2003, the one-for-twelve reverse stock split became effective. The reverse stock split has been retroactively reflected in the accompanying consolidated financial statements and notes to the consolidated financial statements.

### (14) Agreements and Transactions Consummated During the Three Months Ended September 30, 2003 (unaudited)

(a)

#### *Employment agreement*

On September 24, 2003, the Company entered into an employment agreement with the Company's chief financial officer, which was effective September 1, 2003. Under the terms of the agreement the Company is obligated to pay severance under certain circumstances. If the employment agreement is terminated by the Company or by the Company's chief financial officer for reasons other than for cause, the Company must pay (i) an amount equal to the base salary for a period of six months following the date of termination, plus (ii) bonus equal to last annual bonus received by chief financial officer multiplied by a fraction, the numerator of which shall be the number of days in the calendar year elapsed as of the termination date and the denominator of which shall be 365.

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(b)

#### *Stock Option Grants*

In September 2003, the Company granted 1,374,997 stock options, that had been authorized for issuance under the Plan in May 2003, to employees under the Plan at exercise prices of \$5.88 per share, which is below the estimated fair value of the Company's common stock at the date of grant. Compensation expense of approximately \$10.5 million, attributable to the fair value of the options granted, was recognized for the three month period ended September 30, 2003, as a certain number of options issued to employees vested immediately and the balance of \$6.6 million will be recognized over the remaining respective vesting periods of the options. Such compensation expense was calculated utilizing the estimated projected midpoint of the range of the Company's initial public offering price per share at the date the accompanying consolidated financial statements were prepared as the estimated fair value of the Company's common stock on the date of grant.

(c)

#### *Stock Options Repricing*

In September 2003, the Company re-priced 150,251 stock options issued to employees, which had an exercise price per option of more than \$5.88, with a new exercise price per share of \$5.88. As a result of this repricing, the Company will recognize an additional compensation charge based on the fair value of the repriced options estimated at approximately \$604,000, of which \$452,000 has been recognized for the three month period ended September 30, 2003, with the balance to be recognized over the remaining respective vesting periods of the repriced options. Such compensation expense was calculated utilizing the estimated projected midpoint of the range of the Company's initial public offering price per share at the date the accompanying consolidated financial statements were prepared as the estimated fair value of the Company's common stock on the date of grant.

(d)

#### *R&D and Product Collaborations, Alliances and License Agreements*

##### *Elan*

In January 1997, the Company licensed from Elan exclusive worldwide rights to Elan's sustained release formulation of fampridine, Fampridine-SR, for the treatment of spinal cord injury. In April 1998, the Company formed MS Research & Development Corporation, or MSRD, with Elan and one of its affiliates to develop Fampridine-SR for treatment of multiple sclerosis. At that time, MSRD licensed from Elan exclusive worldwide rights to Fampridine-SR for the treatment of multiple sclerosis.

*Termination and Assignment Agreement.* In September 2003, the Company entered into a termination and assignment agreement with Elan, Elan's affiliate, and MSRD pursuant to which MSRD (83% owned by Acorda immediately prior to



entering into the agreement) assigned to the Company its assets, including the license from Elan for Fampridine-SR for treatment of multiple sclerosis. The Company paid MSRD approximately \$11.5 million for all the assets and liabilities of MSRD. MSRD will distribute the purchase price to its shareholders according to their equity ownership interest. The Company has received a distribution of approximately \$9.5 million as a result of this distribution and the remaining distribution of \$2 million has been expensed for the three month period ended September 30, 2003 as acquired in-process research and development and classified under Research and Development-Related party. The Company also purchased Elan's

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affiliate shares at par value and now owns approximately 88% of MSRD, which now has no assets or liabilities and is inactive.

*Amended and Restated License.* In September 2003, the Company entered into an amended and restated license with Elan, which replaced the two prior licenses for Fampridine-SR. Under this agreement, Elan granted the Company exclusive worldwide rights to Fampridine-SR, as well as Elan's formulation for any other mono- or di-aminopyridines, for all indications, including spinal cord injury and multiple sclerosis. The Company agreed to pay Elan milestone payments and royalties based on net sales of the product.

