# SECURITIES AND EXCHANGE COMMISSION

# FORM S-1/A

General form of registration statement for all companies including face-amount certificate companies [amend]

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# **FILER**

# **EPICEPT CORP**

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Mailing Address 270 SYLVAN AVENUE ENGLEWOOD CLIFFS NJ 07632 Business Address 270 SYLVAN AVENUE ENGLEWOOD CLIFFS NJ 07632 2018948980

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 5

to

# Form S-1

# REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

# **EpiCept Corporation**

(Exact name of Registrant as specified in its charter)

#### **Delaware**

(State or other jurisdiction of incorporation or organization)

#### 2834

(Primary Standard Industrial Classification Code Number)

#### 52-1841431

(I.R.S. Employer Identification Number)

270 Sylvan Avenue

Englewood Cliffs, NJ 07632 (201) 894-8980

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

John V. Talley

Chief Executive Officer
EpiCept Corporation
270 Sylvan Avenue
Englewood Cliffs, NJ 07632
(201) 894-8980

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

Copies to:

Alexander D. Lynch, Esq. Weil, Gotshal & Manges LLP 767 Fifth Avenue New York, NY 10153 (212) 310-8000 Danielle Carbone, Esq. Shearman & Sterling LLP 599 Lexington Avenue New York, NY 10022 (212) 848-4000

<b>Approximate date of commencement of proposed sale to the public:</b> As soon as practicable after the effective date of this Registration Statement.
If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), check the following box.
If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.
If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.
If 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.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

**PROSPECTUS** 

#### **SUBJECT TO COMPLETION, DATED MAY 2, 2005**

5,500,000 Shares



# Common Stock

This is EpiCept Corporation's initial public offering. We are offering 5,500,000 shares of our common stock. We expect the initial public offering price to be between \$11.00 and \$13.00 per share.

Prior to this offering, there has been no public market for our common stock. We have filed an application for our common stock to be quoted on The Nasdaq National Market under the symbol "EPCT."

# Investing in our common stock involves risks. See "Risk Factors" beginning on page 8.

	Per Share	Total
Public Offering Price	\$	\$
Underwriting Discounts and Commissions	\$	\$
Proceeds to EpiCept (before expenses)	\$	\$

Delivery of the shares of common stock will be made on or about , 2005.

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

We have granted the underwriters an option to purchase up to a maximum of 825,000 shares of our common stock to cover overallotments of shares, exercisable at any time until 30 days after the date of this prospectus.

# Wachovia Securities

C.E. Unterberg, Towbin

Jefferies & Company, Inc.

The date of this prospectus is

, 2005.

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CONSENT OF DELOITTE & TOUCHE LLP	

You may rely on the information contained in this prospectus. Neither we nor any of the underwriters have authorized anyone to provide information different from that contained in this prospectus. When you make a decision about whether to invest in our common stock, you should not rely upon any information other than the information in this prospectus. Neither the delivery of this prospectus nor sale of common stock means that information contained in this prospectus is correct after the date of this prospectus. This prospectus is not an offer to sell or solicitation of an offer to buy these shares of common stock in any circumstances under which the offer of solicitation is unlawful.

#### PROSPECTUS SUMMARY

The following summary is qualified in its entirety by, and should be read in conjunction with, the more detailed information and consolidated financial statements and notes thereto appearing elsewhere in this prospectus. You should read the entire prospectus carefully before making an investment decision. This prospectus contains forward-looking statements that involve risks and uncertainties. Our results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in 'Risk Factors' and elsewhere in this prospectus. Except as otherwise indicated, all information in this prospectus assumes no exercise of the underwriters' over-allotment option. References to 'we," "us," "our," and 'EpiCept' mean EpiCept Corporation and our subsidiary, EpiCept GmbH. References in this prospectus to particular notes in our consolidated financial statements refer to the notes to our audited consolidated financial statements for the fiscal years ended December 31, 2002, 2003 and 2004 included elsewhere in this prospectus. "EpiCept," the EpiCept logo and 'LidoPAIN' are our trademarks. Other service marks, trademarks and trade names referred to in this prospectus are the property of their respective owners.

#### **OUR COMPANY**

We are a specialty pharmaceutical company focused on the development and commercialization of topically-delivered prescription pain management therapeutics. We have six product candidates in clinical development; three in late-stage clinical development that are ready to enter, or have entered, pivotal Phase III or Phase III clinical trials, and three that have completed initial Phase II clinical trials. All of our product candidates target moderate-to-severe pain that is influenced, or mediated, by nerve receptors located just beneath the skin's surface. Our product candidates utilize proprietary formulations and several topical delivery technologies to administer FDA-approved pain management therapeutics, or analgesics, directly on the skin's surface at or near the site of the pain. We believe using FDA-approved analgesics reduces the risks associated with new drug development, lowers our development costs and speeds time-to-market. Our product candidates are designed to provide effective pain relief with fewer adverse side effects than systemically-delivered drugs, which are generally either injected, swallowed or otherwise consumed or applied so that they are absorbed into the bloodstream. None of our product candidates has been approved by the U.S. Food and Drug Administration, or FDA, or any comparable agency in another country. Consequently, we may not sell our products for use by patients.

IMS Health, a healthcare information provider, has estimated that the total U.S. market for prescription analgesics has increased from \$5.3 billion in 1998 to \$14.7 billion in 2003, representing an approximate 23% compounded annual growth rate. In 2003, analgesics were the third most prescribed class of medications in the United States with approximately 313 million prescriptions written. We believe that growth in this market has been primarily attributable to:

increased physician recognition of the need for effective pain management;

patient demand for more effective pain treatments;

an aging population, with an increased prevalence of chronic pain conditions, such as cancer, arthritis, neuropathies and lower back pain;

increased number of surgeries;

introduction of new and reformulated branded products; and

increased active and healthy lifestyles, resulting in additional sports and fitness related injuries.

We are targeting peripheral nerve receptors using topical analgesics as a novel mechanism to effectively treat both acute and chronic pain, without the liabilities of traditional systemically-delivered analgesics. We are developing innovative topically-delivered analgesics using a combination of our proprietary internally-developed and in-licensed technologies and know-how to address the unmet medical needs and adverse side effects associated with systemically-delivered analgesics. Our topical delivery technologies and formulations are designed to deliver FDA-approved analgesics safely, effectively and conveniently to the appropriate peripheral nerves while preventing or limiting the amount of drug that enters the bloodstream. We utilize patch, cream and spray gel matrix delivery methods to topically deliver the active ingredients to the pain site. In some instances, we combine existing FDA-approved analgesics to create a new product having a therapeutic profile superior to either one of the standalone analgesics.

#### **Our Product Candidates**

The following table summarizes the current status of our development programs for our three late-stage product candidates:

Product Candidates EpiCept NP-1	Topical  Dosage Form  Cream	Initial Indication Post- herpetic neuralgia	Clinical Status Phase II completed	Next Steps Initiate Phase III during second half of 2005	Marketing Rights EpiCept
LidoPAIN SP	Sterile patch	Surgical incision pain	Phase III initiated in Germany	Adolor has announced plans for Phase IIb and Phase III clinical trials in United States	Adolor Corporation in North America; EpiCept outside of North America; EpiCept retains right to negotiate future co-promotion agreement
LidoPAIN BP	Patch (non-sterile)	Acute lower back pain	Phase II completed	Initiate pivotal Phase IIb clinical trial during second half of 2005	Endo Pharmaceuticals, Inc. worldwide; EpiCept retains right to negotiate future co-promotion agreement

## EpiCept NP-1

Our lead late-stage product candidate, EpiCept NP-1, is a prescription topical analgesic cream containing a patented formulation, the contents of which include two FDA-approved drugs, amitriptyline and ketamine. Amitriptyline is a widely-used antidepressant, and ketamine is an NMDA, or N-methyl-D-aspartate, antagonist (i.e., a compound that blocks the effects of NMDA, a protein associated with the feeling of pain) that is used as an anesthetic. EpiCept NP-1 is designed to provide effective, long-term relief from the pain of peripheral neuropathies. We believe the topical delivery of our patented combination represents a fundamentally new approach for the treatment of pain associated with peripheral neuropathy and will significantly reduce the risk of adverse side effects associated with the systemic delivery of the active ingredients. Peripheral neuropathies are medical conditions caused by damage to the nerves in the nervous system. The initial indication for this product candidate is post-herpetic neuralgia, a specific type of peripheral neuropathy associated with shingles, a condition caused by the herpes zoster virus. We have completed Phase II clinical trials in the United States and Canada that included 343 subjects and plan to commence a Phase III clinical trial in the United States during the second half of 2005 that will include at least 800 subjects.

#### LidoPAIN SP

LidoPAIN SP, our second late-stage product candidate, is a sterile prescription analgesic patch designed to provide sustained topical delivery of lidocaine to a post-surgical or post-traumatic sutured wound while also providing a sterile protective covering for the wound. If approved, we believe that LidoPAIN SP would be the first sterile prescription analgesic patch on the market. We have completed a Phase II clinical trial in Germany that included 221 subjects who underwent hernia repair and commenced a Phase III clinical trial in Europe during the fourth quarter of 2004 that will include at least 400 subjects who have undergone hernia repair. In July 2003, we entered into an agreement with Adolor Corporation for the development and commercialization of LidoPAIN SP in North America.

# LidoPAIN BP

Our third late-stage product candidate is LidoPAIN BP, a prescription analgesic non-sterile patch designed to provide sustained topical delivery of lidocaine for the treatment of acute or recurrent lower back pain. We have completed Phase IIa and Phase IIb clinical trials in the United States that included

242 subjects and plan to commence a pivotal Phase IIb clinical trial in the United States during the second half of 2005 that will include at least 400 subjects. In December 2003, we entered into an agreement with Endo Pharmaceuticals Inc. for the commercialization of LidoPAIN BP worldwide.

#### **Other Product Candidates**

We have three earlier-stage product candidates in clinical development: (1) EpiCept MP/ DP, a topical spray gel matrix containing morphine and lidocaine for the treatment of oral mucositis, an inflammation of the mucosa of the mouth typically resulting from chemotherapy and radiation therapy, and dental pain; (2) LidoPAIN TV, a topical lidocaine patch for the treatment of tinnitus, a constant or intermittent buzzing or ringing noise in the ear; and (3) LidoPAIN HM, a topical anesthetic patch for the treatment of headache pain. We have completed initial Phase II clinical trials and expect to conduct additional Phase II clinical trials for each of these product candidates. We filed our IND applications with the FDA for EpiCept MP/DP and LidoPAIN HM in June 2000 and December 2000, respectively. We have not filed an IND application with the FDA for LidoPAIN TV, but we have filed a foreign IND equivalent in Europe in June 2001.

#### **Our Strategy**

Our objective is to address unmet medical needs in pain management by developing a broad portfolio of topically-delivered prescription analgesics for the treatment of moderate-to-severe pain where existing treatments are ineffective or cause significant adverse side effects. To achieve our objective, the three key elements of our strategy are to:

focus our development efforts on topically-delivered analgesics targeting peripheral nerve receptors;

focus our development efforts on FDA-approved drugs; and

opportunistically enter into development and commercialization alliances for our products.

#### Strategic Alliances

We have established strategic alliances with Adolor with respect to our LidoPAIN SP product candidate for the treatment of pain associated with surgical incisions and with Endo with respect to our LidoPAIN BP product candidate for the treatment of lower back pain. These strategic alliances are designed to provide us with operating capital and marketing capabilities and to supplement our development efforts. Under these agreements, we have received \$10.0 million and are eligible to receive up to an additional \$102.5 million in milestone payments. The agreements also provide for royalty payments from each of Adolor and Endo based on the net sales of certain licensed products. We also intend to pursue other strategic alliances as appropriate.

### Risks Affecting Us

We are subject to a number of risks of which you should be aware before you decide to buy our common stock. These risks are discussed more fully under the heading "Risk Factors." All of our product candidates are in development. We have not received regulatory approval for, or generated commercial revenues from, any of our product candidates. We may never obtain regulatory approval for our product candidates or successfully commercialize any of our product candidates. If we do not successfully obtain regulatory approval for, and commercialize any of our product candidates or enter into successful strategic alliances, we will be unable to achieve our business objective. Since inception, we have incurred net losses. As of December 31, 2004, we had an accumulated deficit of \$59.3 million. We expect to continue to incur increasing net losses for the foreseeable future, and we may never become profitable. Our independent registered public accounting firm's report stated that our recurring losses from operations and stockholders' deficit raise substantial doubt about our ability to continue as a going concern.

#### **Corporate Information**

We were incorporated in Delaware in March 1993. We have a 100%-owned subsidiary, EpiCept GmbH, based in Munich, Germany, which is engaged in research and development activities on our behalf. Our principal executive offices are located at 270 Sylvan Avenue, Englewood Cliffs, New Jersey, and our telephone number is (201) 894-8980. Our website address is *www.epicept.com*. Our website, and the information contained in our website, is not a part of this prospectus.

#### THE OFFERING

Common stock offered 5,500,000 shares

Common stock to be outstanding after

this offering

17,339,576 shares

Use of proceeds

We intend to use the proceeds from this offering for working capital and general corporate purposes, including continuing our clinical trials and research and development efforts and the continued preparation for the manufacturing and commercialization of our product candidates. We will also repay approximately \$9.8 million of our outstanding indebtedness (including accrued interest and net of proceeds from the exercise of the bridge warrants), which includes our new senior notes due 2006, our convertible bridge loan and our loan from IKB Private Equity GmbH, or "IKB." The lenders under our convertible bridge loan include our President and Chief Executive Officer. The lenders under our new senior notes and our convertible bridge loan include affiliates of certain of our shareholders. See "Use of Proceeds."

See "Risk Factors" and other information in this prospectus for information you should consider

before deciding whether to invest in shares of our common stock.

Proposed Nasdaq National Market

symbol

Risk factors

**EPCT** 

The number of shares of our common stock to be outstanding after this offering is based on the number of shares of our common stock outstanding as of December 31, 2004 and also reflects the automatic conversion of our outstanding preferred stock into 6,063,331 shares of common stock, the issuance of 3,861,464 shares of common stock upon the exercise of warrants granted in connection with our convertible bridge loan, which we refer to in this prospectus as the bridge warrants, and the conversion of a convertible term loan with Technologie-Beteiligungs Gesellschaft mbH der Deutschen Ansgleichsbank, which we refer to in this prospectus as the tbg convertible loan, into 227,660 shares of common stock.

This number does not include:

466,625 shares of our common stock issuable upon exercise of options outstanding as of December 31, 2004, at a weighted average exercise price of \$1.48 per share;

4,736,943 shares of our common stock reserved for issuance under our 1995 Stock Option Plan, our 2005 Equity Incentive Plan and our 2005 Employee Stock Purchase Plan as of December 31, 2004; and

1,748,875 shares of our common stock issuable upon the exercise of options to be granted on the date of this offering, at an exercise price equal to the initial public offering price.

Except as otherwise indicated, all information in this prospectus:

reflects the automatic conversion of our outstanding preferred stock into 6,063,331 shares of common stock;

reflects the exercise of the bridge warrants into 3,861,464 shares of common stock;

reflects the conversion of the tbg convertible loan into 227,660 shares of common stock; assumes an initial public offering price of \$12.00 per share, the midpoint of the offering range set forth on the cover of this prospectus; gives effect to a 1-for-4 reverse split of our common stock;

gives effect to our amended and restated certificate of incorporation, which we will file immediately prior to the closing of this offering, and our amended and restated bylaws, which will be adopted effective immediately prior to the closing of this offering; and

assumes the underwriters do not exercise their option to purchase 825,000 additional shares from us in this offering.

#### SUMMARY CONSOLIDATED FINANCIAL DATA

You should read the following financial information together with the information under "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the notes thereto included elsewhere in this prospectus.

The following tables present our summary consolidated balance sheet and statement of operations data as of and for the fiscal years ended December 31, 2002, 2003 and 2004. Our consolidated balance sheet data as of December 31, 2004 is presented on an actual basis and on a pro forma as adjusted basis to reflect the sale of 5,500,000 shares of our common stock in this offering at an assumed public offering price of \$12.00 per share (the midpoint of the price range set forth on the cover of this prospectus), after deducting the estimated underwriting discounts and commissions and the estimated offering expenses and reflecting the conversion of our preferred stock and the tbg convertible loan and the exercise of the bridge warrants. Our consolidated statement of operations data for the fiscal years ended December 31, 2002, 2003 and 2004 and our consolidated balance sheet data as of December 31, 2004 were derived from our audited consolidated financial statements included elsewhere in this prospectus.

\$ 2002		(Dolla	2003  Restated(		ept	2004	
\$		(Dolla	rs in thousai		ept		
\$		(Dolla		nds, exc	ept		
\$							
\$			per share d	ata)			
\$							
-		\$	377		\$	1,115	
3,493			3,407			4,408	
4,874			1,641			1,785	
	_			_			_
8,367			5,048			6,193	
	_			_			_
(8,367	)		(4,671	)		(5,078	)
(1,509	)		(5,364	)		(2,806	)
	_			_			_
(9,876	)		(10,035	)		(7,884	)
225			74			275	
	_			_			_
(9,651	)		(9,961	)		(7,609	)
(1,288	)		(1,254	)		(1,404	)
	_			_			_
\$ (10,939	)	\$	(11,215	)	\$	(9,013	)
				-			_
\$ (6.63	)	\$	(6.79	)	\$	(5.35	)
				-			_
1,649,40	9		1,650,71	7		1,683,199	9
					\$	(0.73	)
	4,874  8,367  (8,367  (1,509  (9,876  225  (9,651  (1,288  \$ (10,939)  \$ (6.63	4,874  8,367  (8,367 )  (1,509 )  (9,876 )  225  (9,651 )  (1,288 )  (10,939 )	4,874  8,367  (8,367  (1,509  (9,876  225  (9,651  (1,288 )  (10,939 )  \$ (6.63 )  \$	4,874       1,641         8,367       5,048         (8,367)       (4,671         (1,509)       (5,364         (9,876)       (10,035         225       74         (9,651)       (9,961         (1,288)       (1,254         \$ (10,939)       \$ (11,215         \$ (6.63)       \$ (6.79)	4,874       1,641         8,367       5,048         (8,367)       (4,671)         (1,509)       (5,364)         (9,876)       (10,035)         225       74         (9,651)       (9,961)         (1,288)       (1,254)         (10,939)       \$ (11,215)         \$ (6.63)       \$ (6.79)	4,874       1,641         8,367       5,048         (8,367)       (4,671)         (1,509)       (5,364)         (9,876)       (10,035)         225       74         (9,651)       (9,961)         (1,288)       (1,254)         (10,939)       (11,215)         (6.63)       (6.79)         (1,649,409)       1,650,717	4,874       1,641       1,785         8,367       5,048       6,193         (8,367 )       (4,671 )       (5,078 )         (1,509 )       (5,364 )       (2,806 )         (9,876 )       (10,035 )       (7,884 )         225

As of December 3	31,
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		2004		
	_	Actual		Pro Forma as Adjusted
	(Dollars in thousands)			sands)
Consolidated Balance Sheet Data:				
Cash and cash equivalents	\$	1,254	\$	56,238
Working capital (deficit)		(4,953)		49,214
Total assets		2,627		57,611
Long-term debt, net of current portion		11,573		2,089
Redeemable convertible preferred stock		25,354		_
Accumulated deficit		(59,292)		(76,916)
Total stockholders' equity (deficit)		(52,379)		24,402

- (1) For a discussion of the calculation of unaudited pro forma loss per share, see Note 2 to our consolidated financial statements.
- (2) See Note 11 to our consolidated financial statements.
- (3) See Note 13 to our consolidated financial statements.

#### RISK FACTORS

Any investment in our common stock involves a high degree of risk. You should carefully consider the risks described below together with all of the other information included in this prospectus before making an investment decision. If any of the following risks actually occurs, our business, results of operations or financial condition would likely suffer. In such an event, the trading price of our common stock could decline and you could lose all or part of your investment.

#### Clinical and Regulatory Risks

If we are unable to successfully design, conduct and complete clinical trials, we will not be able to obtain regulatory approval for our product candidates, which could delay or prevent us from being able to generate revenue from product sales.

We currently have no products for sale, and we cannot guarantee you that we will ever have marketable products. Before our product candidates can be commercialized, we or our partners must submit a New Drug Application, or NDA, to the FDA. The NDA must demonstrate that the product candidate is safe and effective in humans for its intended use. To support our NDAs, we or our partners must conduct extensive human tests, which are referred to as clinical trials. Satisfaction of all regulatory requirements typically takes many years and requires the expenditure of substantial resources.

We currently have several product candidates in various stages of clinical testing. The results of pre-clinical studies and early-stage clinical trials do not necessarily predict the results of later-stage clinical trials. All of our product candidates are prone to the risks of failure inherent in drug development and testing. Product candidates in later-stage clinical trials may fail to show desired safety and efficacy traits despite having progressed through initial clinical testing. In addition, the data collected from clinical trials of our product candidates may not be sufficient to support FDA approval, or FDA officials could interpret the data differently than we do. The FDA may require us or our partners to conduct additional clinical testing, in which case we would have to expend additional time and resources. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review.

Any failure or significant delay in completing clinical trials for our product candidates, or in receiving regulatory approval for the sale of our product candidates, may severely harm our business and delay or prevent us from being able to generate revenue from product sales, and our stock price will likely decline.

The results of our clinical trials are uncertain, which could substantially delay or prevent us from bringing our product candidates to market.

Before we can obtain regulatory approval for a product candidate, we must undertake extensive clinical testing in humans to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory agencies. Clinical trials are very expensive and difficult to design and implement. The clinical trial process is also time consuming. The commencement and completion of our clinical trials could be delayed or prevented by several factors, including:

delays in obtaining regulatory approvals to commence or continue a study;

delays in reaching agreement on acceptable clinical trial parameters;

slower than expected rates of patient recruitment and enrollment;

inability to demonstrate effectiveness or statistically significant results in our clinical trials;

unforeseen	safety	issues

uncertain dosing issues;

inability to monitor patients adequately during or after treatment; and

inability or unwillingness of medical investigators to follow our clinical protocols.

We cannot assure you that our planned clinical trials will begin or be completed on time or at all, or that they will not need to be restructured prior to completion. Significant delays in clinical testing will impede our ability to commercialize our product candidates and generate revenue from product sales and could materially increase our development costs. Completion of clinical trials may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a drug candidate. The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including:

the number of sites included in the trials;
the length of time required to enroll suitable patient subjects;
the number of patients that participate in the trials;
the number of doses that patients receive;
the duration of follow-up with the patient;
the product candidate's phase of development; and
the efficacy and safety profile of the product.

The use of FDA-approved therapeutics in our product candidates could require us to conduct additional preclinical studies and clinical trials, which could increase development costs and lengthen the regulatory approval process.

Our product candidates utilize proprietary formulations and topical delivery technologies to administer FDA-approved pain management therapeutics. Although the therapeutics utilized in our product candidates are FDA-approved, we may still be required to conduct preclinical studies and clinical trials to determine if our product candidates are safe and effective. In addition, we may also be required to conduct additional preclinical studies and Phase I clinical trials to establish the safety of the topical delivery of these therapeutics and the level of absorption of the therapeutics into the bloodstream. The FDA may also require us to conduct clinical studies to establish that our delivery mechanisms are safer or more effective than the existing methods for delivering these therapeutics. As a result, we may be required to conduct complex clinical trials even though we are not developing new chemical entities, which could be expensive and time-consuming and lengthen the anticipated regulatory approval process.

In some instances, we rely on third parties, over which we have little or no control, to conduct clinical trials for our products and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates.

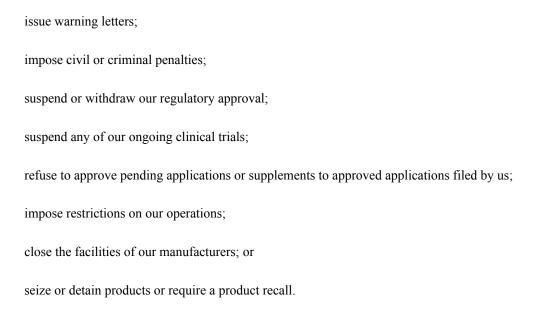
Pursuant to our license agreement with Adolor for LidoPAIN SP, Adolor is responsible for conducting clinical studies relating to LidoPAIN SP in North America. In addition, Adolor has the exclusive control over, and authority and responsibility for, the North American regulatory strategies relating to LidoPAIN SP, including the preparation and filing of all documents submitted to the FDA. We may enter into similar agreements from time to time with additional third parties for our other product candidates whereby these third parties undertake significant responsibility for research, clinical trials or other aspects of obtaining FDA approval. As a result, we may face delays if Adolor or these additional third parties do not conduct clinical studies and trials, or prepare or file regulatory related documents, in a timely or competent fashion. The conduct of the clinical studies by, and the regulatory strategies of, Adolor or these additional third parties, over which we have limited or no control, may delay or prevent regulatory approval of our product candidates, which would delay or limit our ability to generate revenue from product sales.

Clinical trial designs that were discussed with regulatory authorities prior to their commencement may subsequently be considered insufficient for approval at the time of application for regulatory approval.

We or our partners discuss with and obtain guidance from regulatory authorities on several of our clinical trial protocols. Over the course of conducting our clinical trials, circumstances may change, such as standards of safety, efficacy or medical practice, which could affect regulatory authorities' perception of the adequacy of any of our clinical trial designs or the data we develop from our studies. Changes in circumstances could affect our ability to conduct clinical trials as planned. Even with successful clinical safety and efficacy data, we may be required to conduct additional, expensive trials to obtain regulatory approval.

If we receive regulatory approval, our marketed products will also be subject to ongoing FDA obligations and continued regulatory review and if we fail to comply with these regulations, we could lose approvals to market any products and our business would be seriously harmed.

Following initial regulatory approval of any of our product candidates, we will be subject to continuing regulatory review, including review of adverse experiences and clinical results that are reported after our products become commercially available. This would include results from any post-marketing tests or vigilance required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our product candidates will also be subject to periodic review and inspection by the FDA or foreign regulatory agencies. If a previously unknown problem or problems with a product, manufacturing or laboratory facility used by us is discovered, the FDA or foreign regulatory agency may impose restrictions on that product or on the manufacturing facility, including requiring us to withdraw the product from the market. Any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. We and our manufacturers will be subject to ongoing FDA requirements for submission of safety and other post-market information. If we and our manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:



In addition, the FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad.

Even if the FDA approves our product candidates, the approval will be limited to those indications and conditions for which we are able to show clinical safety and efficacy.

Any regulatory approval that we may receive for our current or future product candidates will be limited to those diseases and indications for which such product candidates are clinically demonstrated to be safe and effective. In addition to the FDA approval required for new formulations, any new indication to an approved product also requires FDA approval. If we are not able to obtain FDA approval for a broad range of indications for our product candidates, our ability to effectively market and sell our product candidates may be greatly reduced and may harm our ability to generate revenue.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by regulatory authorities, our regulatory approvals will be limited to those indications that are specifically submitted to the FDA for

review. These "off-label" uses are common across medical specialties and may constitute the best treatment for many patients in varied circumstances. Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to delay its approval or refuse to approve a product, the suspension or withdrawal of an approved product from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecutions, any of which could harm our business.

## **Risks Relating to Commercialization**

If we fail to enter into and maintain successful strategic alliances for our product candidates, we may have to reduce or delay our product commercialization or increase our expenditures.

Our strategy for developing, manufacturing and commercializing potential product candidates in multiple therapeutic areas currently requires us to enter into and successfully maintain strategic alliances with pharmaceutical companies that have product development resources and expertise, established distribution systems and direct sales forces to advance our development programs and reduce our expenditures on each development program and market any products that we may develop. We have formed a strategic alliance with Adolor with respect to our LidoPAIN SP product candidate and with Endo with respect to our LidoPAIN BP product candidate. Although we have ongoing discussions with other companies with respect to certain of our product candidates, we may not be able to negotiate additional strategic alliances on acceptable terms, or at all. If we are unable to maintain our existing strategic alliances or establish and maintain additional strategic alliances, we may have to limit the size or scope of, or delay, one or more of our product development or commercialization programs, or undertake the various activities at our own expense. In addition, our dependence on strategic alliances is subject to a number of risks, including:

the inability to control the amount or timing of resources that our collaborators may devote to developing the product candidates:

the possibility that we may be required to relinquish important rights, including intellectual property, marketing and distribution rights;

the receipt of lower revenues than if we were to commercialize such products ourselves;

our failure to receive future milestone payments or royalties should a collaborator fail to commercialize one of our product candidates successfully;

the possibility that a collaborator could separately move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors;

the possibility that our collaborators may experience financial difficulties;

business combinations or significant changes in a collaborator's business strategy that may adversely affect that collaborator's willingness or ability to complete its obligations under any arrangement; and

the chance that our collaborators may operate in countries where their operations could be negatively impacted by changes in the local regulatory environment or by political unrest.

If the market does not accept and use our product candidates, we will not achieve sufficient product revenues and our business will suffer.

Even if we receive regulatory approval to market our product candidates, physicians, patients, healthcare payors and the medical community may not accept and use them. The degree of market acceptance and use of any approved products will depend on a number of factors, including:

perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products;

cost effectiveness of our products relative to competing products;

relative convenience and ease of administration;

availability of reimbursement for our products from government or healthcare payors; and

effectiveness of marketing and distribution efforts by us and our licensees and distributors.

Because we expect to rely on sales and royalties generated by our current lead product candidates for a substantial portion of our product revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional funding to continue our other development programs.

Our product candidates could be rendered obsolete by technological change and medical advances, which would adversely affect the performance of our business.

Our product candidates may be rendered obsolete or uneconomical by the development of medical advances to treat the conditions that our product candidates are designed to address. Pain management therapeutics are the subject of active research and development by many potential competitors, including major pharmaceutical companies, specialized biotechnology firms, universities and other research institutions. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or product candidates obsolete or noncompetitive or result in treatments or cures superior to any therapy we developed. Technological advances affecting costs of production could also harm our ability to cost-effectively produce and sell products.

#### We have no manufacturing capacity and anticipate continued reliance on third parties for the manufacture of our product candidates.

We do not currently operate manufacturing facilities for our product candidates. We lack the resources and the capabilities to manufacture any of our product candidates. We currently rely on a single contract manufacturer for each product candidate to supply, store and distribute drug supplies for our clinical trials. Any performance failure or delay on the part of our existing manufacturers could delay clinical development or regulatory approval of our product candidates and commercialization of our drugs, producing additional losses and depriving us of potential product revenues.

If the FDA or other regulatory agencies approve any of our product candidates for commercial sale, the product will need to be manufactured in larger quantities. Since to date our product candidates have only been manufactured in small quantities for preclinical and clinical trials, our third party manufacturers may not be able to successfully increase their manufacturing capacity in a timely or economical manner, or at all. We may be forced to identify alternative or additional third party manufacturers, which may prove difficult because the number of potential manufacturers is limited and the FDA must approve any replacement contractor prior to manufacturing our products. Such approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our product candidates. It may be difficult or impossible for us to find a replacement

manufacturer on acceptable terms quickly, or at all. If we are unable to successfully increase the manufacturing capacity for a drug candidate in a timely and economical manner, the regulatory approval or commercial launch of any related products may be delayed or there may be a shortage in supply, both of which may have an adverse effect on our business.

Our product candidates require precise, high quality manufacturing. A failure to achieve and maintain high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business. Manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. These manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Agency, or DEA, and corresponding state agencies to ensure strict compliance with current Good Manufacturing Practice and other applicable government regulations and corresponding foreign standards; however, we do not have control over third party manufacturers' compliance with these regulations and standards. If one of our manufacturers fails to maintain compliance, the production of our product candidates could be interrupted, resulting in delays, additional costs and potentially lost revenues. Additionally, third-party manufacturers must pass a preapproval inspection before we can obtain marketing approval for any of our products in development.

Furthermore, our existing and future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our product candidates. Even if any third party manufacturer or licensee makes improvements in the manufacturing process for our product candidates, we may not own, or may have to share, the intellectual property rights to such innovation. In the event of a natural disaster, equipment failure, power failure, strike or other difficulty, we may be unable to replace our third party manufacturers in a timely manner.

We may be the subject of costly product liability claims or product recalls, and we may be unable to obtain or maintain insurance adequate to cover potential liabilities.

The risk of product liability is inherent in the development, manufacturing and marketing of human therapeutic products. Regardless of merit or eventual outcome, product liability claims may result in:

delays in, or failure to complete, our clinical trials; withdrawal of clinical trial participants; decreased demand for our product candidates; injury to our reputation;

litigation costs;

substantial monetary awards against us; and

diversion of management or other resources from key aspects of our operations.

If we succeed in marketing our products, product liability claims could result in an FDA investigation of the safety or efficacy of our products or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, or limitations on the indications for which our products may be used, or suspension or withdrawal of approval.

We currently have product liability insurance that covers our clinical trials up to a \$1,000,000 limit per occurrence. We intend to increase this coverage by \$2,000,000 to \$3,000,000 upon the policy's renewal in May 2005. We further intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. However, insurance coverage is increasingly expensive. We may not be able to obtain additional insurance or maintain our existing insurance coverage at a reasonable cost or at all. While we believe our product liability insurance coverage is adequate, our existing insurance or any insurance coverage that we obtain in the future may not cover at all, or may not adequately cover, any potential claims or losses.

The coverage and reimbursement status of newly approved healthcare drugs is uncertain and failure to obtain adequate coverage and reimbursement could limit our ability to market our products.

Our ability to commercialize any products successfully will depend in part on the extent to which reimbursement will be available from governmental and other third-party payors, both in the United States

and in foreign markets. Even if we succeed in bringing one or more products to the market, the amount reimbursed for our products may be insufficient to allow them to compete effectively with products that are reimbursed at a higher level. If the price we are able to charge for any products we develop is inadequate in light of our development costs, our profitability would be reduced.

Reimbursement by a governmental and other third-party payor may depend upon a number of factors, including the governmental and other third-party payor's determination that the use of a product is:

a covered benefit under its health plan;
safe, effective and medically necessary;
appropriate for the specific patient;
cost-effective; and
neither experimental nor investigational.

Obtaining reimbursement approval for a product from each third-party and governmental payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to obtain reimbursement.

Eligibility for coverage does not imply that any drug product will be reimbursed in all cases or at a rate that allows us to make a profit. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not become permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost drugs that are already reimbursed, may be incorporated into existing payments for other products or services and may reflect budgetary constraints and/or Medicare or Medicaid data used to calculate these rates. Net prices for products also may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

The health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products. There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect reimbursement levels for our future products. In addition, the Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions.

#### Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our profitability would be reduced.

## **Risks Relating to our Financial Condition**

Our independent registered public accounting firm determined that a material weakness related to our internal controls and procedures existed, which could adversely impact our ability to report our consolidated financial results accurately and on a timely basis.

As a result of numerous journal entry adjustments and corrections recorded in the latter part of 2004 in connection with the audit of our 2003 and 2002 consolidated financial statements and the restatement of our 2001 consolidated financial statements, our independent registered public accounting firm determined that a reportable condition constituting a material weakness related to our financial reporting internal controls and procedures existed in those prior periods. In addition, solely as a result of a correction in our revenue recognition policy related to our agreement with Endo and the resultant restatement of our consolidated financial statements for 2003 and the nine months ended September 30, 2004, our independent registered public accounting firm determined that the material weakness applied to these periods as well. Such journal entry adjustments and corrections related to our accounting for revenue recognition, patents, redeemable preferred stock dividends, beneficial conversion features of our debt and equity instruments, interest and other individually insignificant items.

Our auditors have made various recommendations to improve our financial reporting internal controls, including establishing formal technical accounting training for financial personnel, reviewing our internal financial and accounting resources, performing periodic detailed financial analysis of EpiCept's and its German subsidiary's financial results, documenting our conclusions on technical accounting issues and determinations on a timely basis and ensuring the technical proficiency of our audit committee to oversee our financial reporting function. We are addressing these issues and have acted upon many of these recommendations. We hired a Chief Financial Officer in the second quarter of 2004. We also hired a certified public accountant for our finance department. We have installed a new general ledger system and have adopted stricter journal entry authorization procedures. We have had only limited experience with the improvements we have made to date. We cannot assure you that the steps we have taken to date or any future measures will remediate the material weakness reported by our independent registered public accounting firm or that we will implement and maintain adequate controls over our financial reporting in the future. Our independent registered public accounting firm has not evaluated the steps we have taken or intend to take to address the material weakness described above. We cannot assure you that additional material weaknesses or reportable conditions in our financial reporting internal controls will not be discovered in the future. Any failure to remediate any reported material weaknesses or implement required new or improved internal controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Inadequate internal controls could also cause investors to lose confidence in our reported financial statements. which could result in a decline in trading prices for our stock.

In addition, in 2006 we will be required to comply with Section 404(a) of the Sarbanes-Oxley Act of 2002, which requires annual management assessments of the effectiveness of our internal controls over financial reporting and an attestation to, and testing and assessment of, our internal controls over financial reporting by our independent registered public accounting firm. While we have begun the development and execution of a plan to ensure the effectiveness of our internal controls over financial reporting, our failure to satisfy the requirements of Section 404 on a timely basis could result in a decline in the trading price of our common stock.

Our recurring losses and stockholders' deficit has raised substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations and our stockholders' deficit raise substantial doubt about our ability to continue as a going concern and as a result our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements for the year ended December 31, 2004 with respect to this uncertainty. In March 2005, we raised \$4.0 million in a debt financing, which we expect will be sufficient to fund our operations through the third quarter of 2005. We

will need to raise additional debt or equity capital to fund our product development efforts and to meet our obligations, including servicing our existing indebtedness and performing our contractual obligations under our license agreements and strategic alliances. In addition, the perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

We have had limited operating activities, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our activities to date have been limited to organizing and staffing our operations, acquiring, developing and securing our technology and undertaking preclinical and clinical studies and clinical trials. We have not yet demonstrated our ability to obtain regulatory approval, manufacture products or conduct sales and marketing activities. Consequently, it is difficult to make any predictions about our future success, viability or profitability based on our historical operations.

We have incurred significant losses since our inception, may not generate revenue from product sales for the foreseeable future.

Since our inception in 1993, we have incurred significant net losses in each year. Our losses have resulted principally from costs incurred in connection with our development activities and from general and administrative costs associated with our operations. Our net loss for the fiscal year ended December 31, 2004 was \$7.6 million. As of December 31, 2004, we had an accumulated deficit of \$59.3 million. Even if we succeed in developing and commercializing one or more of our products, we may never become profitable. We expect to continue to incur increasing expenses over the next several years as we:

continue to conduct clinical trials for our product candidates;

seek regulatory approvals for our product candidates;

develop, formulate and commercialize our product candidates;

implement additional internal systems and develop new infrastructure;

acquire or in-license additional products or technologies or expand the use of our technologies;

maintain, defend and expand the scope of our intellectual property; and

hire additional personnel.

We will need to generate significant revenues to achieve and maintain profitability. If we cannot successfully develop and commercialize our products, we will not be able to generate significant revenue from product sales or achieve profitability in the future. Our failure to achieve or maintain profitability could cause the market price of our common stock and the value of your investment to decline.

We may need substantial additional funding, may be unable to raise additional capital when needed and may not continue as a going concern. This could force us to delay, reduce or eliminate our product development and commercialization activities.

Developing drugs, conducting clinical trials and commercializing products is time-consuming and expensive. Our future funding requirements will depend on many factors, including:

the progress and cost of our clinical trials and other development activities;

the costs and timing of obtaining regulatory approval;

the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patent and other intellectual property rights; the cost and timing of securing manufacturing capabilities for our clinical product candidates and commercial products, if any; the costs of establishing sales, marketing and distribution capabilities; and the terms and timing of any collaborative, licensing and other arrangements that we may establish.

We believe that the net proceeds from this offering, together with our cash on hand, will be sufficient to fund our projected operating requirements for the next two years. However, we may need to raise additional capital or incur indebtedness to continue to fund our operations in the future. The audit report from our independent registered public accounting firm, included elsewhere in this prospectus, states that our recurring losses from operations and our accumulated deficit raise substantial doubt about our ability to continue as a going concern. We cannot assure you that sufficient funds will be available to us when required or on satisfactory terms. If necessary funds are not available, we may have to delay, reduce the scope of or eliminate some of our development programs, which could delay the time to market for any of our product candidates.

Our quarterly financial results are likely to fluctuate significantly, which could have an adverse effect on our stock price.

Our quarterly operating results are difficult to predict and may fluctuate significantly from period to period, particularly because we are a relatively small company with no approved products. The level of our revenues, if any, and results of operations at any given time could fluctuate as a result of any of the following factors:

research and development expenses incurred in connection with our Endo license agreement;
results of our clinical trials;
our ability to obtain regulatory approval for our product candidates;
our ability to achieve milestones under our strategic relationships on a timely basis or at all;
timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
regulatory approvals and legislative changes affecting the products we may offer or those of our competitors;
our ability to establish and maintain a productive sales force;
demand and pricing of any products we may offer;
physician and patient acceptance of our products;
levels of third-party reimbursement for our products;
interruption in the manufacturing or distribution of our products;
the effect of competing technological and market developments;
litigation involving patents, licenses or other intellectual property rights; and

product failures or product liability lawsuits.

Until we obtain regulatory approval for any of our product candidates, we cannot begin to market or sell them. As a result, it will be difficult for us to forecast demand for our products with any degree of certainty. It is also difficult for us to predict the timing of the achievement of various milestones under our strategic relationships. In addition, we will be increasing our operating expenses as we develop our product candidates and build our commercial capabilities. Accordingly, we may experience significant, unanticipated quarterly losses. Because of these factors, our operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our stock price to decline significantly.

Raising additional capital may cause dilution to existing stockholders or require us to relinquish valuable rights.

We may raise additional capital through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Our ability to raise additional capital will depend on financial, economic and market conditions and other factors, many of which are beyond our control. We cannot be certain that such additional funding will be available upon acceptable terms, or at all. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience further dilution.

Debt financing, if available, may subject us to restrictive covenants that could limit our flexibility in conducting future business activities. To the extent that we raise additional capital through collaboration and licensing arrangements, it may be necessary for us to relinquish valuable rights to our product candidates that we might otherwise seek to develop or commercialize independently.

# **Risks Relating to Intellectual Property**

If we are unable to protect our intellectual property, our competitors could develop and market products with features similar to our products and demand for our products may decline.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our technologies and product candidates as well as successfully defending these patents and trade secrets against third party challenges. We will only be able to protect our intellectual property from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. In addition, changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents, and we could lose our patent rights as a result;

we might not have been the first to file patent applications for these inventions or our patent applications may not have been timely filed, and we could lose our patent rights as a result;

others may independently develop similar or alternative technologies or duplicate any of our technologies;

it is possible that none of our pending patent applications will result in issued patents;

our issued patents may not provide a basis for commercially viable drugs or therapies, may not provide us with any protection from unauthorized use of our intellectual property by third parties, may not provide us with any competitive advantages;

our patent applications or patents may be subject to interference, opposition or similar administrative proceedings;

we may not develop additional proprietary technologies that are patentable; or

the patents of others may have an adverse effect on our business.

Moreover, the issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be afforded by our patents if we attempt to enforce them and they are challenged in court or in other proceedings, such as oppositions, which may be brought in U.S. or foreign jurisdictions to challenge the validity of a patent. A third party may challenge the validity or enforceability of a patent after its issuance by the U.S. Patent and Trademark Office, or USPTO. It is possible that a third party could attempt to challenge the validity or enforceability of the two issued patents related to LidoPAIN SP based upon a short videotape prepared by the inventor more than one year prior to the filing of the initial patent application related to LidoPAIN SP. It is possible that a third party could attempt to challenge the validity and enforceability of these patents based on the videotape and/or its nondisclosure to the USPTO.

The defense and prosecution of intellectual property suits, interferences, oppositions and related legal and administrative proceedings in the United States are costly, time consuming to pursue and result in diversion of resources. The outcome of these proceedings is uncertain and could significantly harm our business.

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific partners and other advisors may unintentionally or willfully disclose our confidential information to competitors. Enforcing a claim that a third party improperly obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we are not able to defend the patent protection position of our technologies and product candidates, then we will not be able to exclude competitors from marketing product candidates that directly compete with our product candidates, and we may not generate enough revenue from our product candidates to justify the cost of their development and to achieve or maintain profitability.

If we are sued for infringing intellectual property rights of third parties, such litigation will be costly and time consuming, and an unfavorable outcome could increase our costs or have a negative impact on our business.

Our ability to commercialize our products depends on our ability to sell our products without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending applications, which are owned by third parties, exist with respect to the therapeutics utilized in our product candidates and topical delivery mechanisms. Because we are utilizing existing therapeutics, we need to ensure that we can utilize these therapeutics without infringing existing patent rights. Accordingly, we have reviewed related patents known to us and, in some instances, licensed related patented technologies. In addition, because patent applications can take several years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates may infringe.

There could also be existing patents of which we are not aware that our product candidates may inadvertently infringe.

Although we are not aware that any of our product candidates infringe the intellectual property of others, we cannot assure you that this is the case. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we infringe on their technology, we could face a number of issues that could increase our costs or have a negative impact on our business, including:

infringement and other intellectual property claims which, with or without merit, can be costly and time consuming to litigate and can delay the regulatory approval process and divert management's attention from our core business strategy;

substantial damages for past infringement, which we may have to pay if a court determines that our product infringes a competitor's patent;

an injunction prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it is not required to do; and

if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents.

We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary claims, we may lose valuable intellectual property rights or personnel. A loss of key research

personnel or their work product could hamper or prevent our ability to commercialize certain product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

# Risks Relating to our Business and Industry

### Our failure to attract and retain skilled personnel could impair our product development and commercialization efforts.

Our success is substantially dependent on our continued ability to attract, retain and motivate highly qualified management, scientific and technical personnel and our ability to develop and maintain important relationships with leading institutions, clinicians and scientists. We are highly dependent upon our key management personnel, particularly John V. Talley, our President and Chief Executive Officer, and Robert Cook, our Chief Financial Officer. We are also dependent on our scientific and technical personnel. The loss of the services of any member of our senior management, scientific or technical staff may significantly delay or prevent the achievement of product development, commercialization and other business objectives. Messrs. Talley and Cook have entered into employment agreements with us. However, either of them may decide to voluntarily terminate his employment with us. We do not maintain key-man life insurance on any of our employees.

We also rely on consultants and advisors to assist us in formulating our research and development strategy. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments such as consulting or advisory contracts with other organizations that may affect their ability to contribute to us.

As of December 31, 2004, we had 13 employees. We believe that we will need to recruit additional management and technical personnel. There is currently a shortage of, and intense competition for, skilled executives and employees with relevant scientific and technical expertise, and this shortage is likely to continue. The inability to attract and retain sufficient scientific, technical and managerial personnel could limit or delay our product development efforts, which would reduce our ability to successfully commercialize our product candidates and grow our business.

We expect to expand our operations, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to have significant growth in the scope of our operations as our product candidates are commercialized. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business strategy or disrupt our operations.

Our competitors may develop and market drugs that are less expensive, safer, or more effective, which may diminish or eliminate the commercial success of any of our product candidates.

The biotechnology and pharmaceutical industries are highly competitive and characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in technology. If we fail to stay at the forefront of technological change, we will be unable to compete effectively. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of different approaches by one or more of our current or future competitors.

We will compete with Pfizer and Endo in the treatment of neuropathic pain; Purdue Pharmaceuticals, Johnson & Johnson and Endo in the treatment of post-operative pain; Johnson & Johnson and others in the treatment of back pain. Our competitors may:

develop and market product candidates that are less expensive and more effective than our future product candidates;

adapt more quickly to new technologies and scientific advances;

commercialize competing product candidates before we or our partners can launch any product candidates developed from our product candidates;

initiate or withstand substantial price competition more successfully than we can;

have greater success in recruiting skilled scientific workers from the limited pool of available talent;

more effectively negotiate third party licenses and strategic alliances; and

take advantage of acquisition or other opportunities more readily than we can.