Elan may terminate the Company's license in the United States, the major European markets or Japan if the Company does not file to obtain regulatory approval or launch the product after regulatory approval in the applicable country within specified periods. If Elan terminates the Company's license in any applicable country, Elan is entitled to license from the Company patents rights and know-how relating to the product and to market the product in the applicable country, subject to royalty payments.

As a result of the amendments, the Company's right to recover up to \$2.5 million of the license fee paid against future royalty payments was canceled.

Elan is responsible for completing the chemistry, manufacturing and controls section of the NDA and equivalent regulatory applications outside the United States. Elan is also responsible for supplying the product for clinical trials under this agreement.

Subject to early termination provisions, the Elan license terminates on a country by country basis on the latter to occur of fifteen years from the date of the agreement, the expiration of the last to expire Elan patent or the existence of competition in that country.

*Supply agreement.* In September 2003, the Company entered into a supply agreement with Elan relating to the manufacture and supply of Fampridine-SR by Elan. The Company agreed to purchase at least 75% of its annual requirements of product from Elan, unless Elan is unable or unwilling to meet its requirements, for a purchase price based on a specified percentage of net sales. In those circumstances, where the Company elects to purchase less than 100% of its requirements from Elan, the Company agreed to make certain compensatory payments to Elan. Elan agreed to assist the Company in qualifying a second manufacturer to manufacture and supply the Company with Fampridine-SR subject to its obligations to Elan.

*Securities Amendment Agreement.* In September 2003, the Company entered into a securities amendment agreement with Elan to modify certain provisions in some existing agreements between Elan and the Company. These included:

The modification of certain transfer restrictions

The automatic conversion of the \$5 million limited recourse notes into the underlying common shares, if the board of directors of the Company determines that regulatory approval of Fampridine-SR is unlikely to be obtained, subject to Elan's consent.

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Repayment of the \$2.5 million full recourse note will start no later than September 30, 2008, either on a seven year schedule or a 15 year schedule depending on whether the Company deems the market opportunity to be economically significant, unless the Company extends the date because regulatory approval is considered likely in a timely manner, or unless the note had been already converted into common stock.

### *Teva Pharmaceuticals Industries Ltd.*

In September 2003, the Company entered into a collaboration agreement with Teva Pharmaceuticals Industries Ltd. ("Teva") under which the Company was granted a co-exclusive license with Teva to jointly develop and promote in the United States products containing valroceamide as an active ingredient in any formulation and dosage form for any indication, except multiple sclerosis. However, in the event that Teva seeks to develop and promote products containing valroceamide for multiple sclerosis it must provide the Company with notice and negotiate an amendment to the agreement. The agreement provides that Teva will own all right, title and interest in and to all intellectual property jointly developed by the parties while Teva has the sole right and obligation to defend against any infringement claims.

The agreement further provides that Teva is responsible for seeking and maintaining regulatory approval from the FDA upon the completion of any co-developed product and that Teva will consult in preparing the filings to obtain regulatory approval. Teva is also solely responsible for the commercializing, manufacture and supply of the product, and has the sole responsibility to commercialize the products in the territory.

The Company made an initial payment to Teva of \$2 million (which is included in research and development expense for the three months ended September 30, 2003) upon execution of the collaboration agreement, and is obligated to make payments to Teva upon achieving certain milestones. The Company is also responsible for the payment of costs as well as conducting the next clinical trial of a product for the treatment of therapy. The Company must make the best reasonable efforts to complete the next clinical trial by the first quarter of 2006; if further clinical trials are required after the completion of the next clinical trial, then the costs of such trials will be shared. Such costs will be shared equally with Teva during any calendar quarter based on the net sales of any co-developed product. However, in the event the costs incurred by both parties under the agreement exceed net sales, the Company is obligated to pay Teva a fee equal to 50% of the amount by which the aggregate costs have exceeded net sales. Under the agreement, the Company is entitled to receive a fee on a country by country basis, based on sales by Teva of co-developed products outside the United States, if clinical data used to obtain regulatory approval of sale of the product in such country was jointly developed, or independently by the Company, under this Agreement.