We will compete for market share against fully-integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors, either alone or together with their partners, may develop new product candidates that will compete with ours, as these competitors may operate larger research and development programs or have substantially greater financial resources than we do. Our competitors may also have significantly greater experience in:

developing drugs;

undertaking preclinical testing and human clinical trials;

building relationships with key customers and opinion-leading physicians;

obtaining and maintaining FDA and other regulatory approvals of drugs;

formulating and manufacturing drugs; and

launching, marketing and selling drugs.

These and other competitive factors may negatively impact our financial performance.

# EpiCept GmbH, our German subsidiary, is subject to various risks associated with its international operations.

Our subsidiary, EpiCept GmbH, operates in Germany and we face a number of risks associated with its operations, including:

difficulties and costs associated in complying with German laws and regulations;

changes in the German regulatory environment;

increased costs associated with operating in Germany;

increased costs and complexities associated with financial reporting; and

difficulties in maintaining international operations.

Expenses incurred by our German operations are typically denominated in euros. In addition, EpiCept GmbH has incurred indebtedness that is denominated in euros and requires that interest payments be paid in euros. As a result, our costs of maintaining and operating our German subsidiary, and the interest payments and costs of repaying its indebtedness, increase if the value of the U.S. dollar relative to the euro declines.

#### Risks Relating to our Common Stock and this Offering

We expect that our stock price will fluctuate significantly, and you may not be able to resell your shares at or above the initial public offering price.

Prior to this offering, there has been no public market for our common stock. An active and liquid trading market for our common stock may not develop or be sustained following this offering. We will negotiate and determine the initial public offering price with the representatives of the underwriters based on several factors. This price may vary from the market price of our common stock after this offering. The volatility of biopharmaceutical stocks often does not relate to the operating performance of the companies represented by the stock. Factors that could cause this volatility in the market price of our common stock include:

results from and any delays in our clinical trial programs;

announcements concerning our collaborations with Adolor and Endo or future strategic alliances;

delays in the development and commercialization of our product candidates due to inadequate allocation of resources by our strategic collaborators or otherwise;

market conditions in the broader stock market in general, or in the pharmaceutical and biotechnology sectors in particular;

issuance of new or changed securities analysts' reports or recommendations;

actual and anticipated fluctuations in our quarterly financial and operating results;

developments or disputes concerning our intellectual property or proprietary rights;

introduction of technological innovations or new commercial products by us or our competitors;

additions or departures of key personnel;

FDA or international regulatory actions affecting us or our industry;

issues in manufacturing our product candidates;

market acceptance of our product candidates;

third party healthcare reimbursement policies; and

litigation or public concern about the safety of our product candidates.

These and other factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise reduce the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

If the ownership of our common stock continues to be highly concentrated, it may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

Our executive officers, directors and their affiliates will beneficially own or control approximately 34.6% of the outstanding shares of our common stock (after giving effect to the conversion of all outstanding convertible preferred stock and the exercise of all outstanding vested and unvested options and warrants) following the completion of this offering. Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may

also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may cause the trading price of our common stock to decline due to investor perception that conflicts of interest may exist or arise.

If securities or industry analysts do not publish research or reports about our business, if they change their recommendations regarding our stock adversely or if our operating results do not meet their expectations, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if one or more of the analysts who cover us downgrade our stock or if our operating results do not meet their expectations, our stock price could decline.

#### Future sales of common stock by our existing stockholders may cause our stock price to fall.

The market price of our common stock could decline as a result of sales by our existing stockholders in the market after this offering, or the perception that these sales could occur. These sales might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate. Our officers and directors as well as substantially all of our stockholders and option holders, who collectively beneficially own 99.7% of our common stock in the aggregate, have entered into lock-up agreements. The lock-up agreements provide that Wachovia Capital Markets, LLC, in its sole discretion, may release those parties, at any time or from time to time and without notice, from their obligation not to dispose of shares of common stock for a period of 180 days after the date of this prospectus. Wachovia Capital Markets, LLC has no pre-established conditions to waiving the terms of the lock-up agreements, and any decision by it to waive those conditions would depend on a number of factors, which may include market conditions, the performance of the common stock in the market and our financial condition at that time. See "Shares Eligible for Future Sale."

We will have broad discretion in how we use the proceeds of this offering, and we may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds of this offering. We currently intend to use the net proceeds for working capital and general corporate purposes, including:

clinical trials;

research and development expenses;

general and administrative expenses; and

potential acquisitions of companies, products and technologies that complement our business.

The amounts and timing of our actual expenditures depend on several factors, including the progress of our research and development efforts and the amount of cash used by our operations. We have not yet determined the amount or timing of the expenditures listed above. We also intend to use approximately \$9.8 million of the net proceeds to repay existing indebtedness (including accrued interest and net of proceeds from the exercise of the bridge warrants). We may use the net proceeds in ways in which stockholders do not agree, or for corporate purposes that do not yield a significant return or any return at all for our stockholders.

Provisions of our charter documents or Delaware law could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders, and could make it more difficult for you to change management.

Provisions of our cer	tificate of incorporation and	d bylaws may discourage,	delay or prevent a merger,	, acquisition or of	ther change in
control that stockholders	may consider favorable, inc	cluding transactions in			

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which stockholders might otherwise receive a premium for their shares. This is because these provisions may prevent or frustrate attempts by stockholders to replace or remove our current management. These provisions include:

a classified board of directors;

a prohibition on stockholder action through written consent;

a requirement that special meetings of stockholders be called only by the board of directors or a committee duly designated by the board of directors whose powers and authorities include the power to call such special meetings;

advance notice requirements for stockholder proposals and nominations; and

the authority of the board of directors to issue preferred stock with such terms as the board of directors may determine.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person that together with its affiliates owns or within the last three years has owned 15% of our voting stock, 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. Accordingly, Section 203 may discourage, delay or prevent a change in control of our company.

As a result of these provisions in our charter and Delaware law, the price investors may be willing to pay in the future for shares of our common stock may be limited.

#### The requirements of being a public company may strain our resources and distract management.

As a public company, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the Sarbanes-Oxley Act and the listing requirements of The Nasdaq National Market, Inc. We expect that the obligations of being a public company will require significant additional expenditures and will place additional demands on our management as we comply with the reporting requirements of a public company. We will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

#### We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have not paid cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our businesses. In addition, the terms of existing or any future debt may preclude us from paying these dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

# Investors in this offering will pay a much higher price than the book value of our common stock.

If you purchase common stock in this offering, you will pay more for your shares than the amounts paid by existing stockholders for their shares. New investors will pay 71% of the total consideration we have received from stockholders since inception but will only own 32% of the total shares of common stock outstanding. You will incur immediate and substantial dilution of \$9.72 per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and an assumed initial public offering price of \$12.00 (the midpoint of the price range set forth on the cover of this prospectus). In the past, we issued options and warrants to acquire common stock at prices significantly below the initial public offering price. To the extent these outstanding options or warrants are ultimately exercised, you will sustain further dilution.

# SPECIAL NOTE REGARDING 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.

Forward-looking statements include, but are not limited to, statements about:

the progress of preclinical development and laboratory testing and clinical trials;

the time and costs involved in obtaining regulatory approvals;

delays that may be caused by evolving requirements of regulatory agencies;

the number of drug candidates we pursue;

the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;

the establishment of sales, marketing and/or manufacturing capabilities;

our ability to establish, enforce and maintain selected strategic alliances and activities required for product commercialization;

the acquisition of technologies, products and other business opportunities that require financial commitments; and

our revenues, if any, from successful development and commercialization of our drug candidates.

These statements relate to future events or 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. These risks and other factors include those listed under "Risk Factors" and elsewhere in this prospectus. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We do not intend to update any of the forward-looking statements after the date of this prospectus or to conform these statements to actual results. Neither the Private Securities Litigation Reform Act of 1995 nor Section 27A of the Securities Act provides any protection to us for statements made in this prospectus.

#### **USE OF PROCEEDS**

Our net proceeds from the sale of 5,500,000 shares of common stock in this offering are estimated to be approximately \$59.3 million, based on an assumed offering price of \$12.00 per share (the midpoint of the price range set forth on the cover of this prospectus), after deducting estimated underwriting discounts and commissions and estimated offering expenses, which are payable by us.

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

approximately \$19 to \$20 million to further the clinical development of NP-1;

approximately \$5 million to further the clinical development of LidoPAIN SP; and

approximately \$5 to \$6 million to further the clinical development of LidoPAIN BP.

We expect that net proceeds will be sufficient to fund our anticipated clinical trials and the filing of our NDAs for these product candidates if our clinical trials are successful.

We also intend to use a portion of the proceeds to repay approximately \$9.8 million of our outstanding indebtedness (including accrued interest and net of proceeds from the exercise of the bridge warrants), which includes our new senior notes due 2006, our convertible bridge loan and our loan from IKB. The senior notes mature on October 30, 2006 and bear interest at a rate of 8% per annum. The convertible bridge loan matures on October 30, 2006 and bears interest at a rate of 8% per annum. The term loan with IKB matures on June 30, 2007 and currently bears interest at a rate of 20% per annum, payable quarterly. We used the proceeds from our senior notes, convertible bridge loan and our loan from IKB to fund working capital and general corporate purposes. For more detail on the senior notes, the convertible bridge loan and our term loan from IKB, see "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

We intend to use the balance of our net proceeds of this offering to continue development of our earlier-stage products, fund operations, to provide working capital and for other general corporate purposes, which may include in-licensing or acquiring additional product candidates. We have no current agreements or commitments with respect to any future acquisitions or in-licensing, and we are not currently engaged in any negotiations with respect to any transactions of that nature.

The amounts and timing of our actual expenditures depend on several factors, including the progress of our research and development efforts and the amount of cash used by our operations. Pending their use, we intend to invest the net proceeds in short-term, investment-grade, interest-bearing instruments.

#### DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business.

#### **CAPITALIZATION**

The following table sets forth our cash and cash equivalents and our capitalization as of December 31, 2004 on an actual basis and on a pro forma as adjusted basis, to give effect to:

the filing of an amended and restated certificate of incorporation to authorize 50,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock;

the conversion of all of our preferred stock into an aggregate of 6,063,331 shares of common stock immediately prior to the closing of this offering;

the exercise of the bridge warrants into an aggregate of 3,861,464 shares of common stock immediately upon the closing of this offering;

the conversion of the tbg convertible term loan into an aggregate of 227,660 shares of common stock immediately prior to the closing of this offering;

the sale of 5,500,000 shares of common stock in this offering at an assumed initial public offering price of \$12.00 per share (the midpoint of the price range set forth on the cover of this prospectus), after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us; and

the repayment of certain of our outstanding indebtedness as described under "Use of Proceeds."

You should read this table in conjunction with the sections of this prospectus entitled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and with our consolidated financial statements and the notes thereto.

	As of December 31, 2004						
				Pro Forma			
		Actual		As Adjusted			
		(Dolla	Oollars in thousands)				
Cash and cash equivalents	\$	1,254	\$	56,238			
Long-term debt, less current portion	\$	11,573	\$	2,089			
Series B Redeemable Convertible Preferred Stock, \$0.0001 par							
value, 3,440,069 shares authorized, 3,106,736 shares issued and							
outstanding, actual; 0 shares issued and outstanding, pro forma		6,748		_			
Series C Redeemable Convertible Preferred Stock, \$0.0001 par							
value, 12,769,573 shares authorized, 8,839,573 shares issued and							
outstanding, actual; 0 shares issued and outstanding, pro forma		18,606		_			
Warrants		4,584		- (1)			
Stockholders' (deficit) equity:							
Series A Convertible Preferred Stock, \$0.0001 par value,							
3,422,620 shares authorized, 3,368,385 shares issued and							
outstanding, actual; 0 shares issued and outstanding, pro forma		8,226		_			
Common stock, \$0.0001 par value, 60,000,000 shares authorized,							
1,687,121 shares issued and outstanding, actual;							
50,000,000 shares authorized, 17,339,576 shares issued and							
outstanding, pro forma		1		2			
Preferred stock, \$0.0001 par value, 5,000,000 shares authorized,							
0 shares issued and outstanding, actual and pro forma		-		_			
Additional paid-in capital		150		102,781			
Deferred stock compensation		(25)		(25)			
Accumulated deficit		(59,292)		(76,916)(1)(2)			
Accumulated other comprehensive loss		(1,365)		(1,365)			
Treasury stock, 12,500 shares		(75 )		(75 )			
Total stockholders' (deficit) equity		(52,379)		24,402			
Total capitalization	\$	(10,868)	\$	26,491			

<sup>(1)</sup> Warrant value attributable to the Series B and Series C redeemable convertible preferred stock are reclassified as additional paid in capital.

The number of shares of common stock to be outstanding after this offering excludes:

<sup>(2)</sup> Reflects the impact of a beneficial conversion charge resulting from anti-dilution adjustments to the conversion of our preferred stock resulting from the exercise of the bridge warrants.

466,625 shares of our common stock issuable upon exercise of options outstanding as of December 31, 2004, at weighted average exercise price of \$1.48 per share;

4,736,943 shares of our common stock reserved for issuance under our 1995 Stock Option Plan, our 2005 Equity Incentive Plan and our 2005 Employee Stock Purchase Plan as of December 31, 2004; and

1,748,875 shares of our common stock issuable upon exercise of options to be granted on the date of this offering at an exercise price equal to the initial public offering price.

#### DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share and the historical adjusted net tangible book value per share of common stock upon the completion of this offering. The historical adjusted net tangible book value as of December 31, 2004 was approximately \$(19.7) million, or approximately \$(1.66) per share. Historical adjusted net tangible book value per share represents our total tangible assets less total liabilities divided by the pro forma total number of shares of common stock outstanding after giving effect to the automatic conversion of all shares of our outstanding preferred stock. Dilution in historical adjusted net tangible book value per share represents the difference between the amount per share paid by purchasers of common stock in this offering and the net tangible book value per share of common stock immediately after the closing of this offering.

After giving effect to the sale of the shares of common stock at an assumed initial public offering price of \$12.00 per share (the midpoint of the price range set forth on the cover of this prospectus) and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma net tangible book value as of December 31, 2004 would have been approximately \$39.6 million, or \$2.28 per share of common stock. This represents an immediate increase in net tangible book value of \$3.94 per share to existing stockholders and an immediate dilution of \$9.72 per share to new investors purchasing shares of common stock in this offering at the initial offering price.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		\$ 12.00
Historical net tangible book value per share at December 31, 2004	\$ (31.05)	
Pro forma per share increase attributable to preferred stock and		
tbg conversion and bridge warrant exercise	29.39	
Historical adjusted net tangible book value per share as of		
December 31, 2004	(1.66)	
Increase per share attributable to new investors	3.94	
Pro forma net tangible book value per share after this offering		2.28
Dilution per share to new investors		\$ 9.72

The following table summarizes as of December 31, 2004 the number of shares of our common stock purchased from us, the total consideration paid to us, and the average price per share paid to us by existing stockholders and to be paid by new investors purchasing shares of our common stock in this offering. The table assumes an initial public offering price of \$12.00 per share (the midpoint of the price range set forth on the cover of this prospectus), before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purch	<b>Shares Purchased</b>			<b>Total Consideration</b>				
			_				Price Per		
	Number	Percent		Amount	Percent		Share		
Existing stockholders	11,839,576	68 %	\$	26,700,000	29 %	\$	2.26		
New investors	5,500,000	32		66,000,000	71		12.00		

Total 17,339,576 100% \$ 92,700,000 100%

The above discussion and tables exclude:

466,625 shares of our common stock issuable upon exercise of options outstanding as of December 31, 2004, at a weighted average exercise price of \$1.48 per share;

4,736,943 shares of our common stock reserved for issuance under our 1995 Stock Option Plan, our 2005 Equity Incentive Plan and our 2005 Employee Stock Purchase Plan as of December 31, 2004;

1,748,957 shares of our common stock issuable upon exercise of options to be granted on the date of this offering, at an exercise price equal to the initial public offering price; and

825,000 shares of common stock issuable upon exercise by the underwriters of their over-allotment option.

To the extent the outstanding options are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

#### SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following financial information together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" following this section and our consolidated financial statements and the notes thereto included elsewhere in this prospectus.

The following tables present our selected consolidated balance sheet and statement of operations data as of and for the years ended December 31, 2000, 2001, 2002, 2003 and 2004. Our consolidated balance sheet data as of December 31, 2003 and 2004 and our consolidated statement of operations data for the years ended December 31, 2002, 2003 and 2004 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. Our consolidated statement of operations data for the year ended December 31, 2001 and consolidated balance sheet data as of December 31, 2002 have been derived from our audited consolidated financial statements not included in this prospectus. Our consolidated statement of operations data for the year ended December 31, 2000 and our consolidated balance sheet data as of December 31, 2000 and 2001 have been derived from our unaudited consolidated financial statements not included in this prospectus.

					Yea	r Ended De	cembe	er 31,		Year Ended December 31,									
	2000		2001	2002				2003			2004								
									Restated(3	)									
			(	Dollar	s in th	ousands, ex	cept p	er sha	re data)										
Consolidated Statement of																			
Operations Data:																			
Revenue	\$ -		\$ -		\$	-		\$	377		\$	1,115							
Operating expenses:																			
General and administrative	1,904		3,394			3,493			3,407			4,408							
Research and development	2,784		4,085			4,874			1,641			1,785							
Total operating expenses	4,688		7,479	_		8,367	_		5,048	_		6,193	_						
Loss from operations	(4,688	)	(7,479	)		(8,367	)		(4,671	)		(5,078							
Other income (expense), net	(2,070	)	186			(1,509	)		(5,364	)		(2,806	)						
Loss before benefit for income taxes	(6,758	)	(7,293	)		(9,876	)		(10,035	)		(7,884	)						
Benefit for income taxes	235	_	278	_		225	_		74	_		275							
Net loss	(6,523	)	(7,015	)		(9,651	)		(9,961	)		(7,609	)						
Deemed dividend and redeemable																			
convertible preferred stock dividends	(301	_)	(1,254	_)		(1,288	_)		(1,254	) _		(1,404							
Loss attributable to common																			
stockholders	\$ (6,824	)	\$ (8,269	)	\$	(10,939	)	\$	(11,215	)	\$	(9,013	)						
Basic and diluted loss per common		_								_			_						
share(1)	\$ (4.19	)	\$ (5.05	)	\$	(6.63	)	\$	(6.79	)	\$	(5.35	)						
Weighted average shares outstanding(1)	1,626,83	30	1,637,90	)5		1,649,40	9		1,650,71	7		1,683,19	9						
	-,0,00		-,,	-		-,,	-		-,,1			-,,-							

10,422,171

Shares used in computing unaudited pro forma basic and diluted loss per common share(1)(2)

	As of December 31,										
		2000		2001	2002		2003			2004	
								Restated(3)			
					(D	ollars in thousa	ands)				
Consolidated Balance Sheet Data:											
Cash and cash equivalents	\$	10,791	\$	5,356	\$	620	\$	8,007	\$	1,254	
Working capital (deficit)		9,896		4,590		(933)		4,518		(4,953)	
Total assets		11,232		5,654		951		8,196		2,627	
Long-term debt, net of current portion		5,709		5,407		7,085		10,272		11,573	
Redeemable convertible preferred stock		17,147		19,201		20,456		24,099		25,354	
Accumulated deficit		(22,998)		(30,013)		(39,664)		(50,411)		(59,292)	
Total stockholders' deficit		(13,931)		(21,174)		(31,430)		(43,652)		(52,379)	

<sup>(1)</sup> See Note 13 to our consolidated financial statements.

<sup>(2)</sup> For a discussion of the calculation of unaudited pro forma loss per common share, see Note 2 to our consolidated financial statements.

<sup>(3)</sup> See Note 11 to our consolidated financial statements.

#### MANAGEMENT'S DISCUSSION AND ANALYSIS

#### OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, including those set forth under the section entitled "Risk Factors" and elsewhere in this prospectus, our actual results may differ materially from those anticipated in these forward-looking statements.

#### Overview

We are a specialty pharmaceutical company focused on the development and commercialization of topically-delivered prescription pain management therapeutics. We have six product candidates in clinical development; three in late-stage development that are ready to enter, or have entered, Phase IIb or Phase III clinical trials, and three that have completed initial Phase II clinical trials. All of our product candidates target moderate-to-severe pain that is influenced, or mediated, by nerve receptors located just beneath the skin's surface. Our product candidates utilize proprietary formulations and several topical delivery technologies to administer FDA-approved pain management therapeutics, or analgesics.

Our late stage product candidates are:

EpiCept NP-1, a prescription topical analgesic cream designed to provide effective, long-term relief from the pain of peripheral neuropathies;

LidoPAIN SP, a sterile prescription analgesic patch designed to provide sustained topical delivery of lidocaine to a post-surgical or post-traumatic sutured wound while also providing a sterile protective covering for the wound; and

LidoPAIN BP, a prescription analgesic non-sterile patch designed to provide sustained topical delivery of lidocaine for the treatment of acute or recurrent lower back pain.

Our objective is to address unmet medical needs in pain management by developing a broad portfolio of topically-delivered prescription analyses for the treatment of moderate-to-severe pain where existing treatments are ineffective or cause significant adverse side effects. We have a strategy consisting of three key elements to achieve our objective:

focus our development efforts on topically-delivered analgesics targeting peripheral nerve receptors;

focus our development efforts on FDA-approved drugs; and

opportunistically enter into development and commercialization alliances for our products.

None of our product candidates has been approved by the FDA or any comparable foreign agencies. We have yet to generate revenues from product sales. We have not generated any significant revenues. During 2003, we entered into two agreements, the first in July with Adolor for the development and commercialization of certain products, including LidoPAIN SP in North America, and the second in December with Endo for the worldwide commercialization of certain products, including LidoPAIN BP. We received a total of \$10.0 million in upfront license fees upon the closing of these license agreements. Under these relationships, we are eligible to receive an additional \$102.5 million in milestone payments and, upon receipt of appropriate regulatory approvals, royalties based on net sales of products. There is no assurance that any of these milestones will be earned or any royalties paid. Our ability to generate additional revenue in the future will depend on our ability to meet development or regulatory milestones under our existing license agreements that trigger additional payments to

us, to enter into new license agreements for other products or territories and to receive regulatory approvals for, and successfully commercialize, our product candidates either directly or through commercial partners.

Since our inception we have incurred significant net losses each year. Our net loss for the year ended December 31, 2004 was \$7.6 million, and as of December 31, 2004, we had an accumulated deficit of

\$59.3 million. Our losses have resulted principally from costs incurred in connection with our development activities and from general and administrative expenses. Even if we succeed in developing and commercializing one or more of our product candidates, we may never become profitable. We expect to continue to incur increasing expenses over the next several years as we:

continue to conduct clinical trials for our product candidates;

seek regulatory approvals for our product candidates;

develop, formulate, and commercialize our product candidates;

implement additional internal systems and develop new infrastructure;

acquire or in-license additional products or technologies or expand the use of our technologies;

maintain, defend and expand the scope of our intellectual property; and

hire additional personnel.

Our operations to date have been funded principally through the proceeds from the sales of common and preferred securities, debt, revenue from collaborative relationships, investment income earned on cash balances and short-term investments and the sales of a portion of our New Jersey net operating loss carry forwards.

We have a 100%-owned subsidiary, EpiCept GmbH, based in Munich, Germany, which is engaged in research and development activities on our behalf. Historically, a significant amount of our debt was denominated in euros. Following this offering, more than half of our euro-denominated debt will either be repaid or converted into common stock.

# **Financial Operations Review**

# Revenues

Our revenues are limited to amounts earned under licenses and related development agreements. We have not generated any significant revenue from product sales or royalties, nor do we expect to generate such revenues in the near term. We are currently recognizing the payment of upfront license fees from our licensees as revenues either on the proportional performance method or on a straight-line basis over the anticipated development period for the respective product candidates. Ratable revenue recognition is only utilized if the research and development services are performed systematically over the development period. Proportional performance is measured based on costs incurred compared to total estimated costs over the development period which approximates the proportion of the value of the services provided compared to the total estimated value over the development period. The proportional performance method currently results in revenue recognition at a slower pace than the ratable method as many of our costs are incurred in the latter stages of the development period. We periodically review our estimates of cost and the length of the development period and, to the extent such estimates change, the impact of the change is recorded at that time. Licensing fees of \$2.5 and \$7.5 million were received in 2003 from Adolor and Endo, respectively, of which \$1.5 million in the aggregate was recognized as revenue through December 31, 2004. We expect that any revenue we generate as a result of the recognition of upfront license fees and the timing and amount of milestone payments we may receive from our strategic relationships, as well as those we may receive upon the sale of our product candidates, to the extent any are successfully commercialized, will vary from quarter-to-quarter and from year-to-year.

In connection with the review of our revenue recognition policy and subsequent to the issuance of our consolidated financial statements for the nine-month period ended September 30, 2004 and year ended December 31, 2003, we determined such statements contained an error relating to the accounting treatment that had been applied to the recognition of revenue under the Endo license agreement. We had previously

recognized revenue from the upfront license fee received from Endo ratably over the development period in which we are obligated to
participate on a continuing and substantial basis in the research and development activities as outlined in the contract. We subsequently
determined that such revenue should be recognized on the proportional performance method as costs for the research and

development are incurred. The effect of this error for the period beginning from the contract signing date through September 30, 2004 was a \$1.0 million reduction in recorded revenue (\$0.1 million for the year ended December 31, 2003 and \$0.9 million for the nine-month period ended September 30, 2004), from \$1.9 million to \$0.9 million, and a corresponding increase in our net loss from \$4.6 million to \$5.6 million. Our accumulated deficit as of September 30, 2004 increased from \$56.0 million to \$56.9 million. We restated our consolidated financial statements for the year ended December 31, 2003 and the nine-month period ended September 30, 2004 to reflect this correction. See Note 11 in the notes to the consolidated financial statements for additional information relating to December 31, 2003.

### Royalty Expense

Upon receipt of marketing approval and commencement of commercial sales, which may not occur for several years, we will owe royalties to licensors of certain patents. Under a royalty agreement with Dr. R. Douglas Cassel, we are obligated to pay a royalty based on net sales of any of our products for the treatment of pain associated with surgically closed wounds. Under a sublicense agreement with Epitome Pharmaceuticals Limited that relates to EpiCept NP-1, we are obligated to pay royalties based on annual net sales derived from the products incorporating the licensed technology. In each case, our royalty obligation expires upon the expiration of the last to expire related patent.

### Research and Development Expense

Research and development expense consists of development work associated with product candidates, including employee compensation, costs of preclinical studies, clinical trials and clinical supplies, consultant fees and payments to our research partners. We are responsible for all of the research and development costs related to EpiCept NP-1 and LidoPAIN BP and for continuing and completing our European Phase III clinical trial for LidoPAIN SP that we anticipate will be used to support an application for marketing approval in Europe. As we commence more extensive development activities, including Phase III clinical trials and commercial scale-up, we expect research and development expense to increase substantially.

For the years ended December 31, 2004, 2003 and 2002, we incurred the following research and development expense:

	 Year Ended December 31,						
	 2004		2003		2002		
		(Dollar	s in thousa	nds)			
Direct Expenses							
EpiCept NP-1	\$ 305	\$	447	\$	2,069		
LidoPAIN SP	359		186		842		
LidoPAIN BP	34		22		527		
Other Projects	42		43		345		
Total Direct Expenses	740		698		3,783		
Indirect Expenses							
Staffing	820		637		681		
Other Indirect	224		306		410		
Total Indirect Expenses	1,044		943		1,091		
					-		
Total Research & Development	\$ 1,784	\$	1,641	\$	4,874		

The total direct costs incurred through December 31, 2004 for our major research and development projects are approximately \$4.3 million for EpiCept NP-1, \$2.2 million for LidoPAIN SP and \$2.0 million for LidoPAIN BP.

Direct expenses consist primarily of fees paid to vendors and consultants for services related to preclinical product development, clinical trials, and manufacturing of the respective products. We generally maintain few

fixed commitments; therefore, we have flexibility with respect to the timing and magnitude of a significant portion of our direct expenses. Indirect expenses are those expenses we incur that are not allocated by project, which consist primarily of the salaries and benefits of our research and development staff.

We expect that a large percentage of our future research and development expenses will be incurred in support of our current and future preclinical and clinical development programs. These expenditures are subject to numerous uncertainties in timing and cost to completion. We test our product candidates in numerous preclinical studies for toxicology, safety and efficacy. We then conduct early stage clinical trials for each drug candidate. As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for certain product candidates or programs in order to focus our resources on more promising product candidates or programs. Completion of clinical trials may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a drug candidate. The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including:

the number of sites included in the trials;
the length of time required to enroll suitable patients;
the number of patients that participate in the trials;
the number of doses that patients receive;
the duration of follow-up with the patient;
the product candidate's phase of development; and
the efficacy and safety profile of the product.

Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

None of our drug candidates has received FDA or foreign regulatory marketing approval. In order to grant marketing approval, the FDA or foreign regulatory agencies must conclude that our and our collaborators' clinical data establishes the safety and efficacy of our drug candidates. Furthermore, our strategy includes entering into collaborations with third parties to participate in the development and commercialization of our products. In the event that third parties have control over the preclinical development or clinical trial process for a product candidate, the estimated completion date would largely be under control of that third party rather than under our control. We cannot forecast with any degree of certainty which of our drug candidates will be subject to future collaborations or how such arrangements would affect our development plan or capital requirements.

As a result of these uncertainties, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will receive cash inflows from the commercialization and sale of a product.

#### General and Administrative Expense

General and administrative expense consists primarily of compensation for employees in executive and operational functions, including finance and accounting, business development and corporate development. Other significant costs include facilities costs and professional fees for accounting and legal services. After completion of this offering, we anticipate our general and administrative expenses to increase due to

increased costs for insurance, professional fees, external reporting requirements, Sarbanes-Oxley compliance and investor relations associated
with operating as a publicly-traded company. These increases will also likely include the hiring of additional personnel.

#### Stock-Based Compensation

In connection with the grant of stock options to employees, we recorded deferred stock-based compensation as a component of stockholders' deficit. Deferred stock compensation for options granted to employees is the difference between the fair value of our common stock on the date such options were granted and their exercise price. We amortize this stock-based compensation as charges to operations over the vesting periods of the options, generally 36 months.

We recorded \$0.4 million in amortization of deferred stock-based compensation during the year ended December 31, 2004 related to options previously granted to employees. The amortization of our deferred stock-based compensation has been substantially completed. We also recorded approximately \$0.1 million of stock-based compensation expense during the year ended December 31, 2004 related to options granted to non-employees in previous years. Stock-based compensation expense for non-employees is recorded based on the fair value method utilizing the Black-Scholes option pricing model. The value of the underlying option is periodically re-measured at each reporting date and income or expense is recognized during the vesting period. Stock-based compensation expense is classified as either research and development expense or general and administrative expense depending on the nature of the compensated services.

The amount of stock-based compensation expense we expect to incur in future periods may increase when we adopt Statement of Financial Accounting Standards ("SFAS") No. 123 (revised), *Share-Based Payment* ("SFAS 123R"), which must be adopted for fiscal years beginning after June 15, 2005, although earlier adoption is permitted.

### Other Income (Expense)

Other income (expense) consists of non-operating items, including interest income, interest expense and foreign exchange transaction gains or losses. Interest income is earned from funds on deposit. Interest expense is incurred from our various financing arrangements. A portion of our interest expense is from non-cash charges for debt discount and beneficial conversion features present in certain of our debt obligations. Foreign exchange transaction gains and losses are principally related to the payment of intercompany debt obligations denominated in foreign currencies.

#### **Results of Operations**

#### Years Ended December 31, 2004 and 2003

**Revenues.** We recorded \$1.1 million in revenue during the year ended December 31, 2004, representing the recognized portion of the deferred revenue from upfront licensing fees received from Adolor and Endo in 2003. In July 2003, we entered into a license agreement with Adolor relating to certain products, including LidoPAIN SP, which resulted in our receipt of a \$2.5 million payment upon signing. This amount has been deferred and is being recognized as revenue on a straight-line basis over the estimated development period of LidoPAIN SP. In December 2003, we signed a license agreement with Endo, which resulted in our receipt of a \$7.5 million payment upon signing. This payment has also been deferred and is being recognized as revenue on the proportional performance method.

Revenue in the year ended December 31, 2003 amounted to \$0.4 million representing the recognized portion of the deferred revenue from the upfront licensing fee received from Adolor in July 2003 and Endo in December 2003.

Research and development expense. Research and development expense increased approximately \$0.2 million in the year ended December 31, 2004 to \$1.8 million compared to \$1.6 million during the year ended December 31, 2003. Primary research and development activity during 2004 included preparations leading to the commencement of the Phase III clinical trial of LidoPAIN SP in Germany in November 2004, an End of Phase II meeting with the FDA for EpiCept NP-1, ongoing work with respect to the design of pivotal clinical trials

for EpiCept NP-1 and LidoPAIN BP, and the selection of manufacturers for the commercial scale-up of our product candidates. Incl	luded in
2004 research and	

development expense was a \$0.1 million maintenance fee payment relating to our license agreement for EpiCept NP-1.

Research and development expenses during 2003 consisted primarily of salaries and benefits, payments to consultants and clinical trial expenses related to EpiCept NP-1 and LidoPAIN SP. We completed two Phase II clinical trials for EpiCept NP-1 and one Phase II clinical trial for LidoPAIN SP during 2003.

General and administrative expense. General and administrative expense increased \$1.0 million to \$4.4 million from \$3.4 million for the years ended December 31, 2004 and 2003, respectively. The increase in general and administrative expense was primarily due to a \$1.1 million increase in audit and legal expense and \$0.2 million increase in consulting expense partially offset by a \$0.2 million decrease in stock-based compensation, a \$0.1 million decrease in depreciation and amortization and other individually insignificant expense reductions. We incurred higher legal and audit expenses during 2004 in preparation for our transition to becoming a public company.

Other income (expense). Other expense, net, decreased \$2.6 million to \$2.8 million for the year ended December 31, 2004 from \$5.4 million for the year ended December 31 2003. Loan discount and beneficial conversion feature related to the convertible bridge loan taken in 2002 and early 2003 were fully accreted during the first half of 2004. As a result, interest expense for the year ended December 31, 2004 decreased to \$2.7 million from \$4.6 million for the year ended December 31, 2003, a decline of \$1.9 million. Components of interest expense for 2004 were non-cash charges of \$1.3 million related to the accretion of the discount on the convertible bridge loan, \$1.1 million in coupon interest payable on loans, \$0.1 million increase in additional interest and \$0.2 million for the increase in contingent interest on certain debt obligations. Other expense, net, was also affected by net foreign exchange transaction losses related to intercompany debt recognized in 2004 of \$0.2 million compared with net foreign exchange transaction losses recognized in 2003 of \$0.8 million, a net improvement of \$0.6 million. Since a portion of our transactions is denominated in euros, foreign exchange transaction gains and losses result from changes in the exchange rate between the U.S. dollar and the euro during the relevant period.

**Benefit for Income Taxes.** Income tax benefit for the year ended December 31, 2004 was \$0.3 million compared to a benefit of \$0.1 million for the year ended December 31, 2003. The 2004 income tax benefit consists of a New Jersey state income tax benefit resulting from the sale of state NOLs. Income tax benefit for the year ended December 31, 2003 consisted of a \$0.1 million New Jersey state income tax benefit reduced by a \$31,000 federal income tax expense. We did not recognize a federal income tax expense for 2004.

The sales of cumulative state NOLs are a result of a New Jersey law enacted January 1, 1999 allowing emerging technology and biotechnology companies to transfer or "sell" their unused New Jersey net operating loss carryforwards and New Jersey research and development tax credits to any profitable New Jersey company qualified to purchase them for cash. We received approval from the State of New Jersey to sell NOLs in November 2004 and 2003 and entered into a contract with a third party to sell the NOLs for approximately \$0.3 million and \$0.2 million in December 2004 and 2003, respectively.

**Deemed Dividend and Redeemable Convertible Preferred Stock Dividends.** In addition to accreted redeemable convertible preferred stock dividends of \$1.3 million relating to our Series B and C redeemable convertible preferred stock in 2004 and 2003, we recorded a beneficial conversion charge of \$0.2 million in 2004 related to the exercise of warrants into Series A convertible preferred stock. A total of 74,259 warrants were exercised via a net share issuance of 53,225 shares of Series A convertible preferred stock.

#### Years Ended December 31, 2003 and 2002

**Revenues.** We recorded \$0.4 million in revenue during the year ended December 31, 2003, representing the recognized portion of the deferred revenue from upfront licensing fees received from Adolor and Endo. In July 2003, we entered into a license agreement with Adolor relating to certain products, including LidoPAIN SP, which resulted in our receipt of a \$2.5 million non-refundable payment upon signing. This amount has been deferred and is being recognized as revenue on a straight-line basis over the estimated development period of LidoPAIN SP. In December 2003, we signed a license agreement with Endo, which

resulted in our receipt of a non-refundable \$7.5 million payment upon signing. This payment has also been deferred and is being recognized as revenue on the proportional performance method. We did not recognize any revenues in 2002.

**Research and development expense.** Our research and development expenses were \$1.6 and \$4.9 million for the years ended December 31, 2003 and 2002, respectively. In early 2003, we completed three clinical trials for two of our late-stage product candidates: one Phase II trial for LidoPAIN SP in Germany and two Phase II trials for EpiCept NP-1. We undertook no new significant clinical activity during the balance of the year, resulting in the reduction of expense from 2002 as compared to 2003.

In 2002, we conducted three clinical trials for two of our late stage product candidates, including two Phase II trials for EpiCept NP-1 that involved more than 25 centers in the United States and Canada. Direct expenses related to the EpiCept NP-1 clinical trial totaled \$2.1 million, or 42%, of our total research and development expenses in 2002. A Phase II clinical trial for LidoPAIN SP at nine centers in Germany commenced in December 2001 and continued throughout 2002. Direct expenses for the LidoPAIN SP clinical trial totaled \$0.8 million, or 17%, of total research and development expenses in 2002.

General and administrative expense. General and administrative expense amounted to \$3.4 and \$3.5 million for the years ended December 31, 2003 and 2002, respectively. In 2003, a \$0.2 million increase in legal expense and \$0.1 million increase in depreciation and amortization were offset by a \$0.1 million decrease each in stock-based compensation, recruiting and marketing expenses, as well as decreases in other individually insignificant expense.

Other income (expense). Other income (expense), net, consisted of net other expense of \$5.4 and \$1.5 million for the years ended December 31, 2003 and 2002, respectively. The increase in net expense in 2003 of \$3.9 million from 2002 was primarily attributable to an increase of \$3.8 million in interest expense, principally due to the amortization of the debt discount and the beneficial conversion feature in connection with our convertible bridge loan that closed in tranches beginning in November 2002. The discount was accreted over the original scheduled term of the convertible bridge loan and totaled \$2.5 million for the year ended December 31, 2003. The beneficial conversion feature of approximately \$1.2 million was recorded in April 2003, of which \$0.8 million was recognized in 2003.

Other expense, net of \$1.5 million in 2002 was principally due to \$0.7 million in net foreign exchange transaction losses recognized in 2002 as well as reduced interest income and increased interest expense as cash on hand declined while notes and loans payable increased.

*Benefit for income taxes.* Income tax benefit for the year ended December 31, 2003 and 2002 amounted to \$0.1 million and \$0.2 million, respectively. Income tax benefit for the year ended December 31, 2003 consisted of a \$0.1 million New Jersey state income tax benefit reduced by a \$31,000 federal income tax expense. The state income tax benefit is comprised of current state income tax expense of \$0.1 million offset by a state income tax benefit resulting from the sale of some state NOLs of \$0.2 million.

During the years ended December 31, 2003 and 2002, we sold a portion of our state NOLs resulting in a state tax benefit of approximately \$0.2 million in each of those years. The sales of cumulative net operating losses are a result of a New Jersey state law enacted January 1, 1999 allowing emerging technology and biotechnology companies to transfer or "sell" their unused New Jersey net operating loss carryforwards and New Jersey research and development tax credits to any profitable New Jersey company qualified to purchase them for cash. We received approval from the State of New Jersey to sell NOLs in November 2003 and November 2002 and entered into a contract with a third party to sell the NOLs at a discount for approximately \$0.2 million in December of each year.

### License Agreements

In December 2003, we entered into a license agreement with Endo under which we granted Endo (and its affiliates) the exclusive (including as to us and our affiliates) worldwide right to commercialize

LidoPAIN BP. We also granted Endo worldwide rights to certain of our other patents used by Endo in the development of certain Endo products, including Lidoderm, Endo's topical lidocaine-containing patch, for the treatment of chronic lower back pain. We remain responsible for continuing and completing the development of LidoPAIN BP, including the conduct of all clinical trials and the supply of the clinical products necessary for those trials and the preparation and submission of the NDA in order to obtain regulatory approval for LidoPAIN BP. Upon the execution of the Endo agreement, we received a payment of \$7.5 million, which has been deferred and is being recognized as revenue on the proportional performance method, and we may receive payments of up to \$52.5 million upon the achievement of various milestones relating to product development and regulatory approval for both our LidoPAIN BP product candidate and Endo's own back pain product candidate, so long as, in the case of Endo's product candidate, our patents provide protection thereof. We will also receive royalties from Endo based on the net sales of LidoPAIN BP. These royalties are payable until generic equivalents of the LidoPAIN BP product candidate are available or until expiration of the patents covering LidoPAIN BP, whichever is sooner. We are also eligible to receive milestone payments from Endo of up to approximately \$30.0 million upon the achievement of specified net sales milestones of covered Endo products, including Lidoderm, Endo's chronic lower back pain product candidate, so long as our patents provide protection thereof. The total amount of upfront and milestone payments we are eligible to receive under the Endo agreement is \$90.0 million. There is no certainty that any of these milestones will be achieved or any royalty earned.

In July 2003, we entered into a license agreement with Adolor under which we granted Adolor the exclusive right to commercialize, among other products, LidoPAIN SP throughout North America. Upon the execution of the Adolor agreement, we received a payment of \$2.5 million, which has been deferred and is being recognized as revenue ratably over the estimated development period of LidoPAIN SP. The agreement also requires Adolor to pay us up to \$20.0 million upon reaching certain development, regulatory and commercial milestones and a royalty on sales of licensed products, including LidoPAIN SP. There is no certainty that any of these milestones will be achieved or any royalty earned.

### **Liquidity and Capital Resources**

We have devoted substantially all of our cash resources to research and development programs and general and administrative expenses. To date, we have not generated any meaningful revenues from the sale of products and we do not expect to generate any such revenues for a number of years, if at all. As a result, we have incurred an accumulated deficit of \$59.3 million as of December 31, 2004, and we expect to incur operating losses, potentially greater than losses in prior years, for a number of years in the future. The audit report from our independent registered public accounting firm states that our recurring losses from operations and our accumulated deficit raise substantial doubt about our ability to continue as a going concern. Our working capital deficit as of December 31, 2004 amounted to \$5.0 million, including cash and cash equivalents of \$1.3 million. Since our inception through December 31, 2004, we have financed our operations through the proceeds from the sales of common and preferred securities, debt, revenue from collaborative relationships, investment income earned on cash balances and short-term investments and the sales of a portion of our New Jersey net operating loss carryforwards.

We used \$4.8 million in net cash to fund our operations for the year ended December 31, 2004 compared to the year ended December 31, 2003 in which our operations generated net cash of \$4.8 million. This change was primarily driven by the receipt of \$10.0 million in upfront payments from the signing of our license agreements with Adolor and Endo. Net cash flows from operating activities were reduced by \$1.1 million and \$0.4 million in 2004 and 2003, respectively, to account for the portions of the Adolor and Endo deferred revenue recognized as revenue in the respective period. In April 2004, we concluded the accretion of discount on loans and incurred non-cash interest expense of \$1.3 million for the year ended December 31, 2004 compared to \$3.4 million for the year ended December 31, 2003. Foreign exchange loss declined from \$0.8 million in 2003 to \$0.2 million in 2004 due to the decline in the value of the U.S. dollar on our euro-denominated debt. Non-cash stock-based compensation declined from \$0.8 million in 2003 to \$0.4 million in 2004 because we granted no new stock options in 2004. Accounts

payable increased \$1.2 million in 2004 compared to a decline of \$0.2 million because we deferred payments to vendors in the later part of 2004 to conserve cash.

Net cash used in investing activities totaled approximately \$49,000 and \$17,000 during the years ended December 31, 2004 and 2003, respectively, primarily for the purchase of office equipment. Future cash used in investing activities for property and equipment is not expected to be significant.

Net cash used in financing activities totaled approximately \$1.9 million during the year ended December 31, 2004 and consisted of \$0.7 million of scheduled loan repayments and \$1.2 million of costs related to this initial public offering of our common stock. Net cash provided by financing activities totaled \$2.7 million for the year ended December 31, 2003, primarily related to the receipt of a portion of the proceeds from our convertible bridge loan.

In March 2005, we completed a private placement of \$4.0 million aggregate principal amount of 8% Senior Notes due 2006 with a group of investors including several of our existing shareholders. The Senior Notes mature on October 30, 2006. We will repurchase the Senior Notes upon the completion of this offering. Each of the purchasers also purchased stock purchase warrants exercisable into an amount of shares of common stock equal to 35% of the principal amount of such purchaser's senior notes divided by the initial public offering price of our common stock or an aggregate of 116,667 shares of our common stock (based on an assumed offering price of \$12.00, the midpoint of the price range set forth on the cover of this prospectus). The exercise price for the warrants will be 75% of the initial public offering price.

Assuming an initial public offering price of \$12.00 per share (the midpoint of the price range set forth on the cover of this prospectus), the exercise price would be \$9.00 per share. The warrants are exercisable by the purchaser at any time before the earlier to occur of (a) March 3, 2008 or (b) a merger, consolidation, share exchange sale of our company, certain change of control events, and events of liquidation. If our initial public offering has not been consummated by March 3, 2006, the expiration date of the warrants will be extended until March 3, 2009.

We believe that our existing cash resources, the net proceeds of this offering, future payments from our strategic partners, future sales of our New Jersey net operating loss carry forwards and interest earned on cash balances and investments will be sufficient to meet our projected operating requirements for at least the next 24 months. Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash. If we need to raise additional funds in the future, we may raise those funds through public or private financings, strategic relationships or other arrangements.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors include, but are not limited to, the following:

progress in our research and development programs, as well as the magnitude of these programs;

the timing, receipt and amount of milestone and other payments, if any, from present and future collaborators, if any;

our ability to establish and maintain additional collaborative arrangements;

the resources, time and costs required to successfully initiate and complete our preclinical and clinical trials, obtain regulatory approvals, protect our intellectual property and obtain and maintain licenses to third-party intellectual property;

the cost of preparing, filing, prosecuting, maintaining and enforcing patent claims; and

the timing, receipt and amount of sales and royalties, if any, from our potential products.

If, at any time, our prospects for financing our clinical development programs decline, we may decide to reduce research and development expenses by delaying, discontinuing or reducing our funding of development of one or more product candidates. Alternatively, we might raise funds through public or private financings, strategic relationships or other arrangements. We cannot assure you that the funding, if needed, will be available on attractive terms, or at all. Furthermore, any additional equity financing may be dilutive to stockholders and debt financing,

if available, may involve restrictive covenants and increased interest expense. Similarly, financing obtained through future co-development	nt
arrangements may require us	

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to forego certain commercial rights to future drug candidates. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategy.

### **Contractual Obligations**

As of December 31, 2004, the annual amounts of future minimum payments under debt obligations, interest, lease obligations and other long term liabilities consisting of research, development, consulting and license agreements (including maintenance fees) are as follows (in thousands of U.S. dollars, using exchange rates where applicable in effect as of December 31, 2004):

	 12/31/05	 12/31/06	 12/31/07	 12/31/08	 Thereafter	Total
Long-term debt	\$ 817	\$ 6,153	\$ 5,420	-	-	\$ 12,390
Interest expense	751	413	1,420	_	_	2,584
Operating leases	223	76	45	-	-	344
Other obligations	1,494	810	1,225	525	950	5,004
Total	\$ 3,285	\$ 7,452	\$ 8,110	\$ 525	\$ 950	\$ 20,322

Our long-term debt commitments consist of the following:

1.5 million Due 2007. In August 1997, our subsidiary, EpiCept GmbH entered into a ten-year non-amortizing loan in the amount of 1.5 million with Technologie-Beteiligungs Gesellschaft mbH der Deutschen Ausgleichsbank, or "tbg." Proceeds must be directed toward research, development, production and distribution of pharmaceutical products. The loan bears interest at 6% per annum. Tbg is also entitled to receive additional compensation equal to 9% of the annual surplus (income before taxes, as defined in the debt agreement) of EpiCept GmbH, reduced by any other compensation received from EpiCept GmbH by virtue of other loans to or investments in EpiCept GmbH provided that tbg is an equity investor in EpiCept GmbH during that time period. To date, EpiCept GmbH has had no annual surplus. We consider the additional compensation element based on the surplus of the EpiCept GmbH to be a derivative. We have assigned no value to the derivative at each reporting period as no surplus of EpiCept GmbH is anticipated over the term of the agreement.