Unless earlier terminated under provisions of the Teva agreement, the agreement will expire on the earlier to occur of (i) September 2009, if parties have not achieved a statistically significant primary endpoint that is accepted by the FDA for the first pivotal trial in connection with any product, (ii) six months after the first generic version of any product is launched in the United States, or (iii) September 2012, if the parties have not commenced the promotion and/or commercialization of any product under the Teva agreement.

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In addition, the Company granted Teva a right of first negotiation for the co-development and co-promotion of Fampridine-SR in North America.

### *Rush-Presbyterian St. Luke's Medical Center*

In 1990, Elan licensed from Rush know-how relating to fampridine for the treatment of multiple sclerosis. The Company subsequently licensed this know-how from Elan. In September 2003, the Company entered into an agreement with Rush and Elan which terminated the Rush license agreement with Elan. The Company also entered into a license agreement with Rush in which Rush granted the Company an exclusive worldwide license to their know-how relating to fampridine for the treatment of multiple sclerosis. Rush has also assigned to the Company their Orphan Drug Designation for fampridine for the relief of symptoms of multiple sclerosis.

The Company agreed to pay Rush a license fee, milestone payments and royalties based on net sales of the product for neurological indications. The Company also entered into an agreement with Elan relating to the allocation of payments between the Company and Elan of certain payments to Rush under the Rush license.

Subject to early termination provisions, the Rush license terminates upon expiration of the royalty obligations, which expire fifteen years from the date of the agreement.

In September 2003, the Company also entered into an agreement with Rush and Elan, pursuant to which the Company agreed that the payment of license fees, milestones and royalties to Rush under the license agreement with Rush, will be allocated between Elan and the Company.

Upon entering into the above mentioned R&D and Product Collaborations, Alliances and License Agreements, the Company expended approximately \$2.1 million. Upon accomplishment of certain milestones, the Company will be required to make payments aggregating up to approximately \$30 million.

(e)

***Sales and Marketing agreement***

In September 2003, the Company entered into two marketing service agreements with inChord Communication, Inc. and Cardinal Health PTC, Inc. for contract sales and marketing services associated with the commercialization of Fampridine-SR in the United States. RxPedita is a program developed by inChord Communications, Inc. and Cardinal Health PTC, Inc. pursuant to which they provide pharmaceutical drug manufacturers and biotech companies with comprehensive outsourced marketing communications, selling and distribution/manufacturing capabilities. The Company will receive the RxPedita services at a discounted market rate in exchange for full repayment of such discounts, if the product achieves 100% of its revenue targets (based on gross sales) through the twelve month period following launch, plus a risk premium in the event that the product exceeds such target revenues. The repayment terms range between no repayment if the product fails to achieve more than 50% of its revenue target in any quarter and full repayment of all discounts plus 200% of such amounts if the product achieves over 130% of its revenue target. The discount from the market rate is to be determined periodically according to a target product profile, which is in the range of 10-28%. The discounts and premiums will be repaid on a quarterly basis beginning six

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months after product launch and ending eighteen months post launch, with a final reconciliation after the first twelve months of product sales in the event of over/under payment.

A joint commercialization committee, composed of the Company and RxPedita representatives, will coordinate the overall marketing and sales strategies for the product and associated workplans and budgets; however, the Company retains ultimate approval authority over all relevant decisions. The Company is responsible for all regulatory affairs including: filings and approvals, compliance of promotional materials, adverse event reporting, product recalls, and communication with regulatory authorities. Acorda owns all work product developed pursuant to the marketing service agreements unless otherwise agreed in a specific work plan.

The marketing service agreements designate RxPedita as the "agency of record" with respect to the services provided and contain buy-out provisions in the event that the Company enters into a co-promote agreement with a third party and can no longer allocate a substantial amount of the services to RxPedita. The buy-out provision may also be implicated in the event that the Company merges with, or sells the product to, a company that creates a conflict of interest with one of RxPedita's other clients. In addition to being the "agency of record" with respect to Fampridine-SR, RxPedita is also designated as the "agency of record" for all product related compounds and granted a sixty day right of first negotiation for other molecules developed, licensed or otherwise controlled by the Company.

Subject to early termination provisions, the agreements expire on the later of five years from the effective date of the agreements or twenty-four months following the program launch in the case of the sales services, or eighteen months following product launch for spinal cord indication in the case of the marketing services.

(f)

***Automatic Conversion Terms***

In September 2003, the Company obtained approval by the written consent from the holders of Series J preferred stock voting together as a single class and the holders of the Preferred Stock (as defined in Note 7), voting separately as a single class on an as if converted basis for a reduction in the price per share of common stock offered to the public in an initial public offering which would trigger automatic conversion of the preferred stock into common stock from an offering price of not less than \$14.76 per share to an offering price of not less than \$12.00 per share.

(g)

***Stock Option Plan***

On September 25, 2003, the Company amended the Plan, which will become effective upon consummation of the Company's initial public offering contemplated herein, providing for automatic annual increases to the share reserve under the Plan on the first day of each fiscal year by a number of shares equal to the lesser of: (a) the number that will bring the total reserve to 2.5% of then outstanding shares of common stock; (b) 647,151 shares; (c) or a number determined by the board of directors.

(h)

***Initial Public Offering***

On September 25, 2003, the Board of Directors authorized the filing of a registration statement with the SEC for the sale of shares of common stock. If the offering is consummated under the terms presently anticipated, all shares of Series A, B, C, E, F, H, I and J preferred stock outstanding as of the Consummation of the Offering will automatically convert into shares of common stock. No dividends will be payable on any of the Series A, B, C, E, F, H, I and J preferred stock.

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(i)

***Director Compensation***

Upon consummation of an initial public offering, each of the Company non-employee directors will receive non-qualified stock options to purchase 20,000 shares at the initial public offering price per share, which options will vest in 12 equal quarterly installments commencing 180 days after the date of grant.

Upon consummation of an initial public offering, each of the Company directors will receive an annual option grant to purchase 10,000 shares on the date of the Company annual stockholder meeting. In addition, the Company's directors will receive an annual grant of 5,000 options exercisable to purchase shares for each committee on which they serve. Directors will also be reimbursed for expenses incurred in attending meetings.

(j)

***Preferred and common stock***

In accordance with the Company's amended and restated certificate of incorporation which the Company plans to file upon consummation of an initial public offering, the Company's authorized capital stock will consist of 75,000,000 shares of common stock and 1,000,000 shares of preferred stock. In accordance with this amended and restated certificate of incorporation, the Company's board of directors has the authority, without further action by the stockholders, to issue up to 1,000,000 shares of preferred stock in one or more series and may determine the rights, preferences, privileges, qualifications and restrictions granted to or imposed upon the preferred stock, including dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preferences and sinking fund terms, any or all of which may be greater than the rights of the common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and reduce the likelihood that common stockholders will receive dividend payments and payments upon liquidation. The issuance of preferred stock could also have the effect of decreasing the market price of the common stock and could delay, deter or prevent a change in control of the company.

**(15) Subsequent Events (Unaudited)**

(a)

***Stock Option Grants***

In October 2003, the Company granted 50,000 stock options to its chief executive officer and 12,500 stock options to its executive director marketing and commercialization at exercise prices of \$5.88 per share, which is below the estimated fair value of the Company's common stock at the date of grant. Estimated compensation expense of approximately \$425,000 attributable to the fair value of the options granted will be recognized immediately in the second quarter of fiscal 2004, as a certain number of options issued to employees vested immediately and the balance of \$355,000 will be recognized over the remaining respective vesting periods of the options.