At the demand of tbg, additional amounts may be due at the end of the loan term up to 30% of the loan amount, plus 6% of the principal balance of the loan for each year after the expiration of the fifth complete year of the loan period, such payments to be offset by the cumulative amount of all payments made to tbg from the annual surplus of EpiCept GmbH. We are accruing these additional amounts as additional interest up to the maximum amount due over the term of the loan. Accrued interest attributable to these additional amounts totaled \$0.4 and \$0.3 million at December 31, 2004 and 2003, respectively. The effective rate of interest of this loan is 9.7%.

2.0 Million Due 2007. In February 1998, EpiCept GmbH entered into a ten-year non-amortizing convertible term loan in the amount of 2.0 million with tbg. The loan is non-interest bearing; however, the loan agreement provides for potential future annual payments from surplus of EpiCept GmbH up to 6% of the outstanding loan principal balance, not to exceed 9% of all payments made from surplus of EpiCept GmbH and limited to 7% of the total financing from tbg. To date, EpiCept GmbH has had no annual surplus. We consider the additional compensation element based on the surplus of the EpiCept GmbH to be a derivative. We have assigned no value to the derivative at each reporting period as no surplus of EpiCept GmbH is anticipated over the term of the agreement.

The loan is convertible into shares of our common stock at any time by tbg at a conversion price of \$28.28 per share. We can require conversion upon a defined triggering event (such as a sale of substantially all our assets, a public offering of our securities, a sale of more than 50% of the voting power of our outstanding equity securities, a merger, etc.) at a calculated conversion price ranging between \$8.08 and \$28.28 based on provisions pertaining to the applicable triggering event. Shares of our common stock issuable upon conversion of this loan range from 80,824 to 282,885. We intend to require tbg to convert this loan upon consummation of this offering.

2.6 Million Due 2007. In March 1998. EpiCept GmbH entered into a term loan in the amount of 2.6 million with IKB Private Equity GmbH, or "IKB," which we guaranteed. The interest rate on the loan varies and was 10.5% per annum from August 1, 2000 through March 31, 2001, 15% per annum through June 30, 2003 and 20% per annum thereafter. The loan was amended in December 2002 to extend the maturity to December 31, 2006 and incorporate a principal repayment schedule, which commenced April 30, 2004. Quarterly principal payments are 0.2 million (approximately \$0.3 million as of December 31, 2004) except for the payment due December 31, 2006, which will be approximately 0.4 million (approximately \$0.5 million as of December 31, 2004). Principal and interest payments have been deferred from December 31, 2004 until June 30, 2005, at which time principal payments will recommence in accordance with the original repayment schedule. Payments due December 31, 2004 and March 31, 2005 have been deferred until March 31, 2007 and June 30, 2007, respectively. As a result of the deferral, the maturity date has been extended until June 30, 2007. Payment of accrued interest during the period of October 1, 2004 through March 31, 2005 has been deferred until June 30, 2005 although interest continues to accrue in accordance with the terms of the agreement. The loan agreement provides for contingent interest of 4% per annum of the principal balance, becoming due only upon our realization of a profit and payable up to two years thereafter, as defined in the agreement. We have not realized a profit through December 31. 2004. We value the contingent interest as a derivative using the fair value method in accordance with SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, as amended by SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities ("SFAS 133"). Changes in the fair value of the contingent interest are recorded as an adjustment to interest expense. The fair value of the contingent interest was approximately \$0.7 and \$0.5 million as of December 31, 2004 and 2003, respectively. We intend to repay this term loan with a portion of the proceeds of this offering.

Convertible Bridge Loan Due 2006. In November 2002, we entered into a convertible bridge loan with several of our shareholders in an aggregate amount of up to \$5.0 million. At December 31, 2004 and 2003, we had outstanding borrowings of \$4.8 million. The convertible bridge loan bears interest at 8% per annum. The convertible bridge loan is convertible into the next round of preferred stock financing and also has provisions for optional conversion into preferred stock or common stock. The conversion rate is equal to the lowest price per share paid by any purchaser in a financing of the next round of preferred stock or at anti-dilutive conversion rates for optional conversion into preferred stock or common stock based upon the results of certain milestones. In addition, warrants to purchase preferred stock were issued to the lenders in connection with the convertible bridge loan. Such warrants were valued utilizing the Black-Scholes options pricing model and resulted in recording warrants at \$3.6 million and a discount of \$3.6 million to the convertible bridge loan. The discount was accreted over the original scheduled term of the loans. During the years ended December 31, 2004 and 2003, we recognized approximately \$0.9 and \$2.5 million, respectively, of non-cash interest expense related to the accretion of the debt discount. The term of the convertible bridge loan has been extended from April 30, 2004 until October 30, 2006. We intend to repay all amounts outstanding under the convertible bridge loan with a portion of the proceeds of this offering.

Senior Notes due 2006. In March 2005, we completed a private placement of \$4.0 million aggregate principal amount of 8% Senior Notes due 2006 with a group of investors including several of our existing shareholders. The Senior Notes mature on October 30, 2006 and the proceeds will be used for general working capital purposes. We are required to repurchase the Senior Notes upon the completion of this offering. Each of the purchasers also purchased stock purchase warrants exercisable into an amount of shares of common stock equal to 35% of the principal amount of such purchaser's senior notes divided by the initial public offering price of our common stock or an aggregate of 116,667 shares of our common stock (based on an assumed offering price of \$12.00, the midpoint of the price range set forth on the cover of this prospectus). The exercise price for the warrants will be 75% of the initial public offering price. Assuming an initial public offering price of \$12.00 per share (the midpoint of the price range set forth on the cover of this prospectus), the exercise price would be \$9.00 per share. The warrants are exercisable by the purchaser at any time before the earlier to occur of (a) March 3, 2008 or (b) a merger, consolidation, share exchange sale of our company, certain change of control events, and events of liquidation. If our

initial public offering has not been consummated by March 3, 2006, the expiration date of the warrants will be extended until March 3, 2009.

*Other Commitments.* Our long-term commitments under operating leases shown above consist of payments relating to our facility leases in Englewood Cliffs, New Jersey, which expires in September 2005, and Munich, Germany, which expires in July 2009, but is cancelable at our option in July 2007.

We have a number of research, consulting and license agreements that require us to make payments to the other party to the agreement upon us attaining certain milestones as defined in the agreements. In 2004, we made payments of approximately \$0.8 million under these agreements, the majority of which were in connection with milestones relating to preclinical and clinical trials and manufacturing. As of December 31, 2004, we may be required to make future milestone payments, totaling approximately \$5.0 million, under these agreements, depending upon the success and timing of future clinical trials and the attainment of other milestones as defined in the respective agreement. Under our agreement with Epitome, we are obligated to pay an annual maintenance fee that is equal to twice the fee paid in the previous year as long as no commercial product sales have occurred. We recorded a maintenance expense of \$0.1 millions in 2004. Our current estimate as to the timing of other research, development and license payments, assuming all related research and development work is successful, is listed in the table above in "Other obligations." In 2004, we entered into a clinical research agreement for approximately \$1.2 million with a contract research organization to conduct a clinical trial of our LidoPAIN SP product in Germany. The terms of the agreement require payment upon reaching certain milestones, including patient recruitment. If the contract is cancelled for any reason, we are subject to a 15% penalty for any offered but unperformed services. We have paid the contract research organization approximately \$0.1 million for services in 2004.

We are also obligated to make future royalty payments to two of our collaborators under existing license agreements, one based on net sales of EpiCept NP-1 and the other based on net sales of LidoPAIN SP, to the extent revenues on such products are realized. We have not estimated the amount or timing of such royalty payments.

### Qualitative and Quantitative Disclosures about Market Risks

The financial currency of our German subsidiary is the euro. As a result, we are exposed to various foreign currency risks. First, our consolidated financial statements are in U.S. dollars, but a portion of our consolidated assets and liabilities is denominated in euros. Accordingly, changes in the exchange rate between the euro and the U.S. dollar will affect the translation of our German subsidiary's financial results into U.S. dollars for purposes of reporting consolidated financial results. We also bear the risk that interest on our euro-denominated debt, when translated from euros to U.S. dollars, will exceed our current estimates and that principal payments we make on those loans may be greater than those amounts currently reflected on our consolidated balance sheet. If the U.S. dollar depreciation to the euro had been 10% greater throughout 2004, we estimate that our interest expense and the fair value of our euro-denominated debt would have increased by \$0.1 and \$0.8 million, respectively. Historically, fluctuations in exchange rates resulting in transaction gains or losses have had a material effect on our consolidated financial results. We have not engaged in any hedging activities to minimize this exposure, although we may do so in the future. Our exposure to changes in the exchange rate between U.S. dollars and euros will be substantially reduced following completion of this offering when the majority of our euro-denominated debt will be prepaid or converted into common stock.

Our exposure to interest rate risk is limited to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term debt securities and bank deposits. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. To minimize risk, we maintain our portfolio of cash and cash equivalents in a variety of interest-bearing instruments, primarily bank deposits and money market funds, which may also include U.S. government and agency securities, high-grade U.S. corporate bonds and commercial paper. Due to the nature of our short-term and restricted investments, we believe that we are not exposed to any material interest rate risk.

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. Therefore, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships. We do not have relationships or transactions with persons or entities that derive benefits from their non-independent relationship with our related parties or us.

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

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to our financial statements included in this prospectus, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

# Revenue recognition

We recognize revenue relating to our collaboration agreements in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin ("SAB") No. 104, *Revenue Recognition*, and Emerging Issues Task Force ("EITF") Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. Revenue under collaborative arrangements may result from license fees, milestone payments, research and development payments and royalties.

Application of these standards requires subjective determinations and requires management to make judgments about value of the individual elements and whether they are separable from the other aspects of the contractual relationship. We evaluate our collaboration agreements to determine units of accounting for revenue recognition purposes. To date, we have determined that our upfront non-refundable license fees cannot be separated from our ongoing collaborative research and development activities and, accordingly, do not treat them as a separate element. We recognize revenue from non-refundable, up-front licenses and related payments, not specifically tied to a separate earnings process, either on the proportional performance method or ratably over the development period in which we are obligated to participate on a continuing and substantial basis in the research and development activities outlined in the contract. Ratable revenue recognition is only utilized if the research and development services are performed systematically over the development period. Proportional performance is measured based on costs incurred compared to total estimated costs over the development period which approximates the proportion of the value of the services provided compared to that estimated value over the development period. The proportional performance method currently results in revenue recognition at a slower pace than the ratable method as many of our costs are incurred in the latter stages of the development period. We periodically review our estimates of cost and the length of the development period and, to the extent such estimates change, the impact of the change is recorded at that time.

We will recognize milestone payments as revenue upon achievement of the milestone only if (1) it represents a separate unit of accounting as defined in EITF Issue No. 00-21; (2) the milestone payments are nonrefundable; (3) substantive effort is involved in achieving the milestone; and (4) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with the achievement of the milestone. If any of these conditions is not met, we will recognize milestones as revenue in accordance with our accounting policy in effect for the respective contract. At the time of a milestone payment receipt, we will recognize revenue based upon the portion of the development services that are completed to date and defer the remaining portion and recognize it over the remainder of the development services on the proportional or ratable method, whichever is applicable. To date, we have not recognized revenue

from any milestone payment. When payments are specifically tied to a separate earnings process, revenue will be recognized when the specific performance obligation associated with the payment has been satisfied.

### Stock-Based Compensation

As permitted by Statement No. 123, Accounting for Stock-Based Compensation ("SFAS 123"), we account for employee stock-based compensation in accordance with Accounting Principles Board ("APB") Opinion No. 25, Accounting for Stock Issued to Employees ("APB 25"), using intrinsic values with appropriate disclosures using the fair value based method. Accordingly, we have recorded stock-based compensation expense for stock options issued to employees in fixed amounts with exercise prices that are, for financial reporting purposes, deemed to be below fair market value on the measurement date – generally being the date of grant. In the notes to our consolidated financial statements, we provide pro forma disclosures required by SFAS No. 123 and related pronouncements. We account for stock-based transactions with non-employees in which services are received in exchange for the equity instruments based upon the fair value of the equity instruments issued, in accordance with SFAS No. 123 and EITF 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." The two factors that most affect charges or credits to operations related to stock-based compensation are the estimated fair market value of the common stock underlying stock options for which stock-based compensation is recorded and the estimated volatility of such fair market value.

Accounting for equity instruments granted by us requires fair value estimates of the equity instrument granted or sold. If our estimates of fair value of these equity instruments are too high or too low, it would have the effect of overstating or understating expenses. When equity instruments are granted in exchange for the receipt of goods or services, we estimate the value of the equity instruments based upon consideration of factors that we deem to be relevant at the time using cost, market and/or income approaches to such valuations. Because shares of our common stock have not been publicly traded, market factors historically considered in valuing stock and stock option grants include comparative values of public companies discounted for the risk and limited liquidity provided for in the shares we are issuing, pricing of private sales of our convertible preferred stock, prior valuations of stock grants and the effect of events that have occurred between the time of such grants, economic trends, perspective provided by investment banks and the comparative rights and preferences of the security being granted compared to the rights and preferences of our other outstanding equity. As a result of these factors, some of which are subjective, changes in our estimates of fair market value and volatility could have a significant effect on the determination of stock-based compensation.

The fair value of our common stock for options granted during 2003 and 2002 was determined contemporaneously at the time of the grant by our board of directors, with input from management. Prior to our entering into the Adolor license agreement in July 2003, we utilized the value paid for each of our series of preferred stock as an estimate of the fair value of our common stock. During the year ended 2004, we did not grant any options to employees. During the years ended December 31, 2003 and 2002, we granted options to employees at prices, which, for financial reporting purposes, were deemed to be below fair market value on the dates of grant. As a result, we recorded deferred compensation related to these grants for the difference between the deemed fair market value and the exercise price. We are amortizing this deferred compensation as a charge to operations over the vesting period of the options. In 2002, we also granted options to non-employees for which we recorded stock-based compensation in the statements of operations based upon the fair market value of these options, as determined using the Black-Scholes model, over the service period, which is usually the vesting period. We did not grant any options to non-employees in 2004 or 2003. Stock-based compensation for third parties is re-measured through the vesting period at fair value. The following weighted average assumptions were used for grants in 2003 and 2002; dividend yield of 0% percent, risk free interest rate from 2.79% to 4.74%, volatility of 101% and expected life of four to five years. As discussed above, these stock-based compensation charges will fluctuate based primarily on the volatility and fair value of our common stock.

### Derivatives

We comply with SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities ("SFAS 149"). SFAS 149 clarifies under what circumstances a contract with an initial net investment meets the characteristics of a derivative as discussed in SFAS 133. It also specifies when a derivative contains a financing component that warrants special reporting in the statement of cash flows. As a result of certain financings, derivative instruments were created that we measured at fair value and mark to market at each reporting period. Fair value of the derivative instruments will be affected by estimates of our cost of capital, future foreign exchange rates of the U.S. dollar to the euro and future profitability of our German subsidiary. Changes in fair value of the derivative instruments will be reflected in interest expense.

### Foreign Exchange Gains and Losses

We have a 100%-owned subsidiary in Germany, EpiCept GmbH, that performs certain research and development activities on our behalf pursuant to a research collaboration agreement. EpiCept GmbH has been unprofitable since its inception. Its functional currency is the euro. The process by which EpiCept GmbH's financial results are translated into U.S. dollars is as follows: income statement accounts are translated at average exchange rates for the period and balance sheet asset and liability accounts are translated at end of period exchange rates. Translation of the balance sheet in this manner affects the stockholders' equity account, referred to as the cumulative translation adjustment account. This account exists only in EpiCept GmbH's U.S. dollar balance sheet and is necessary to keep the foreign balance sheet stated in U.S. dollars in balance.

Several of our debt instruments, originally expressed in German deutsche marks, are now denominated in euros. Changes in the value of the euro relative to the value of the U.S. dollar could affect the U.S. dollar value of our indebtedness at each reporting date as substantially all of our assets are held in U.S. dollars. These changes are recognized by us as a foreign currency transaction gain or loss, as applicable, and are reported in other expense or income in our consolidated statements of operations.

# **Recent Accounting Pronouncements**

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 153, Exchanges of Nonmonetary Assets ("SFAS 153"). SFAS 153 amends Accounting Principles Board ("APB") Opinion No. 29 ("APB 29"), Accounting for Nonmonetary Transactions, which requires that exchanges of nonmonetary assets be measured based on the fair value of the assets exchanged, but which includes certain exceptions to that principle. SFAS 153 eliminates the exception in APB 29 for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have a commercial substance. SFAS 153 is effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of SFAS 153 is not expected to have a material impact on our consolidated financial position or results of operations.

In December 2004, the FASB issued SFAS 123R. SFAS 123R replaces SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions and is effective as of the beginning of the fiscal year that begins after June 15, 2005 for public entities that do not file as small business issuers. We have illustrated the effect on our earnings as if we had adopted the fair value method of accounting for stock-based compensation under SFAS 123 in Note 2 to our Consolidated Financial Statements for the years ended December 31, 2004, 2003 and 2002. At this time, we are unable to predict the future impact of the adoption of SFAS 123R on our consolidated financial position or results of operations.

In May 2003, SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity ("SFAS 150") was issued. This statement establishes how a company classifies and measures certain financial instruments with characteristics of both liabilities and equity, including

redeemable convertible preferred stock. This statement is effective for financial instruments entered into or modified after May 31, 2003 and otherwise effective at the beginning of the interim period commencing July 1, 2003, except for mandatorily redeemable financial instruments of nonpublic companies. The FASB has indefinitely deferred implementation of certain provisions of SFAS 150. Our Series B and Series C redeemable convertible preferred stock are redeemable at the option of the investor ratably on each of December 31, 2006, 2007 and 2008, or in any amount thereafter at a price of \$1.50 per share and are automatically converted into our common stock upon consummation of our initial public offering. The adoption of SFAS 150 did not have a significant impact on our consolidated financial position or results of operations.

### **BUSINESS**

We are a specialty pharmaceutical company focused on the development and commercialization of topically-delivered prescription pain management therapeutics. We have six product candidates in clinical development; three in late-stage clinical development that are ready to enter, or have entered, pivotal Phase IIb or Phase III clinical trials, and three that have completed initial Phase II clinical trials. All of our product candidates target moderate-to-severe pain that is influenced, or mediated, by nerve receptors located just beneath the skin's surface. Our product candidates utilize proprietary formulations and several topical delivery technologies to administer FDA-approved pain management therapeutics, or analgesics. We believe using FDA-approved analgesics reduces the risks associated with new drug development, lowers our development costs and speeds time-to-market. Our product candidates are designed to provide effective pain relief with fewer adverse side effects than systemically-delivered drugs, which are absorbed into the bloodstream. None of our products has been approved by the FDA or its counterparts in other countries.

Our lead late-stage product candidate, EpiCept NP-1, is a prescription topical analgesic cream containing a patented formulation, the contents of which include two FDA-approved drugs, amitriptyline and ketamine. Amitriptyline is a widely-used antidepressant, and ketamine is an NMDA antagonist that is used as an anesthetic. EpiCept NP-1 is designed to provide effective, long-term relief from the pain of peripheral neuropathies. Peripheral neuropathies are medical conditions caused by damage to the nerves in the nervous system. The initial indication for this product candidate is post-herpetic neuralgia, a specific type of peripheral neuropathy associated with shingles, a condition caused by the herpes zoster virus. We have completed Phase II clinical trials in the United States and Canada that included 343 subjects and plan to commence a Phase III clinical trial in the United States by the second half of 2005 that will include at least 800 subjects.

LidoPAIN SP, our second late-stage product candidate, is a sterile prescription analgesic patch designed to provide sustained topical delivery of lidocaine to a post-surgical or post-traumatic sutured wound while also providing a sterile protective covering for the wound. If approved, we believe that LidoPAIN SP would be the first sterile prescription analgesic patch on the market. We have completed a Phase II clinical trial in Germany that included 221 hernia repair subjects and commenced a Phase III clinical trial in Europe during the fourth quarter of 2004 that will include at least 400 hernia repair subjects. In July 2003, we entered into an agreement with Adolor for the development and commercialization of LidoPAIN SP in North America.

Our third late-stage product candidate is LidoPAIN BP, a prescription analgesic non-sterile patch designed to provide sustained topical delivery of lidocaine for the treatment of acute or recurrent lower back pain. We have completed Phase IIa and Phase IIb clinical trials in the United States that included 242 subjects and plan to commence a pivotal Phase IIb clinical trial in the United States during the second half of 2005 that will include at least 400 subjects. In December 2003, we entered into an agreement with Endo for the commercialization of LidoPAIN BP worldwide.

We have three earlier-stage product candidates in clinical development: (1) EpiCept MP/DP, a topical spray gel matrix containing morphine and lidocaine for the treatment of oral mucositis, an inflammation of the mucosa of the mouth typically resulting from chemotherapy and radiation therapy, and dental pain; (2) LidoPAIN TV, a topical lidocaine patch for the treatment of tinnitus, a constant or intermittent buzzing or ringing noise in the ear; and (3) LidoPAIN HM, a topical anesthetic patch for the treatment of headache pain. We have completed initial Phase II clinical trials and expect to conduct additional Phase II clinical trials for each of these product candidates.

### Pain and Pain Management

Pain occurs as a result of surgery, trauma or disease. It is generally provoked by a harmful stimulus to a pain receptor in the skin or muscle. Pain can range in severity (mild, moderate or severe) and duration (acute or chronic). Acute pain, such as pain resulting from an injury or surgery, is of short duration, generally less than a month, but may last up to three months. Chronic pain is more persistent, extending

long after an injury has healed, and typically results from a chronic illness or appears spontaneously and persists for undefined reasons. Examples of chronic pain include chronic lower back pain and pain resulting from bone cancer or advanced arthritis. If treated inadequately, unrelieved acute and chronic pain can slow recovery and healing and adversely affect a person's quality of life.

IMS Health has estimated that the total U.S. market for prescription analgesics has increased from \$5.3 billion in 1998 to \$14.7 billion in 2003, representing an approximate 23% compounded annual growth rate. In 2003, analgesics were the third most prescribed class of medications in the United States with approximately 313 million prescriptions written. We believe that growth in this market has been primarily attributable to:

increased physician recognition of the need for effective pain management;

patient demand for more effective pain treatments;

an aging population, with an increased prevalence of chronic pain conditions, such as cancer, arthritis, neuropathies and lower back pain;

increased number of surgeries;

introduction of new and reformulated branded products; and

increased active and healthy lifestyles, resulting in additional sports and fitness related injuries.

Analgesics typically fall into one of three categories:

opioid analgesics or narcotics, such as morphine, codeine, oxycodone (OxyContin) and tramadol (Ultram);

non-narcotic analgesics, primarily non-steroidal anti-inflammatory drugs (NSAIDs), including prostaglandin inhibitors (such as aspirin, acetaminophen and ibuprofen) and inhibitors of the enzyme cycloxygenase-2 (COX-2), so-called COX-2 inhibitors (such as Celebrex); and

adjuvant therapeutics, such as anesthetics (lidocaine), antidepressants (amitriptyline), anti-convulsives and corticosteriods.

# Limitations of Current Therapies

Until recently, analgesics primarily have been delivered systemically and absorbed into the bloodstream where they can then alleviate the pain. Systemic delivery is achieved either orally, via injection or through a transdermal patch. Systemic delivery of analgesics can have significant adverse side effects because the concentration of analgesics in the bloodstream can impact other organs and systems throughout the body.