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## Shares

### Common Stock

Prospectus  
, 2003

**Banc of America Securities LLC**  
**Lazard**  
**U.S. Bancorp Piper Jaffray**  
**RBC Capital Markets**

Until \_\_\_\_\_, 2004, all dealers that buy, sell or trade the common stock may be required to deliver a prospectus, regardless of whether they are participating in this offering. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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## PART II INFORMATION NOT REQUIRED IN PROSPECTUS

### Item 13. Other expenses of issuance and distribution

The following table sets forth all expenses payable by Acorda Therapeutics, Inc. (the "Registrant") in connection with the sale of the common stock being registered, other than underwriting commissions and discounts. All amounts are estimates, except for the SEC registration fee, the NASD filing fee and the Nasdaq National Market listing application fee.

	<u>Amount to Be Paid</u>
SEC registration fee	\$ 6,067
NASD filing fee	8,000
Nasdaq National Market listing application fee	100,000
Blue sky qualification fees and expenses	20,000
Printing and engraving expenses	185,000
Legal fees and expenses	495,000
Accounting fees and expenses	530,000
Transfer agent and registrar fees	5,000
Miscellaneous	100,933
	<hr/>
Total	\$ 1,450,000
	<hr/>

**Item 14. Indemnification of officers and directors**

Under Section 145 of the Delaware General Corporation Law, the Registrant has broad powers to indemnify its directors and officers against liabilities they may incur in such capacities, including liabilities under the Securities Act of 1933, as amended (the "Securities Act").

The Registrant's Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws include provisions to (i) eliminate the personal liability of its directors and officers for monetary damages resulting from breaches of their fiduciary duty to the extent permitted by Section 102(b)(7) of the General Corporation Law of Delaware (the "Delaware Law") and (ii) require the Registrant to indemnify its directors and officers to the fullest extent permitted by Section 145 of the Delaware Law, including circumstances in which indemnification is otherwise discretionary. Pursuant to Section 145 of the Delaware Law, a corporation generally has the power to indemnify its present and former directors, officers, employees and agents against expenses incurred by them in connection with any suit to which they are or are threatened to be made, a party by reason of their serving in such positions so long as they acted in good faith and in a manner they reasonably believed to be in or not opposed to, the best interests of the corporation and with respect to any criminal action, they had no reasonable cause to believe their conduct was unlawful. The Registrant believes that these provisions are necessary to attract and retain qualified persons as directors and officers. These provisions do not eliminate the directors' duty of care, and, in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief will remain available under Delaware Law. In addition, each director will continue to be subject to liability for breach of the director's duty of loyalty to the Registrant, for acts or omissions not in good faith or involving intentional misconduct, for knowing violations of law, for acts or omissions that the director believes to be contrary to the best interests of the Registrant or its stockholders, for any transaction from which the director derived an improper personal benefit, for acts or omissions involving a reckless disregard for the director's duty to the Registrant or its stockholders when the director was aware or should have been aware of a risk of serious injury to the Registrant or its stockholders, for acts or omissions that constitute an unexcused pattern of inattention that amounts to an abdication of the director's duty to the Registrant or its stockholders, for improper transactions between the director and the Registrant and for improper distributions to stockholders and loans to directors and officers. The provision also does not affect a director's responsibilities under any other law, such as the federal securities law or state or federal environmental laws.

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The Registrant has entered into indemnification agreements with certain directors and executive officers and intends to enter into indemnification agreements with all of its other directors and executive officers prior to the consummation of the offering. Under these agreements, the Registrant will indemnify its directors and executive officers against amounts actually and reasonably incurred in connection with actual or threatened proceedings if any of them may be made a party because of their role as a director or officer. The Registrant is obligated to pay these amounts only if the officer or director acted in good faith and in a manner that he or she reasonably believed to be in or not opposed to the Registrant's best interests. For any criminal proceedings, the Registrant is obligated to pay these amounts only if the officer or director had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth procedures that will apply in the event of a claim for indemnification thereunder.