Adverse side effects of systemically-delivered analgesics are well documented. Systemically-delivered opioid analgesics can cause respiratory distress, nausea, vomiting, dizziness, sedation, constipation, urinary retention and severe itching. In addition, chronic use of opioid analgesics can lead to the need for increased dosing and potential addiction. Concerns about addiction and abuse often influence physicians to prescribe less than adequate doses of opioids or to prescribe opioids less frequently. Systemically-delivered NSAIDs and adjuvant therapeutics can also have significant adverse side effects, including kidney failure, liver dysfunction, gastric ulcers and nausea. In the United States, there are approximately 16,500 NSAID-related deaths each year, and over 103,000 patients are hospitalized annually due to NSAID complications. These adverse side effects may lead doctors to prescribe analgesics less often and at lower doses than may be necessary to alleviate pain. Further, patients may take lower doses for shorter periods of time and opt to suffer with the pain rather than risk the adverse side effects. Systemic delivery of these drugs may also result in significant interactions with other drugs, which is of particular concern when treating elderly patients who typically take multiple pharmaceutical therapies.

### Recent Scientific Developments

Almost every disease and every trauma is associated with pain. Injury or inflammation stimulates the pain receptors, causing electrical pain signals to be transmitted from the pain receptors through nerve fibers into the spinal cord and eventually to the brain. Pain receptors include central pain receptors, such as those found in the brain and spinal cord, and peripheral nerve receptors, also called "nociceptors," such as those located directly beneath the skin and in joints, eyes and visceral organs. Within the spinal cord, the electrical pain signals are received by a second set of nerve fibers that continue the transmission of the signal up the spinal cord and through the central nervous system into the brain. Within the brain, additional nerve fibers transmit the electrical signals to the "pain center" of the brain. The brain decodes the messages being sent to the central nervous system from the peripheral nervous system, and the signals are perceived as "pain" and pain is "felt." These messages can be disrupted with pharmaceutical intervention either at the source of the pain, such as the pain receptor, or at the point of receipt of the pain message, in the brain. Topical delivery of analgesics blocks the transmission of pain at the source of the pain message, whereas systemic delivery of analgesics primarily blocks the perception of pain within the brain.

Not until recently has the contribution of peripheral nerve receptors to the perception of pain been well understood. Recent studies have indicated that peripheral nerve receptors can play an important role in both the sensory perception of pain and the transmission of pain impulses. Specifically, certain types of acute and chronic pain depend to some degree on the activation of peripheral pain receptors located beneath the skin's surface. The topical administration of well-known analysesics can localize drug concentrations at the point where the pain signals originate, resulting in dramatically lower systemic blood levels. We believe this results in a new treatment strategy that provides significant pain relief, with fewer adverse side effects, fewer drug to drug interactions and lower potential for abuse.

#### **Our Solution**

We are targeting peripheral nerve receptors using topical analgesics as a novel mechanism to effectively treat both acute and chronic pain, without the liabilities of traditional systemically-delivered analgesics. We are developing innovative topically-delivered analgesics using a combination of our internally-developed and in-licensed proprietary technologies and know-how to address the unmet medical needs and adverse side effects associated with systemically-delivered analgesics. Our topical delivery technologies and formulations are designed to deliver FDA-approved analgesics safely, effectively and conveniently to the appropriate peripheral nerves while preventing or limiting the amount of drug that enters the bloodstream. We utilize patch, cream and spray gel matrix delivery methods to topically deliver the active ingredients to the pain site. In some instances, we combine existing FDA-approved analgesics to create a new product having a therapeutic profile superior to either one of the standalone analgesics.

#### **Our Products**

We have six product candidates in clinical development; three in late-stage clinical development that ready to enter, or have entered, pivotal Phase IIb or Phase III clinical trials, and three that have completed initial Phase II clinical trials. The following table summarizes the current status of our development programs for our three late-stage product candidates:

	Topical				
Product	Dosage Form	Initial Indication	Clinical Status	Next Steps	Marketing Rights
EpiCept NP-1	Cream	Post-herpetic	Phase II	Initiate Phase III	EpiCept
		neuralgia	completed	during second	
				half of 2005	
LidoPAIN SP	Sterile patch	Surgical incision	Phase III	Adolor has	Adolor in North America;
		pain	initiated in	announced plans	EpiCept outside of North
			Germany	for Phase IIb and	America EpiCept retains
				Phase III clinical	right to negotiate future
				trials in United	co-promotion agreement
				States	
LidoPAIN BP	Patch	Acute or recurrent	Phase IIa	Initiate pivotal	Endo worldwide; EpiCept
	(non-sterile)	lower back pain	completed	Phase IIb clinical	retains right to negotiate
				trial during	future co-promotion
				second half of	agreement
				2005	

The clinical trials for our current portfolio of product candidates have included over 2,300 patients in 21 clinical trials, including over 660 patients in six clinical trials for EpiCept NP-1; over 570 patients in four clinical trials for LidoPAIN SP; and over 720 patients in five clinical trials for LidoPAIN BP.

We conduct our clinical trials in pain centers throughout North America and in Europe. There are various ways in which to assess a subject's severity of pain. Pain is a subjective phenomenon, and each person has a different pain threshold. We utilize various types of validated pain assessment scales in our clinical trials that are self-administered by each subject in the form of questionnaires. The first is the numerical pain scale, or "11-point numerical pain scale," which is generally a number line from 0 (no pain) to 10 (worst possible pain). The subject is asked how much pain he or she feels at a given moment or over a period of time and is asked to rank it based on the 11-point numerical pain scale. A second pain assessment tool we often utilize is the McGill Pain Questionnaire, which is a two part questionnaire that asks the subject to rate both type and intensity of pain experienced. We analyze the data from these studies in a number of ways, including a responder analysis. In this type of analysis, subjects serve as their own control and are required to demonstrate a clinically-significant level of response depending upon the structure of the particular clinical trial.

We utilize various statistical analyses to evaluate the data from our clinical trials. We commonly utilize the "area under the curve" analysis as a measure of efficacy. The term "area under the curve" is a recognized statistical analytical tool that refers to the measurement of the total sum of pain that a patient experiences over a particular period of time. We also use statistical analyses to estimate the probability that a positive effect is actually produced by the product candidate. This probability is expressed as a "P-value," which refers to the likelihood that the difference measured between the drug group and the placebo group occurred just "by chance." For example, when a P-value is reported as "P<0.05," the probability that the drug produced an effect just by chance is less than 5%. A P-value of 0.05 or less is generally considered to be statistically significant.

Peripheral Neuropathy and Post-Herpetic Neuralgia

Peripheral neuropathy is a medical condition caused by damage to the nerves in the peripheral nervous system. The peripheral nervous system includes nerves that run from the brain and spinal cord to the rest of the body. According to Datamonitor's study "Stakeholder Insight: Neuropathic Pain," published in February 2004, peripheral neuropathy affects over 15 million people in the United States and is associated with conditions that injure peripheral nerves, including herpes zoster, or shingles, diabetes, HIV and AIDS and other diseases. It can also be caused by trauma or may result from surgical procedures. Peripheral neuropathy is usually first felt as tingling and numbness in the hands and feet. Symptoms can

be experienced in many ways, including burning, shooting pain, throbbing or aching. Peripheral neuropathy can cause intense chronic pain that, in many instances, is debilitating.

Post-herpetic neuralgia (PHN) is one type of peripheral neuropathic pain associated with herpes zoster, or shingles, that exists after the rash has healed. According to Datamonitor, PHN affects over 100,000 people in the United States each year. PHN causes pain on and around the area of skin that was affected by the shingles rash. Most people with PHN describe their pain as "mild" or "moderate." However, the pain can be severe in some cases. PHN pain is usually a constant, burning or gnawing pain but can be an intermittent sharp or stabbing pain. Current treatments for PHN have limited effectiveness, particularly in severe cases and can cause significant adverse side effects. The initial indication for our EpiCept NP-1 product candidate is for the treatment of peripheral neuropathy in PHN patients.

There are currently three FDA-approved treatments for post-herpetic neuralgia: Neurontin (gabapentin), Lidoderm (lidocaine patch 5%) and Lyrica (pregabalin). Neurontin generated sales of approximately \$2.7 billion in the United States in 2004. According to the Scott-Levin Physician Drug and Diagnosis Audit, approximately 55% of the 5.1 million prescriptions for Neurontin relate to some form of neuropathic pain. Some patients also receive Tegretol (carbamazepine) to manage the symptoms of peripheral neuropathy. However, these drugs only work in some patients, and Neurontin may have significant side adverse effects, such as drowsiness. Often the use of these medications is combined with topical analgesics such as the Lidoderm patch and over-the-counter topical analgesic creams that provide minimal relief with a short duration of action. Lidoderm generated sales of approximately \$300 million in the United States in 2004, much of which we believe was attributable to patients with PHN. Lyrica was approved for the treatment of neuralgia in December 2004.

EpiCept NP-1. EpiCept NP-1 is a prescription topical analgesic cream containing a patented formulation, the contents of which include two FDA-approved drugs, amitriptyline (a widely-used antidepressant) and ketamine (an NMDA antagonist that is used as an anesthetic). EpiCept NP-1 is designed to provide effective, long-term relief from the pain caused by peripheral neuropathies. We believe that EpiCept NP-1 can be used in conjunction with systemically-delivered analgesics, such as Neurontin. The cream contains a 4% concentration of amitriptyline and a 2% concentration of ketamine. Since each of these ingredients has been shown to have significant analgesic effects and because NMDA antagonists, such as ketamine, have demonstrated the ability to enhance the analgesic effects of amitriptyline, we believe the combination is a good candidate for the development of a new class of analgesics. We intend to selectively seek a partner or strategic alliance to enable us to maintain financial and operational flexibility while retaining significant economic and commercial rights to this product candidate.

EpiCept NP-1 is a white vanishing cream that is applied twice daily and is quickly absorbed into the applied area. We believe the topical delivery of our patented combination represents a fundamentally new approach for the treatment of pain associated with peripheral neuropathy. In addition, we believe that the topical delivery of our product candidate will significantly reduce the risk of adverse side effects and drug to drug interactions associated with the systemic delivery of the active ingredients. The results of our clinical trials to date have demonstrated the safety of the cream for use for up to one year and a potent analgesic effect in subjects with both post-herpetic neuralgia and other types of peripheral neuropathy, such as those with diabetic, traumatic and surgical causes.

We believe EpiCept NP-1, if approved, would offer the following favorable attributes:				
analgesic effect comparable to levels provided when using systemically-delivered analgesics;				
additive therapy to systemically-delivered analgesics, such as Neurontin;				
minimal adverse side effects, including reduced drowsiness;				
ease of application and suitability for self-administration;				
low potential for abuse;				
good patient compliance;				

no drug to drug interactions; and

potential to treat a broad range of peripheral neuropathic conditions.

*Clinical Development.* We have completed two Phase II clinical trials, one initiated in Canada in October 2001 and one initiated in the United States in February 2002.

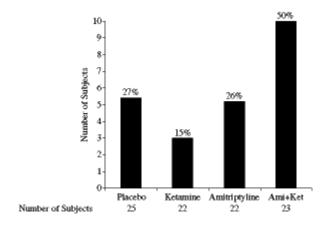
Placebo-controlled Factorial Trial. This four center Canadian Phase II clinical trial in Ontario and Nova Scotia (Dalhousie University) was a placebo-controlled factorial trial, i.e., a trial that evaluates the individual components of a drug that contains more than one component as compared to the effects of the combination, designed to demonstrate that the use of the combination of amitriptyline and ketamine was more effective than either drug alone. A factorial trial is a clinical trial in which the active ingredients in combination are compared with each drug used on its own accompanied by a placebo control. The trial included 92 subjects with a history of diabetic, post surgical or traumatic neuropathy or PHN. The trial tested a low-dose formulation of EpiCept NP-1, consisting of a 2% concentration of amitriptyline and a 1% concentration of ketamine, applied three times daily for three weeks. Subjects were allowed to continue their current pain medications (other than Lidoderm) as long as they did not alter their dosage level or frequency. Subjects who entered the trial had to have a score of at least 4 on the 11-point numerical pain scale. We completed the analysis of data from this clinical trial in February 2004.

We assessed several end points in this clinical trial, including mean daily pain severity as measured on the 11-point numerical pain scale, pain relief, a responder analysis and changes in the McGill Pain Questionnaire. While none of the results was statistically significant, the results of the responder analysis were the most compelling. In the responder analysis, subjects were required to show at least a 30% reduction in their pain as compared to placebo for the duration of the study. The results indicated a desirable rank order of the combination being more effective than either amitriptyline or ketamine alone or placebo. The cream was well-tolerated by a majority of the subjects, and no significant adverse reactions were observed. Based on a review of our Phase II clinical trial results, the FDA concurred in our End of Phase II meeting that we design our Phase III clinical trial as a responder analysis.

The following chart shows the number of subjects that completed the clinical trial with a reduction in pain of two points or more on the 11-point numerical pain scale. The number of subjects in each group were as follows: placebo: 25; ketamine only: 22; and combination of amitriptyline and ketamine: 23:

#### **NP-1 Factorial Trial Results**

Percentage of Subjects with Reduction in Neuropathic Pain>2



Note: p=0.10; (ami + ket vs. placebo)

**Dose-Response Clinical Trial.** In the United States, we conducted a Phase II placebo-controlled dose-response clinical trial in subjects recruited from 21 pain centers to determine an effective clinical dose of EpiCept NP-1. The trial included 251 subjects with post-herpetic neuralgia who had been suffering significant pain for at least three months. We tested two dosage formulations, one containing a 4% concentration of amitriptyline and a 2% concentration of ketamine, which we refer to as "high-dose" and one containing a 2% concentration of amitriptyline and a 1% concentration of ketamine, which we

refer to as "low-dose," as compared to placebo. Subjects were allowed to continue on their current pain medications as long as they did not alter their dosage level or frequency. Subjects who entered the trial had to have a score of at least 4 on the 11-point numerical pain scale. All subjects initially received the high-dose formulation twice daily for seven days. Responders, which were defined in the initial phase of this clinical trial as those experiencing a one point or greater drop on the 11-point numerical pain scale for three or more days, were then randomized into one of three study arms (high-dose, low-dose or placebo). Each study arm applied the applicable formulation of EpiCept NP-1 or placebo twice daily for an additional 14 days. We completed the analysis of the data from this clinical trial in August 2003.

The primary endpoint was the baseline average daily pain score compared to the average daily pain score at day 21, measured on the 11-point numerical pain scale. We measured the score for a 14 day period beginning on the day the subjects were randomized. The clinical trial's primary objective was to determine if the subjects in either the high-dose or low-dose groups experienced better analgesia as reflected by lower pain intensity scores over the length of the trial. Secondary endpoints included pain relief, sleep quality and patient global satisfaction, all measured on the 11-point numerical scale.

The following chart shows the outcome following the selection and evaluation of patients in no particular order, or randomization, of the responding subjects in either the high-dose, low-dose or placebo group:

# 

# **NP-1 Dose-Response Clinical Trial Results**

Note: \*p=0.026 (NP-1 high-dose group versus placebo group – baseline to day 21)

The clinical trial results indicated that the high-dose formulation of EpiCept NP-1 met the primary endpoint for the trial and resulted in a statistically significant reduction in pain intensity and increase in pain relief as compared to placebo. We also observed a dose-related effect, *i.e.* the subjects receiving the high-dose formulation had more favorable results than the subjects receiving the low-dose formulation. In addition, the subjects receiving the high-dose formulation reported better sleep quality and greater overall satisfaction than subjects receiving placebo. In addition, we observed a greater number of "responders," which for purposes of the responder analysis conducted during the 14-day period were defined as subjects with a two or more point drop in average daily pain scores on the 11-point numerical pain scale. No significant adverse reactions were observed other than skin irritation and rash, which were equivalent to placebo.

After the completion of the two Phase II trials, we conducted open label trials in which participants in the clinical trials could continue to use the low-dose formulation for a period of up to one year. The low-dose formulation was well-tolerated and detectable blood concentration levels of the active ingredients were insignificant, which is indicative of the safety and potential long term efficacy of the product.

The results of our Phase II clinical trials helped us decide to use the high-dose formulation of EpiCept NP-1 in our Phase III clinical trials.

Current Clinical Initiatives. We held an End of Phase II meeting with the FDA in April 2004 to discuss the Phase II clinical trial results and the protocols for our planned Phase III clinical trials. In that meeting, the FDA accepted our stability data and manufacturing plans for the combination product, as well as toxicology data on ketamine from studies conducted by others and published literature. The FDA also confirmed that the proposed New Drug Application, or NDA would qualify for a Section 505(b)(2) submission (for details on this submission process, see "Business – Government Regulation – Section 505(b)(2) Drug Applications" below). In addition, the FDA approved our Phase III clinical trial protocol and indicated that a second factorial Phase III clinical trial would be required. The FDA also requested that we conduct an additional pharmacokinetic trial to assess dermal absorption of ketamine and outlined the parameters for long-term safety studies for the high-dose formulation. The pharmacokinetic clinical trial will involve applying the cream twice daily and measuring blood concentration levels of amitriptyline and ketamine over 48 hours.

We will work with the FDA to develop an appropriate toxicology program for amitriptyline and ketamine where existing data is not available. We initiated a supplemental toxicology study in the third quarter of 2004 related to the application of EpiCept NP-1 on the skin. The duration of the study and the number and types of animals to be tested will be determined during further discussions with the FDA.

In addition, we plan to commence our Phase III clinical trial in the United States during the second half of 2005 with at least 800 subjects with PHN. The enrollment of these subjects could take up to one year to complete. This Phase III clinical trial will test the high-dose formulation against each component used on its own accompanied by a placebo control. We expect to utilize primarily the same endpoints that we used in our Phase II clinical trial conducted in the United States. A responder analysis based on pain intensity and pain relief, as well as sleep and patient global satisfaction, will be assessed over the eight-week duration of the clinical trial.

### Surgical Pain

According to Datamonitor's study "Postoperative Pain," published in April 2004, there are over 53 million surgical procedures conducted annually in the United States. Traditional post-surgical pain treatment usually begins with the application of a local anesthetic at the surgical incision site during the surgery. The pain relief provided by the anesthetic applied during surgery typically wears off within the first two hours. Pain relief is then provided by a combination of oral or injectible narcotic analgesics and NSAIDs, with accompanying adverse side effects and drug to drug interactions.

LidoPAIN SP. LidoPAIN SP is a sterile prescription analgesic patch designed to provide sustained topical delivery of lidocaine to a post-surgical or post-traumatic sutured wound while also providing a sterile protective covering for the wound. The LidoPAIN SP patch contains a 10% concentration of lidocaine and is intended to be applied once daily for as many days as needed, typically two to three days. LidoPAIN SP can be targeted for use following both inpatient and ambulatory surgical procedures, including among others: hernia repair, plastic surgery, puncture wounds, biopsy, cardiac catheterization and tumor removal.

Currently, there is no marketed product similar to LidoPAIN SP, and we believe that it would be the first sterile prescription analgesic patch on the market. If approved, we believe LidoPAIN SP would offer the following favorable attributes:

safety and ease of use;
sterility on a sutured wound;
reduced need for systemically-delivered narcotic analgesics and NSAIDs
once daily administration;

minimal adverse side effects, including no observed nausea or vomiting;

additive therapy to systemically-delivered analgesics;

no drug to drug interactions; and

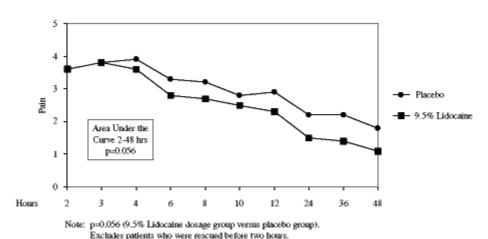
no wound healing interference.

Clinical Development. In December 2001, we initiated a randomized, double-blind, placebo-controlled Phase II clinical trial in 221 subjects who underwent hernia repair. We conducted the clinical trial in nine surgical centers in Germany. Subjects were randomized to receive two different doses of lidocaine, 9.5% and 3.5%, or placebo, in a patch applied once each day for two days. Subjects were not allowed to take any supplemental analysesics. We completed the analysis of this clinical trial in January 2003.

The primary endpoint was subject pain self-assessment at various intervals during the 48-hour period following the subject's surgery and the secondary endpoint was the number of "rescues," i.e. subjects receiving systemically-delivered analgesics to alleviate pain. The results of this trial indicate that the 9.5% formulation of LidoPAIN SP provided a statistically significant analgesic effect in the subjects. A dose-related response was also observed, with subjects receiving the higher dose reporting a greater reduction in pain and fewer rescues. No significant adverse reactions were observed.

The following chart shows the pain scores over time for LidoPAIN SP relative to placebo in a two-day trial following hernia repair surgery:

### **LidoPAIN SP Placebo-Controlled Clinical Trial Results**



Current Clinical Initiatives. Our clinical protocol for a Phase III clinical trial in Europe was approved by Germany's Federal Institute for Drugs and Medical Devices, commonly known as the BfArM. We initiated dosing for this trial during the fourth quarter of 2004. The clinical trial is a randomized, double-blind, placebo-controlled trial in which at least 400 subjects who underwent hernia repair will receive a LidoPAIN SP patch or a placebo patch, for 48 hours. The primary endpoint is self-assessed pain intensity at various times from 4 to 24 hours. The secondary endpoints include pain intensity over the 48-hour duration of the study, global satisfaction and the use of rescue medications. We believe that this clinical trial will be adequate for European registration, but we anticipate that we will need to conduct additional clinical trials in Europe in order to broaden the product labeling. We remain responsible for continuing and completing our ongoing dermal sensitivity study for LidoPAIN SP, but Adolor is responsible for further clinical trials and managing the approval process in North America under our strategic alliance with them. Adolor has announced that it plans to conduct Phase III clinical trials in the United States.

#### Back Pain

In the United States, 80% of the U.S. population will experience significant back pain at some point. Back pain ranks second only to headaches as the most frequent pain people experience. It is the leading reason for visits to neurologists and orthopedists and the second most frequent reason for physician visits overall. Both acute and chronic back pain are typically treated with NSAIDs, muscle relaxants or opioid analgesics. All of these drugs can subject the patient to systemic toxicity, significant adverse side effects and drug to drug interactions.

**LidoPAIN BP.** LidoPAIN BP is a prescription analgesic non-sterile patch designed to provide sustained topical delivery of lidocaine for the treatment of acute or recurrent lower back pain of moderate severity of less than three months duration. The LidoPAIN BP patch contains 140 mg of lidocaine in a 19.5% concentration, is intended to be applied once daily and can be worn for a continuous 24-hour period. The patch's adhesive is strong enough to permit a patient to move and conduct normal daily activities but can be removed easily.

If approved, we believe LidoPAIN BP would offer the following favorable attributes:

safety and ease of use;

reduced need for treatment with NSAIDs, muscle relaxants and narcotic analgesics;

once daily administration;

minimal adverse side effects; and

no drug to drug interactions.

LidoPAIN BP is designed to treat acute or recurrent lower back pain. As part of our strategic alliance with Endo, we licensed to Endo certain of our patents to enable Endo to develop a patch for the treatment of chronic lower back pain. The significant differences between LidoPAIN BP and Endo's product, Lidoderm, are as follows:

LidoPAIN BP is designed for 24-hour use whereas Lidoderm is approved for 12-hour use;

LidoPAIN BP is made with a stronger adhesive;

LidoPAIN BP contains a higher concentration of lidocaine; and

LidoPAIN BP is designed to provide earlier onset of action.

Clinical Development. In May 2001, we initiated a placebo-controlled dose-response trial Phase IIa clinical trial in the United States. In this clinical trial, we tested two dosage formulations of LidoPAIN BP – one patch measuring 150 sq. cm. with a 19.5% concentration of lidocaine and one patch measuring 75 sq. cm. with a 19.5% concentration of lidocaine – compared to placebo. Each patch was applied once daily for three days to 43 subjects with acute lower back pain of at least moderate intensity. Subjects abstained from other analgesics and other therapeutic regimens.

We completed the analysis of this clinical trial in August 2003. The primary endpoint was pain intensity measured by a 5-point numerical pain scale where 0 indicated no pain and 5 indicated severe pain. Pain measurements were made at various times over the three-day duration of the trial. We assessed a number of secondary endpoints, including pain relief, muscle stiffness and global satisfaction. The trial demonstrated a dose-related statistically significant reduction in back pain intensity and muscle stiffness as well as increase in pain relief from the initiation of the trial.

The following chart demonstrates the significant improvement in pain intensity relative to the baseline over the three-day duration of the study:

#### 4.0 3.57 3.5 3.33 3.29 3.0 Pain Intensity (0-5) 2.64 2.434 2.5 1.93\*\* 2.0 1.5 1.0 0.5 0.0 140 mg 70 mg Placebo \*\*p=0.001 (140 mg dosage versus baseline) p=0.01 (70 mg dosage versus baseline)

# **LidoPAIN BP Placebo-Controlled Dose-Response Clinical Trial Results**

In January 2002, we initiated a double-blind, placebo-controlled Phase IIb clinical trial in three centers in the United States. In this clinical trial, we tested a LidoPAIN BP patch measuring 150 sq. cm. with a 19.5% concentration of lidocaine. Each patch was applied once daily for three days to 198 subjects with acute lower back pain of at least moderate intensity. Subjects abstained from other analgesics and other therapeutic regimens.

Baseline

72 Hours

Although the results at two of the three centers in this study did indicate that LidoPAIN BP had a greater analgesic effect as compared to the placebo control, the results at a third center were contradictory. At that center, the trial subjects who received placebo reported an analgesic effect that exceeded the analgesic effect reported by the subjects receiving LidoPAIN BP. After the trial, our consultant concluded that the unusually large placebo effect reported at this center most likely resulted because many of the subjects may have been concerned that a failure to report an analgesic effect would result in a loss of the stipend offered as compensation for participation in the trial. Due to the results reported at this center, this clinical trial did not demonstrate a statistically significant analgesic effect.

Current Clinical Initiatives. Based on the results from our Phase I and Phase II clinical trials, we are designing a new pivotal Phase IIb clinical trial, which we expect to commence by the second half of 2005. Our new trial will be designed to address the issues raised in our previous Phase IIb clinical trial. The trial will be longer and will have more stringent enrollment criteria. Under our strategic alliance with Endo, we remain responsible for the development of LidoPAIN BP, including all clinical trials and regulatory submissions. We intend to request an End of Phase II meeting with the FDA during the first half of 2005.

#### **Other Product Candidates**

The following table summarizes the current status of our development programs for our three earlier-stage product candidates.

	Topical				
Product	Dosage Form	Initial Indication	Clinical Status	Next Steps	Marketing Rights
EpiCept MP/DP	Spray gel matrix	Oral mucositis;	Phase II	Continue Phase II	EpiCept
		Dental pain		development	
LidoPAIN TV	Patch	Tinnitus	Phase II in	Continue Phase II	EpiCept
	(non-sterile)		Europe	development	
LidoPAIN HM	Patch	Headache	Phase II	Continue Phase II	EpiCept
	(non-sterile)			development	

### EpiCept MP/DP

EpiCept MP/DP is a spray gel matrix of morphine and lidocaine for the treatment of oral mucositis and dental pain. A spray gel matrix is a liquid spray that solidifies upon contact with a warm surface. Oral mucositis is an inflammation of the mucosa of the mouth that ranges from redness to severe ulceration and typically results from chemotherapy and radiation therapy. It is anticipated that other clinical uses will be considered to expand upon the initial indications being studied. The FDA cleared our IND for EpiCept MP/DP in July 2001, and we completed a Phase IIa clinical trial on dental pain subjects in Europe in April 2002. Preliminary results have indicated that the product is well tolerated and provided a longer duration of pain relief compared to lidocaine by itself. This product candidate is not in active development, be we do intend to continue dose ranging and dose optimization trials in the future.

### LidoPAIN TV

LidoPAIN TV is a topical lidocaine patch applied to the periauricular skin region (behind the ear) for the treatment of tinnitus. This product releases doses of lidocaine into nerve endings located behind the ear. Tinnitus is characterized by a constant or intermittent hissing, buzzing or ringing noise in the ear that affects over 50 million Americans. There are many causes of tinnitus, including defects in nerve conduction, however, there are no currently approved treatments. We have not filed an IND application with the FDA, but we filed a foreign IND equivalent in Europe in June 2001. We completed a European Phase II clinical trial in subjects with tinnitus in May 2002. Subjects utilizing the LidoPAIN TV patch perceived a beneficial effect as compared to subjects given the placebo patch.

### LidoPAIN HM

LidoPAIN HM is a topical lidocaine patch applied to the forehead for the treatment of headaches. LidoPAIN HM releases analgesic doses of lidocaine directly into the trigeminal nerve, a nerve located in the face and forehead, stimulating the coverings (meninges) of the brain, which is believed to be a cause of migraine pain. The FDA cleared our IND for LidoPAIN HM in January 2001, and we completed a Phase II clinical trial for LidoPAIN HM in headache subjects. Our initial pilot study indicated that the patch was well tolerated and demonstrated statistically significant efficacy of the lidocaine patch over the placebo patch. A second larger study was unable to replicate those results. This product candidate is not in active development, but we do intend to continue our clinical trials to establish efficacy of this product candidate in various types of headache pain in the future.

### **Our Strategy**

Our objective is to address unmet medical needs in pain management by developing a broad portfolio of topically-delivered prescription analgesics for the treatment of moderate-to-severe pain where existing treatments are ineffective or cause significant adverse side effects. To achieve our objective, the key elements of our strategy are to:

Focus our development efforts on topically-delivered analgesics targeting peripheral nerve receptors. We intend to leverage our parameters analgement expertise by developing proprietary products that						
58						

target peripheral nerve receptors as a novel mechanism to effectively treat both acute and chronic pain, with fewer adverse side effects than conventional oral, injectable or transdermal pain therapeutics. We are developing new patent-protected products for conditions that can be treated by blocking the ability of peripheral nerve receptors to transmit pain messages to the brain.

**Focus our development efforts on FDA-approved drugs.** All of our product candidates utilize several proprietary formulations and topical delivery technologies to administer FDA-approved analgesics. We believe using FDA-approved analgesics reduces the risks associated with new drug development, lowers our development costs and speeds time-to-market.

Opportunistically enter into development and commercialization alliances for our products. We plan to market products for which we obtain regulatory approval through co-marketing, co-promotion, licensing and distribution arrangements with third-party collaborators. We may also consider contracting with a third party professional pharmaceutical sales organization to perform the marketing function for our products. Where appropriate, we plan to retain certain rights to the development and commercialization of our product candidates and build our own internal sales and marketing capabilities in order to retain a greater share of any potential revenues. We believe that our current approach allows us maximum flexibility of selecting the marketing method that will optimize market penetration and commercial acceptance of our products and enable us to avoid developing a large internal sales and marketing organization.

### **Our Strategic Alliances**

We have established strategic alliances with Adolor with respect to our LidoPAIN SP product candidate for the treatment of pain associated with surgical incisions and with Endo with respect to our LidoPAIN BP product candidate for the treatment of lower back pain. These strategic alliances are designed to provide us with operating capital and supplement our development and marketing capabilities. We intend to selectively pursue additional strategic alliances as appropriate.

#### Adolor

In July 2003, we entered into a license agreement with Adolor under which we granted Adolor the exclusive right to commercialize a sterile topical patch containing an analgesic alone or in combination, including without limitation, LidoPAIN SP, throughout North America. Upon the execution of the Adolor agreement, we received a non-refundable payment of \$2.5 million, and we may receive additional non-refundable payments of up to \$15.0 million that become due upon the achievement of various milestones relating to product development and regulatory approval. Under the agreement, we will also receive royalties from Adolor based on the net sales of licensed products in North America. These royalties are payable on a country-by-country basis until our last patent covering the licensed product expires or the tenth anniversary of the first commercial sale of licensed product, whichever is later. Under the agreement, Adolor is obligated to pay us a one time bonus payment of up to \$5.0 million upon the achievement of specified net sales milestones of licensed product. The total amount of upfront and milestone payments we are eligible to receive from Adolor is \$22.5 million.

Under the terms of the agreement, Adolor is responsible for conducting further clinical trials and completing the approval process in North America. At Adolor's option, we may be required to supply or to obtain supply of the clinical products necessary to complete clinical trials. Alternatively, Adolor can choose to subcontract these responsibilities to a third party. In North America, Adolor is responsible for the supply and manufacture of LidoPAIN SP for commercial use or, at its option, may subcontract these responsibilities to third parties. In October 2004, we and Adolor entered into an amendment to the license agreement to facilitate our respective clinical development activities. The amendment provided that the we and Adolor would coordinate our independent pre-clinical and clinical activities with respect to the LidoPAIN SP product. In addition, we agreed to provide Adolor with clinical trial data generated from our recent clinical trial conducted in Europe and to permit Adolor to use such data for development, regulatory and commercialization of licensed products. Adolor, in turn, agreed to provide us with certain data generated by Adolor relating to the

lidocaine patches manufactured by Corium International, Inc. and to permit us to use such data for the development, regulatory and commercialization of sterile lidocaine patches. Lastly, the amendment permits us to enter into an agreement with Corium pursuant to which Corium will manufacture and supply our clinical and commercial supplies of sterile lidocaine patches for use outside North America. We have not yet entered into any manufacturing or supply agreement with Corium.

At our option, within 30 days after Adolor's first filing of an NDA (or foreign equivalent) for LidoPAIN SP or similar product, we have the right to negotiate with Adolor regarding a co-promotion arrangement in any country in North America in which such filing has been made. However, neither we nor Adolor is under any obligation to enter into any such arrangement.

The Adolor license terminates on a country-by-country and licensed product-by-licensed product basis upon the expiration of the royalty obligations in the particular country. Adolor may also terminate the agreement upon 120 days advance written notice to us, and either Adolor or EpiCept may terminate the agreement upon an uncured material breach by the other or, subject to the relevant bankruptcy laws, upon a bankruptcy event of the other.

#### Endo

In December 2003, we entered into a license agreement with Endo under which we granted Endo (and its affiliates) the exclusive (including as to us and our affiliates) worldwide right to commercialize LidoPAIN BP. We also granted Endo worldwide rights to use certain of our patents for the development of certain other non-sterile, topical lidocaine patches, including Lidoderm, Endo's non-sterile topical lidocaine-containing patch for the treatment of chronic lower back pain. Upon the execution of the Endo agreement, we received a non-refundable payment of \$7.5 million, and we may receive payments of up to \$52.5 million upon the achievement of various milestones relating to product development, regulatory approval and commercial success for both our LidoPAIN BP product and Endo's own back pain product, so long as, in the case of Endo's product candidate, our patents provide protection thereof. We will also receive royalties from Endo based on the net sales of LidoPAIN BP. These royalties are payable until generic equivalents to the LidoPAIN BP product are available or until expiration of the patents covering LidoPAIN BP, whichever is sooner. We are also eligible to receive milestone payments from Endo of up to approximately \$30.0 million upon the achievement of specified regulatory and net sales milestones of Lidoderm, Endo's chronic lower back pain product candidate, so long as our patents provide protection thereof. The total amount of upfront and milestone payments we are eligible to receive under this agreement is \$90.0 million.

We remain responsible for continuing and completing the development of LidoPAIN BP, including conducting all clinical trials (and supplying the clinical products necessary for those trials) and the preparation and submission of the NDA in order to obtain regulatory approval for LidoPAIN BP. We may subcontract with third parties for the manufacture and supply of LidoPAIN BP. Endo is conducting Phase II clinical trials for its Lidoderm patch and remains responsible for continuing and completing the development, including conducting all clinical trials (and supplying the clinical products necessary for those trials) in connection with that product candidate.

In the event that we have obtained regulatory approval of LidoPAIN BP in a particular country and Endo fails to commercialize LidoPAIN BP in that country within three years from the date on which we receive final regulatory approval in the United States, then the license granted to Endo relating to the commercialization of LidoPAIN BP in that country terminates, and we will have the right to commercialize or license the product in that country. In that event, we will be required to pay Endo a royalty on the net sales of LidoPAIN BP in any such country.

At our option, within 30 days after our first filing of an NDA (or foreign equivalent) for LidoPAIN BP, we have the right to negotiate a co-promotion arrangement with Endo in any country in which such filing has been made. However, neither we nor Endo is under any obligation to enter into any such arrangement.

The license terminates upon the later of the conclusion of the royalty term, on a country-by-country basis, and the expiration of the last applicable EpiCept patent covering licensed Endo product candidates on a country-by-country basis. Either Endo or EpiCept may terminate the agreement upon an uncured material breach by the other or, subject to the relevant bankruptcy laws, upon a bankruptcy event of the other.

# Manufacturing

We have no in-house manufacturing capabilities. We intend to outsource all of our manufacturing activities for the foreseeable future. We believe that this strategy will enable us to direct operational and financial resources to the development of our product candidates rather than diverting resources to establishing a manufacturing infrastructure.

We have entered into arrangements with qualified third parties for the formulation and manufacture of our clinical supplies. We intend to enter into additional written supply agreements in the future and are currently in negotiations with several potential suppliers. We generally purchase our supplies from our current suppliers pursuant to purchase orders. We plan to use a single, separate third party manufacturer for each of our product candidates that we are responsible for manufacturing. In some cases, the responsibility to manufacture product, or to identify suitable third party manufacturers, may be assumed by our licensees. For example, under the Adolor agreement, Adolor is responsible for the manufacture of the commercial supply of LidoPAIN SP in North America. We may source LidoPAIN SP for marketing outside of North America from Adolor or Adolor's third party supplier. Alternatively, we can separately arrange for other third party suppliers to manufacture the commercial supply of LidoPAIN SP outside North America. Pursuant to the October 2004 amendment to the Adolor agreement, Adolor has agreed to permit us to enter into an agreement with Corium pursuant to which Corium would manufacture and supply our clinical and commercial supplies of sterile lidocaine patches for our use outside North America. We have not yet entered into any manufacturing or supply agreement with Corium.

We cannot assure you that our current manufacturers can successfully increase their production to meet full commercial demand. We believe that there are several manufacturing sources available to us, including our current manufacturers, which can meet our commercial supply requirements on commercially reasonable terms. We will continue to look for and secure the appropriate manufacturing capabilities and capacity to ensure commercial supply at the appropriate time.

### Sales and Marketing

We do not currently have internal sales or marketing capabilities. In order to commercially market our product candidates if we obtain regulatory approval, we must either develop an internal sales and marketing infrastructure or collaborate with third parties with sales and marketing expertise. We have retained full rights to commercialize EpiCept NP-1 worldwide. We have granted Adolor exclusive commercialization rights for LidoPAIN SP in North America but have also retained the right to negotiate with Adolor a co-promotion agreement for LidoPAIN SP in North America. In addition, we have granted Endo exclusive worldwide marketing and commercialization rights for LidoPAIN BP but have also retained the right to negotiate with Endo co-promotion rights for LidoPAIN BP worldwide. We will likely market our products in international markets outside of North America through collaborations with third parties. We intend to make decisions regarding internal sales and marketing of our product candidates on a product-by-product and country-by-country basis.

### **Intellectual Property**

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our technologies and drug candidates as well as successfully defending these patents against third-party challenges. We have various composition of matter and use patents, which have claims directed to our product candidates or methods of their use. Our patent policy is to retain and secure

patents for the technology, inventions and improvements related to our core portfolio of product candidates. We currently own 17 issued U.S. patents, five issued foreign patents, one allowed U.S. patent application and seven pending U.S. and foreign patent applications. We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position.

The following is a summary of the patent position relating to our three late-stage product candidates:

*EpiCept NP-1* – We own a U.S. patent with claims directed to a formulation containing a combination of amitriptyline and ketamine, which can be used as a treatment for the topical relief of pain, including neuropathic pain, that expires in August 2021. We also have a license to additional patents, which expire in September 2015 and May 2018, and which have claims directed to topical uses of tricyclic antidepressants, such as amitriptyline, and NMDA antagonists, such as ketamine, as treatments for relieving pain, including neuropathic pain. Additional foreign patent applications are pending related to EpiCept NP-1 in many major pharmaceutical markets outside the United States.

LidoPAIN SP – We own two U.S. patents that have claims directed to the topical use of a local anesthetic or salt thereof, such as lidocaine, for the prevention or relief of pain from surgically closed wounds, in a hydrogel patch, which expire in October 2019. Additionally, we own a pending U.S. patent application that is directed to a breathable, sterile patch that can be used to treat pain caused by various types of wounds, including surgically closed wounds. We have foreign patent applications pending relating to LidoPAIN SP in many major pharmaceutical markets outside the United States.

**LidoPAIN BP** – We own a U.S. patent that has claims directed to the use and composition of a patch containing a local anesthetic, such as lidocaine, to topically treat back pain, myofascial pain and muscular tensions, which expires in July 2016. Equivalent foreign patents have been granted in many major European pharmaceutical markets.

We also seek to protect our proprietary information by requiring our employees, consultants, contractors, outside partners and other advisers to execute, as appropriate, nondisclosure and assignment of invention agreements upon commencement of their employment or engagement. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials.

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, partners and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

The pharmaceutical, biotechnology and other life sciences industries are characterized by the existence of a large number of patents and frequent litigation based upon allegations of patent infringement. While our drug candidates are in clinical trials, and prior to commercialization, we believe our current activities fall within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States and Section 55.2(1) of the Canadian Patent Act, each of which covers activities related to developing information for submission to the FDA and its counterpart agency in Canada. As our drug candidates progress toward commercialization, the possibility of an infringement claim against us increases. While we attempt to ensure that our drug candidates and the methods we employ to manufacture them do not infringe other parties' patents and other proprietary rights, competitors or other parties may assert that we infringe on their proprietary rights.

For a discussion of the risks associated with our intellectual property, see "Risk Factors – Risks Relating to Intellectual Property,"

### **License Agreements**

We have in the past licensed and will continue to license patents from collaborating research groups and individual inventors.

#### Cassel

In October 1999, we acquired from Dr. R. Douglas Cassel certain patent applications relating to technology for the treatment of surgical incision pain. On July 16, 2003, this royalty agreement was amended. Pursuant to this agreement, we have agreed to pay Dr. Cassel a fee of \$4,000 per month until July 2006. We will also pay Dr. Cassel royalties based on the net sales of any of our products for the treatment of pain associated with surgically closed wounds. The \$4,000 per month fee will be credited towards these royalty payments. The royalty obligations will terminate upon the expiration of the last to expire acquired patent. As part of the royalty arrangement, we have engaged Dr. Cassel as a consultant, for which he is paid on a per diem basis. Dr. Cassel provides us with general scientific consulting services, particularly with respect to the development and commercialization of LidoPAIN SP. Dr. Cassel has also granted us an option to obtain, on mutually agreeable terms, an exclusive, worldwide license to any technology discovered by Dr. Cassel outside of his performance of services for us.

### **Epitome**

In August 1999, we entered into a sublicense agreement with Epitome Pharmaceuticals Limited under which we have an exclusive license to certain patents for the topical use of tricyclic anti-depressants and NMDA antagonists as topical analgesics for neuralgia. This technology has been incorporated into EpiCept NP-1. We have been granted worldwide rights to make, use, develop, sell and market products utilizing the licensed technology in connection with passive dermal applications. We are obligated to make payments to Epitome upon achievement of specified milestones and to pay royalties based on annual net sales derived from the products incorporating the licensed technology. At the end of each year in which there has been no commercially sold products, we will be obligated to pay to Epitome a maintenance fee that is equal to twice the fee paid in the previous year, or Epitome will have the option to terminate the contract. The sublicense terminates upon the expiration of the last to expire licensed patents. The sublicense may be terminated earlier under specified circumstances, such as breaches, lack of commercial feasibility and regulatory issues.

### **Government Regulation**

### **United States**

The U.S. Food and Drug Administration and comparable state and local regulatory agencies impose substantial requirements upon the clinical development, manufacture, marketing and distribution of drugs. 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. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and implementing regulations. The process required by the FDA before our product candidates may be marketed in the United States generally involves the following:

completion of extensive pre-clinical laboratory tests, pre-clinical animal studies and formulation studies all performed in accordance with the FDA's good laboratory practice, or GLP, regulations;

submission to the FDA of an IND application that must become effective before clinical trials may begin;

performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;

submission of an NDA to the FDA:

satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced to assess compliance with current GMP, or cGMP, regulations; and

FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

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

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

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

**Phase I:** Studies are initially conducted in a limited population to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in subjects. In some cases, a sponsor may decide to run what is referred to as a "Phase Ib" evaluation, which is a second safety-focused Phase I clinical trial typically designed to evaluate the impact of the drug candidate in combination with currently approved drugs.

**Phase II:** Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the drug candidate for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials. In some instances, a sponsor may decide to run what is referred to as a "Phase IIa" clinical trial, which is designed to provide dose-ranging and additional safety and pharmaceutical data. In other cases, a sponsor may decide to run what is referred to as a "Phase IIb" evaluation, which is a second, confirmatory Phase II clinical trial that could, if positive and accepted by the FDA, serve as a pivotal clinical trial in the approval of a drug candidate.

**Phase III:** These are commonly referred to as pivotal studies. When Phase II clinical trials demonstrate that a dose range of the drug candidate is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

In some cases, the FDA may condition approval of an NDA for a drug candidate on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval. Such post-approval trials are typically referred to as Phase IV clinical trials.

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

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

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

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and

criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

Section 505(b)(2) Drug Applications. Once an FDA-approved new drug is no longer patent-protected, another company may sponsor a new indication, a new use or put the drug in a new dosage form. Each new indication from a different company requires an NDA filing. As an alternate path to FDA approval for new or improved formulations of previously approved products, a company may file a Section 505(b)(2) NDA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. However, this NDA does not have to contain all of the information or data that was submitted with the original NDA because of the FDA's prior experience with the drug product. An original NDA for an FDA-approved new drug would have required numerous animal toxicology studies that have been reviewed by the FDA. These can be referenced in the 505(b)(2) NDA submitted by the new applicant. Many studies in humans that support the safety of the drug product may be in the published literature. The FDA allows the new sponsor company to submit these publications to support its 505(b)(2) NDA. By allowing the new sponsor company to use this information, the time and cost required to obtain approval for a drug product for the new indication can be greatly reduced. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book publication. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired.

#### Foreign Regulation

Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from country to country. Although governed by the applicable country, clinical trials conducted outside of the United States typically are administered with the three-phase sequential process that is discussed above under "Government Regulation – United States." However, the foreign equivalent of an IND is not a prerequisite to performing pilot studies or Phase I clinical trials.

Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is available for medicines produced by biotechnology or which are highly innovative, provides for the grant of a single marketing authorization that is valid for all EU member states. This authorization is a marketing authorization approval, or MAA. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an

application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. This procedure is referred to as the mutual recognition procedure, or MRP.

In addition, regulatory approval of prices is required in most countries other than the United States. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or our collaborators.

# Competition

The pharmaceutical industry, and the pain management sector specifically, is highly competitive and includes a number of established, large and mid-sized pharmaceutical and specialty pharmaceutical companies, as well as smaller emerging companies, whose activities are directly focused on our target markets and areas of expertise. These organizations also compete with us to attract qualified personnel and potential parties for acquisitions, joint ventures or other strategic alliances. Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large pharmaceutical companies in particular have extensive experience in clinical testing, obtaining regulatory approvals and drug commercialization. If approved, our product candidates will compete with a large number of products that include over-the-counter treatments, prescription drugs specifically indicated for pain management and prescription drugs that are prescribed off-label. In addition, new developments occur in the pharmaceutical industry at a rapid pace.

If approved, each of our product candidates will compete for a share of the existing market with products that have become standard treatments recommended or prescribed by physicians.

We believe that the primary competition for our lead product candidates are as follows:

*EpiCept NP-1.* The primary competition for EpiCept NP-1 in the area of post-herpetic neuralgia is Neurontin (gabapentin), which is currently marketed by Pfizer. Gabapentin, the generic equivalent of Neurontin, is now available at a cost substantially below the price of Neurontin. Pfizer has developed a successor product candidate to Neurontin called Lyrica or pregabalin, which has been shown in Phase III clinical trials to effectively treat subjects with neuropathic pain. We also face competition from Endo's Lidoderm patch, which is currently indicated for post-herpetic neuralgia.