At present, there is no pending litigation or proceeding involving a director or officer of the Registrant as to which indemnification is being sought nor is the Registrant aware of any threatened litigation that may result in claims for indemnification by any officer or director.

The Registrant intends to apply for an insurance policy covering the officers and directors of the Registrant with respect to certain liabilities, including liabilities arising under the Securities Act or otherwise.

Reference is made to the indemnification and contribution provisions of the Underwriting Agreement filed as an exhibit to this Registration Statement.

**Item 15. Recent sales of unregistered securities**

The following sets forth information regarding sales of the Registrant's unregistered securities during the last three years (giving effect to a one-for-12 reverse stock split effected on December 15, 2003):

In March 2001, we consummated a private placement of 10,204,047 shares of our Series I Convertible Preferred Stock to a group of accredited investors at a purchase price of \$3.89 per share for aggregate consideration of \$39,693,743.

In May 2003, we consummated a private placement of 112,790,296 shares of our Series J Convertible Preferred Stock to a group of accredited investors at a purchase price of \$0.49 per share for aggregate consideration of \$55,000,000.

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All of the above-described issuances were exempt from registration pursuant to Section 4(2) of the Securities Act, or Regulation D or Rule 144A promulgated thereunder, as transactions not involving a public offering. With respect to each transaction listed above, no general solicitation was made by either us or any person acting on our behalf; the securities sold are subject to transfer restrictions; and the certificates for the shares contained an appropriate legend stating such securities have not been registered under the Securities Act and may not be offered or sold absent registration or pursuant to an exemption therefrom. No underwriters were involved in connection with the sales of securities referred to in this Item 15.

### Item 16. Exhibits and financial statement schedule

(a) Exhibits.

- 1.1 Form of Underwriting Agreement
- 3.1 Form of Amended and Restated Certificate of Incorporation
- 3.2 Form of Amended and Restated Bylaws
- 3.3 Form of Post-IPO Amended and Restated Certificate of Incorporation
- 4.1 Specimen Stock Certificate
- 5.1 Opinion of Loeb & Loeb LLP
- 10.1 Acorda Therapeutics 1999 Employee Stock Option Plan
- 10.2 Proposed Amendment to 1999 Employee Stock Option Plan
- 10.3 Intentionally Left Blank

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- 10.4 Fifth Amended and Restated Registration Rights Agreement, dated May 8, 2003, by and among the Registrant and certain stockholders named therein
  - 10.5 Employment Agreement, dated August 11, 2002, by and between the Registrant and Ron Cohen
  - 10.6 Employment Agreement, dated September 24, 2003, by and between the Registrant and Mark Pinney
  - 10.7 Termination and Assignment Agreement, dated September 26, 2003, by and among the Registrant, Elan Corporation plc, Elan International Services Ltd. and MS Research and Development Corporation
  - 10.8 \*\* Amended and Restated License Agreement, dated September 26, 2003, by and between the Registrant and Elan Corporation plc
  - 10.9 \*\* Supply Agreement, dated September 26, 2003, by and between the Registrant and Elan Corporation plc
  - 10.10 \*\* License Agreement, dated September 26, 2003, by and between the Registrant and Rush-Presbyterian-St. Luke's Medical Center
  - 10.11 Side Agreement, dated September 26, 2003, by and among the Registrant, Rush-Presbyterian-St. Luke's Medical Center, and Elan Corporation plc
  - 10.12 \*\* Payment Agreement, dated September 26, 2003, by and among the Registrant, Rush-Presbyterian-St. Luke's Medical Center, and Elan Corporation plc
  - 10.13 \*\* Amended and Restated License Agreement, dated August 1, 2003, by and between the Registrant and Canadian Spinal Research Organization
  - 10.14 \*\* License Agreement, dated February 3, 2003, by and between the Registrant and Cornell Research Foundation, Inc.
  - 10.15 \*\* License Agreement, dated November 12, 2002, by and between the Registrant and CeNeS Pharmaceuticals, plc
  - 10.16 \*\* License Agreement, dated November 12, 2002, by and between the Registrant and CeNeS Pharmaceuticals, plc
  - 10.17 \*\* Acorda Marketing Services Agreement, dated September 19, 2003, by and between the Registrant and Creative Healthcare Solutions, LLC
  - 10.18 \*\* Acorda Marketing Services Agreement, dated September 19, 2003, by and between the Registrant and Cardinal Health PTS, Inc.
  - 10.19 \*\* Workplan for Detailing Services, dated September 19, 2003, by and between the Registrant and Cardinal Health PTS, Inc.
  - 10.20 \*\* License Agreement, dated September 8, 2000, by and between the Registrant and the Mayo Clinic
  - 10.21 \*\* Research Collaboration and Commercialization Agreement, dated February 27, 2002, by and between the Registrant and AERES Biomedical Limited
  - 10.22 \*\* Collaboration Agreement, dated September 23, 2003, by and between the Registrant and Teva Pharmaceuticals Industries, Ltd., and Letter Agreement, dated September 23, 2003, by and between the Registrant and Teva Pharmaceutical Industries, Ltd.

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- 10.23 Limited Recourse Convertible Promissory Note issued to Elan International Services, Ltd.
- 10.24 Full Recourse Convertible Promissory Note issued to Elan International Services, Ltd.
- 10.25 Securities Amendment Agreement, dated September 26, 2003, by and among the Registrant, Elan Pharmaceutical Investments, Ltd., Elan Pharma International Limited, and Elan International Services, Ltd.
- 10.26 \*\* Technical Transfer Program Proposal for Commercial Registration, dated February 29, 2003, by and between the Registrant and Patheon, Inc.
- 10.27 \*\* Agreement, dated April 4, 2003, by and between the Registrant and Lonza Biologics, plc
- 10.28 Laboratory Services Agreement, dated as of April 1, 2003, between the Registrant and Cardinal Health PTS, Inc.

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- 10.29 Amendment No. 1 to the Termination and Assignment Agreement, dated as of October 27, 2003, by and among the Registrant, Elan Corporation, plc., Elan International Services, Ltd. and MS Research & Development Corporation.
  - 10.30 \*\* Amendment No. 1 to the Payment Agreement, dated as of October 27, 2003, by and between the Registrant and Elan Corporation, plc.
    - 21.1 List of Subsidiaries of the Registrant.
    - 23.1 Consent of KPMG LLP, Independent Auditors.
    - 23.2 Consent of Loeb & Loeb LLP (included in Exhibit 5.1).
    - 24.1 Power of Attorney.
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Confidential treatment has been requested for portions of this Exhibit, which portions are omitted and filed separately with the Securities and Exchange Commission.

Previously filed.

(b) *Financial statement schedules.*

All schedules are omitted because they are not required, are not applicable or the information is included in our financial statements or notes thereto.

### Item 17. Undertakings

The Registrant hereby undertakes to provide to the underwriters at the closing specified in the Underwriting Agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

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

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, 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 shall be deemed to be part of this Registration Statement as of the time it was declared effective.





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23.2	Consent of Loeb & Loeb LLP (included in Exhibit 5.1).
24.1	Power of Attorney.

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Previously filed.

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## QuickLinks

[Overview](#)

[Our Product Candidates](#)

[Our Focus](#)

[Corporate Information](#)

[Figure 1: SCI-F201 Phase 2 Ashworth Scores Post-Treatment with Placebo or Fampridine-SR Treatment vs. Baseline](#)

[Summary Compensation Table](#)

[ACORDA THERAPEUTICS, INC. AND SUBSIDIARY \(A Development Stage Enterprise\) Notes to Consolidated Financial Statements](#)

[Exhibit Index](#)