LidoPAIN SP. The primary competition in the market for acute post-operative pain are narcotic analgesics. Several competitors are seeking product candidates that would be used in combination with opioids to mitigate one or more of the adverse side effects associated with their use. For example, Endo recently announced that the FDA has approved Skyepharma's NDA for DepoDur for the treatment of pain following major surgery, to which product Endo has licensed the commercial rights. Previously referred to as DepoMorphine, DepoDur is a single dose sustained-release injectable formulation of morphine. Other competitors include Purdue Pharmaceuticals, Johnson & Johnson and Endo.

**LidoPAIN BP.** There are a number of competitive products that are used to treat acute lower back pain. We compete with fully-integrated pharmaceutical companies, smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have drugs already approved by the FDA or in development and operate larger research and development programs in these fields than we do.

Although we believe that, if approved, our product candidates will have favorable features for the treatment of their intended indications, existing treatments or treatments currently under clinical development that also receive regulatory approval may possess advantages in competing for market share.

#### **Legal Proceedings**

We are not currently involved in any material legal proceedings.

#### **Facilities**

Our facilities consist of approximately 12,700 square feet of research and office space. We lease 9,600 square feet located at 270 Sylvan Avenue in Englewood Cliffs, New Jersey until September 2005 with an option to renew until September 2010. We also lease 2,766 square feet in Munich, Germany until August 2007, with an automatic year-long extension for an additional three years.

# **Employees**

Our workforce consists of 13 full-time employees, three of whom hold a Ph.D. or M.D., and one of whom holds other advanced degrees. Of our total workforce, five are engaged in research and development, and eight are engaged in business development, finance and administration. We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages. We believe that our relations with our employees are good.

#### **MANAGEMENT**

# **Management and Board of Directors**

EpiCept has a strong team of experienced business executives, scientific professionals and medical specialists. Our executive officers and directors, their ages and positions, as of April 18, 2005, are as follows:

Name	Age	Position/Affiliation		
John V. Talley	49	President, Chief Executive Officer and Director		
Robert W. Cook	49	Chief Financial Officer – Senior Vice President, Finance and Administration		
Dov Elefant	37	Controller - Vice President, Finance and Administration		
Earle Lockhart, M.D.	64	Vice President, Clinical and Regulatory Affairs		
Scott B. Kozak	39	Vice President, Business Development		
Oliver Wiedemann, M.D.	45	Managing Director - Medical Affairs, EpiCept GmbH		
Dileep Bhagwat, Ph.D., M.B.A.	54	Senior Vice President, Pharmaceutical Development		
Robert G. Savage	51	Chairman of the Board		
Ernst-Günter Afting, M.D., Ph.D.	62	Director		
Gert Caspritz, Ph.D.	55	Director		
Mark Docherty	41	Director		
Guy C. Jackson	63	Director		
Reiner Ponschab, Ph.D.	61	Director		
Thorlef Spickschen, Ph.D.	64	Director		

# **Executive Officers and Key Employees**

John V. Talley has been our President, Chief Executive Officer and a Director since October 2001. Mr. Talley has more than 23 years of experience in the pharmaceutical industry. Prior to joining us, Mr. Talley was the Chief Executive Officer of Consensus Pharmaceuticals, a biotechnology drug discovery start-up company that developed a proprietary peptide-based combinatorial library screening process. Prior to joining Consensus, Mr. Talley led Penwest Ltd.' s efforts in its spin-off of its subsidiary Penwest Pharmaceuticals Co. in 1998 and served as President and Chief Operating Officer of Penwest Pharmaceuticals. Mr. Talley started his career at Sterling Drug Inc., where he was responsible for all U.S. marketing activities for prescription drugs, helped launch various new pharmaceutical products and participated in the 1988 acquisition of Sterling Drug by Eastman Kodak Co. Mr. Talley received his B.S. in Chemistry from the University of Connecticut and completed coursework towards an M.B.A. in Marketing from New York University, Graduate School of Business.

Robert W. Cook has been our Chief Financial Officer and Senior Vice President, Finance and Administration since April 2004. Prior to joining us, Mr. Cook was Vice President, Finance and Chief Financial Officer of Pharmos Corporation since January 1998 and became Executive Vice President of Pharmos in February 2001. From May 1995 until his appointment as Pharmos's Chief Financial Officer, he was a vice president in GE Capital's commercial finance subsidiary, based in New York. From 1977 until 1995, Mr. Cook held a variety of corporate finance and capital markets positions at The Chase Manhattan Bank, both in the United States and in several overseas locations. He was named a managing director of Chase and several of its affiliates in January 1986. Mr. Cook received his B.S. in International Finance from The American University, Washington, D.C.

Dov S. Elefant has been our Controller and Vice President of Finance and Administration since April 2004. Prior to being named our Controller and Vice President of Finance and Administration, Mr. Elefant was our Controller from December 1999 through September 2000, our Chief Financial Officer from October 2000 through January 2001 and our Chief Financial Officer and Vice President of Finance and Administration from January 2001 until April 2004. From October 1998 until December 1999, Mr. Elefant was Assistant Controller of Alteon Inc., a publicly traded biotechnology company. Prior to that, he served as Director of Accounting and Finance of Innapharma, Inc., a pharmaceutical contract research organization. Mr. Elefant received his B.S. in Accounting from the Sy Syms School of Business of Yeshiva University in New York.

Earle A. Lockhart, M.D., has been our Vice President of Clinical and Regulatory Affairs since 2000, and prior to that served as our Director of Clinical Research and Medical Affairs since 1998. From 1996 until joining us, Dr. Lockhart was Medical Director supporting the launch and marketing of a controlled release oxycodone (OxyContin) for The Purdue Frederick Company. From 1991 until 1996, Dr. Lockhart served as Senior Medical Director in the OTC Division of American Home Products Corporation. From 1986 to 1991, Dr. Lockhart served as Senior Medical Director of Medical Affairs at Sterling Drug. From 1981 until 1986, Dr. Lockhart held various positions in clinical research at Bristol-Myers Squibb Company and Janssen Pharmaceutica Products, L.P. Dr. Lockhart received his M.D. from the University of Toronto and is Board Certified in both Pediatrics and Nephrology. He has been Associate Professor of Pediatrics at New York Medical College in Valhalla, N.Y. and is currently Clinical Assistant Professor at Albert Einstein College of Medicine in New York.

Scott B. Kozak has been our Vice President of Business Development since April 2002 and has more than 15 years of experience in the pharmaceutical industry. Prior to joining us, Mr. Kozak was the Director of Licensing at Forest Laboratories, Inc. Before joining Forest in September 1999, Mr. Kozak was Assistant Director, Global Licensing and Corporate Development at Hoffmann-La Roche Inc., where he was responsible for the licensing efforts in the Metabolic and Drug Delivery areas and was a member of the Metabolic Therapeutic Area Strategy Team responsible for global planning. From 1989 to 1997, Mr. Kozak held various sales, marketing, and licensing and acquisition positions at Solvay Pharmaceuticals. Mr. Kozak received his B.S. in Marketing from the University of Connecticut and his M.B.A. in Marketing from Kennesaw State University's Michael J. Coles College of Business.

Oliver Wiedemann, M.D., joined our subsidiary EpiCept GmbH in October 1998 as Director of Medical Affairs. Since July 1999, he has been the Managing Director at EpiCept GmbH. From January 1992 until joining us, he was the Department Head CNS/ Muscle of the Medical Department of Sanofi Winthrop, Munich. Prior to that, Dr. Widemann worked as a surgeon at the Olympiapark-Klinik, Munich. He is the author of several scientific publications in the pain area. Dr. Wiedemann received his Medical Doctorate Degree from the University of Munich.

Dileep Bhagwat, Ph.D., M.B.A., has been our Senior Vice President of Pharmaceutical Development since February 2004 and has more than 20 years of pharmaceutical experience developing and commercializing various dosage forms. Prior to joining EpiCept in 2004, Dr. Bhagwat worked at Bradley Pharmaceuticals, as Vice President, Research and Development and Chief Scientific Officer. From November 1994 through September 1999, Dr. Bhagwat was employed at Penwest Pharmaceuticals in various capacities, including Vice President, Scientific Development and Regulatory Affairs and at Purdue Frederick Research Center as Assistant Director of Pharmaceutical Development. Dr. Bhagwat holds many U.S. and foreign patents and has presented and published on dosage form development and drug delivery. Dr. Bhagwat holds a B.S. in Pharmacy from Bombay University, an M.S. and Ph.D. in Industrial Pharmacy from St. John's University in New York and an M.B.A. in International Business from Pace University in New York.

# **Board of Directors**

**Robert G. Savage** has been a member of our Board since December 2004 and serves as the Chairman. Mr. Savage has been a pharmaceutical executive for almost 20 years. He held the position of Worldwide

Chairman of the Pharmaceuticals Group at Johnson & Johnson and was both a company officer and a member of the Executive Committee. He also served Johnson & Johnson in the capacity of a Company Group Chairman and President of Ortho-McNeil Pharmaceuticals. Most recently, Mr. Savage was President for the General Therapeutics and Inflammation Business for Pharmacia Corporation where he was President of the Worldwide Inflammation Group. He has held multiple positions leading marketing, business development and strategic planning at Hoffmann-La Roche and Sterling Drug. Mr. Savage is a director of The Medicines Company, a specialty pharmaceutical company, Noven Pharmaceuticals, a drug delivery company, and NovaDel Pharma, Inc., a drug delivery company. Mr. Savage received a B.S. in Biology from Upsala College and an M.B.A. from Rutgers University.

Ernst-Günter Afting, M.D., Ph.D., has been a member of our board since 1998. Since 1995, Professor Afting has been President and Chief Executive Officer of Munich-based GSF-National Research Center for Environment and Health, a large medical research organization. From 1993 until 1995, he was President and Chief Executive Officer of Roussel Uclaf, a French pharmaceutical company, which was majority owned by Hoechst AG. Professor Afting had previously held various positions with Hoechst AG since 1984, including Chief Executive Officer of the Pharmaceutical Division of the Hoechst Group and Chairman of the Divisional Pharmaceutical Board. He was a member of the Advisory Committee on Science and Technology to the German Chancellor and serves on several boards of entrepreneurial biotechnology companies in Europe and the United States. Professor Afting has been a member of the faculty at the University Göttingen since 1985. Professor Afting received his M.D. and Ph.D. from the University of Freiburg, Germany.

Gert Caspritz, Ph.D., has been a member of our board since 1999 and served as our Chairman from July 2002 until December 2004. Dr. Caspritz joined Techno Venture Management, or "TVM," in 1999 as an Investment Manager in the healthcare and life sciences group and has been a General Partner since 2000. Prior to that, Dr. Caspritz held various positions with Hoechst AG. Most recently he was Vice President, New Technologies Licensing at Hoechst Marion Roussel, the pharmaceutical subsidiary of Hoechst, where he had primary global responsibility for identifying business opportunities in the areas of biotechnology, enabling technologies and early-stage products in both the biotech industry and academia. Additionally, he supervised HMR's various venture capital investments and was a member of their strategy teams for oncology and bone diseases and the oncology opportunity review team. Dr. Caspritz was previously Assistant to the Head of Hoechst's worldwide pharmaceutical research and established or led a number of immuno and neuropharmacology laboratories as well as a drug discovery group. Dr. Caspritz received degrees in Biology and Microbiology from the University of Mainz, Germany where he wrote his doctoral thesis.

*Mark Docherty* has been a member of our board since July 2003. Mr. Docherty is a founding director of Merlin Biosciences Limited and serves as an Investment Director. He has worked on a large number of initial investments and refinancings of biotechnology companies. He was previously associated with Arthur Andersen (UK) in the Corporate Finance Group based in the United Kingdom. Mr. Docherty is a Chartered Accountant and holds a B.Eng. in Mechanical Engineering from Sheffield University in the United Kingdom. Mr. Docherty also holds a number of non-executive directorships on the boards of directors of various private biotechnology companies.

Guy C. Jackson has been a member of our Board since December 2004. In June 2003, Mr. Jackson retired from the Minneapolis office of the accounting firm of Ernst & Young LLP, after 35 years with the firm and one of its predecessors, Arthur Young & Company. During his career, he served as audit partner for numerous public companies in Ernst & Young's New York and Minneapolis offices. Mr. Jackson also serves as a director and member of the audit committee of Cyberonics, Inc. and Urologix, Inc., both medical device companies, as well as Digi International Inc., a technology company, and Life Time Fitness, Inc., an operator of fitness centers. Mr. Jackson received a B.S. in Business Administration from Pennsylvania State University and a M.B.A. from the Harvard Business School.

*Reiner Ponschab, Ph.D.*, has been a member of our board since June 1999. Dr. Ponschab is an of counsel with Heussen Rechtsanwaltsgesellschaft mbH in Munich, working as a lawyer in the field of

commercial law with the main emphasis in the areas of corporate law, merger and acquisitions, venture capital and structuring of companies since 1976, and prior to that working in the tax department of Peat Marwick Mitchell & Co. since 1974. Dr. Ponschab is the Chairman of the Committee for Alternative Dispute Resolution of the German Bar Association and President of the Society of Business Mediation and Conflict Management, and since 1996 he has been conducting a teaching assignment with the University of Passau.

Thorlef Spickschen, Ph.D., has been a member of our board since November 2001. He has worked as a senior executive in the pharmaceutical industry for over 30 years. From 1994 until 2001, he served as Chairman and Chief Executive Officer of BASF Pharma-Knoll AS. From 1991 until 1993, he was Chairman and CEO of Boehringer Mannheim GmbH. Earlier in his career, he held business positions at Eli Lilly and Company and McKinsey & Company. Dr. Spickschen serves on the boards of BioVisioN AG (Vice Chairman), Heidelberg Innovation GmbH (Chairman), Pharmion Corporation and GfK AG, as well as several academic and social institutions. Dr. Spickschen received a Doctorate in Business Management from the University of Cologne.

#### Scientific and Medical Advisory Board

Our Scientific and Medical Advisory Board is composed of individuals with expertise in clinical pharmacology, clinical medicine and regulatory matters. Advisory board members assist us in identifying scientific and product development opportunities and in reviewing with management progress of the our projects.

*Dr. Gavril Pasternak, Chief Advisor*, is a recognized authority on opioid receptor mechanisms. He has published a substantial body of literature on the subject, and he is on the editorial boards of numerous journals related to the subjects of neuropharmacology and pain. Dr. Pasternak is a Member and attending Neurologist at Memorial Sloan-Kettering Cancer Center and is Professor of Neurology and Neuroscience, Pharmacology and Psychiatry at Cornell University Medical College and Graduate School of Medical Sciences.

*Prof. Dr. Christoph Stein* is a recognized authority in experimental and clinical pain research. He has studied mechanisms of peripherally mediated opioid analgesia for over 16 years and has published an extensive body of literature on this topic. He is on editorial boards of several journals related to pain, anesthesia and analgesia. Dr. Stein is Professor and Chairman of the Department of Anesthesiology at Charité – Campus Benjamin Franklin, Freie Universität Berlin, Germany, and Adjunct Professor at Johns Hopkins University.

*Bruce F. Mackler, Ph.D., J.D., M.S.*, received his J.D. from the South Texas College of Law of the Texas A&M University, his Ph.D. from the University of Oregon Medical School, his M.S. from Pennsylvania State University and his B.A. from Temple University. He is a member of the District of Columbia Bar and admitted to practice before the Federal District and Appeals Court and before the Supreme Court. He has published some 100 scientific articles, abstracts and books during his tenure as a scientist and has been an attorney in the food and drug area for 25 years.

**Dr. Howard Maibach** is a dermatologist whose research area is dermatology, dermatopharmacology and dermatotoxicology. Dr. Maibach has published over 1900 articles on various dermatology-related subjects and is a frequent lecturer on various subjects related to dermatology. Dr. Maibach is currently professor in the Department of Dermatology, School of Medicine, at the University of California in San Francisco.

#### **Board Composition**

Prior to the closing of this offering, our board of directors will be divided into three classes, with each director serving a three-year term and one class being elected at each year's annual meeting of stockholders. A majority of the members of our board of directors are "independent" of us and our management. Directors Savage and Caspritz will be in the class of directors whose initial term expires at

the 2005 annual meeting of stockholders. Directors Spickschen, Ponschab and Jackson will be in the class of directors whose initial term expires at the 2006 annual meeting of the stockholders. Directors Talley and Afting will be in the class of directors whose initial term expires at the 2007 annual meeting of stockholders. This classification of our board of directors will make it more difficult for a third party to acquire control of our company. Director Docherty intends to resign upon consummation of this offering.

A majority of our directors are non-U.S. residents and a substantial portion of the assets of those directors are located outside the United States. As a result, you may not be able to effect service of process within the United States upon these persons or to enforce, in U.S. courts, against these persons judgments of U.S. courts predicated upon any civil liability provisions of the U.S. federal or state securities laws against those directors.

#### Committees of the Board

Our board of directors has established three standing committees: the audit committee, the compensation committee and the corporate governance and nominating committee.

*Audit Committee.* Our audit committee is responsible for preparing such reports, statements or charters as may be required by The Nasdaq Stock Market or federal securities laws, as well as, among other things:

overseeing and monitoring the integrity of our financial statements, our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters and our internal accounting and financial controls;

preparing the report that SEC rules require be included in our annual proxy statement;

overseeing and monitoring our independent auditor's qualifications, independence and performance;

providing the board with the results of its monitoring and recommendations; and

providing to the board additional information and materials as it deems necessary to make the board aware of significant financial matters that require the attention of the board.

Directors Jackson, Savage and Afting are currently members of the audit committee, each of whom is a non-employee member of our board of directors. Mr. Jackson serves as Chairman of the audit committee and also qualifies as an "audit committee financial expert," as that term is defined under the SEC rules implementing Section 407 of the Sarbanes-Oxley Act. Our board has determined that each member of our audit committee meets the current independence and financial literacy requirements under the Sarbanes-Oxley Act, The Nasdaq Stock Market, Inc. and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee. Our compensation committee is composed of Directors Savage, Spickschen and Jackson, each of whom is a non-employee member of our board of directors. Mr. Savage serves as Chairman of our compensation committee. Each member of our compensation committee is an "outside director" as that term is defined in Section 162(m) of the Internal Revenue Code of 1986 and a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Securities Exchange Act of 1934 and the rules of the Nasdaq Stock Market, Inc.. The compensation committee is responsible for, among other things:

reviewing and approving for our chief executive officer and other executive officers (a) the annual base salary, (b) the annual incentive bonus, including the specific goals and amount, (c) equity compensation, (d) employment agreements, severance arrangements and change in control arrangements, and (e) any other benefits, compensations, compensation policies or arrangements;

reviewing and making recommendations to our board regarding the compensation policy for such other officers as directed by the board;

preparing a report to be included in our annual proxy statement that describes: (a) the criteria on which compensation paid to our chief executive officer for the last completed fiscal year is based; (b) the relationship of such compensation to our performance; and (c) the committee's executive compensation policies applicable to executive officers; and

acting as administrator of our current benefit plans and making recommendations to the board with respect to amendments to the plans, changes in the number of shares reserved for issuance thereunder and regarding other benefit plans proposed for adoption.

Corporate Governance and Nominating Committee. Our corporate governance and nominating committee is composed of Directors Savage, Ponschab and Spickschen, each of whom is a non-employee member of our board of directors and independent in accordance with the applicable rules of the Sarbanes-Oxley Act and The Nasdaq Stock Market, Inc. Mr. Savage serves as Chairman of our Corporate Governance and Nominating Committee. The corporate governance and nominating committee is responsible for, among other things:

reviewing board structure, composition and practices, and making recommendations on these matters to the board;

reviewing, soliciting and making recommendations to the board and stockholders with respect to candidates for election to the board;

overseeing compliance by our chief executive officer and senior financial officers with our Code of Ethics for the Chief Executive Officer and Senior Financial Officers; and

overseeing compliance by employees with our Code of Business Conduct and Ethics.

#### **Director Compensation**

We reimburse our non-employee directors for their expenses incurred in connection with attending board and committee meetings and for their services as board or committee members. We have in the past granted non-employee directors options to purchase our common stock pursuant to the terms of our 1995 Stock Option Plan, and our board continues to have the discretion to grant options to new and continuing non-employee directors. In April 2005, our stockholders approved our 2005 Equity Incentive Plan, the terms of which also include the grant of stock options to directors who are not our officers or employees. Contemporaneously with this offering, we intend to grant stock options to these directors. We anticipate that the common stock underlying these options will total 250,000 shares approximately. The exercise price for these options will be the initial public offering price. These options will be subject to vesting.

#### **Executive Compensation**

The following table sets forth the compensation earned for services rendered to us in all capacities by our chief executive officer and our executive officers whose total cash compensation exceeded \$100,000 for the year ended December 31, 2004, collectively referred to in this prospectus as the "named executive officers."

Name and Principal Position	Salary (\$)	Bonus (\$)	Other Annual Compensation (\$)	Restricted Stock Awards (\$)	Securities Underlying Options/SARs (#)(1)	LTIP Payouts (\$)	All Other Compensation (\$)
John V. Talley	285,078		27,974(2)				
President and Chief Executive Officer	,		, (,				
Robert W. Cook(3)	155,769	20,000	9,874	_	_	_	_
Chief Financial Officer,							
Senior Vice President,							
Finance and							
Administration							
Dileep Bhagwat(4)	171,731	-	9,967	-	_	_	-
Senior Vice President,							
Pharmaceutical							
Development							
Dov Elefant	181,431	_	17,693(5)	_	_	_	-
Controller and Vice							
President, Finance and							
Administration							
Earle Lockhart	203,688	_	24,835(6)	_	_	_	-
Vice President, Clinical							
and Regulatory Affairs							
Scott Kozak	181,585	-	17,831(7)	_	_	_	_
Vice President, Business							
Development							
Oliver Wiedemann(8)	185,448	_	4,575 (9)	_	_	_	-
Managing Director -							
Medical Affairs, EpiCept							
GmbH							

- (1) Represents the number of shares of common stock on an as converted basis.
- (2) Includes \$19,161 for premiums for health benefits and for life and disability insurance paid on behalf of Mr. Talley and \$8,813 for an automobile allowance.
- (3) Mr. Cook joined us in April 2004.
- (4) Dr. Bhagwat joined us in February 2004.
- (5) Includes premiums for health benefits and for life and disability insurance paid on behalf of Mr. Elefant.

- (6) Includes premiums for health benefits and for life and disability insurance paid on behalf of Dr. Lockhart.
- (7) Includes premiums for health benefits and for life and disability insurance paid on behalf of Mr. Kozak.
- (8) Mr. Wiedemann's compensation was translated from euros to the U.S. dollar using the exchange rate as of December 31, 2004.
- (9) Includes premiums for health benefits and for life and disability insurance paid on behalf of Mr. Wiedemann.

#### **Option Grants in 2004**

We did not grant any stock options to any of the named executive officers during 2004.

#### **Option Grants in 2005**

We intend to grant stock options under our 2005 Equity Incentive Plan to our employees, including named executive officers, contemporaneously with this offering. We anticipate that the common stock underlying these options will total approximately 366,000 shares. The exercise price for these options will be the initial public offering price. These options will be subject to vesting.

# Aggregate Option Exercises in 2004 and Values at December 31, 2004

The following table sets forth information concerning exercisable and unexercisable stock options held by the named executive officers at December 31, 2004. The value of unexercised in-the-money options is based on an assumed initial offering price of \$12.00 per share (the midpoint of the price range set forth on the cover of this prospectus) less the actual exercise prices. All options were granted under our 1995 Stock Option Plan, as amended. Except as otherwise noted, these options vest over three years and otherwise generally conform to the terms of our 1995 Stock Option Plan, as amended.

			Number o	f Securities					
			Underlying Unexercised Options at December 31, 2004 (#)			Value o	f Unexe	rcised	
	Shares					In-the-Money Options at December 31, 2004 (\$)(2)			
	Acquired	Value							
	on	Realized			_				
Name	Exercise	(\$)(1)	Exercisable	Unexercisable		Exercisable		Unexercisable	
John V. Talley	-	_	168,500	_	\$	1,819,800	\$	_	
Robert Cook	_	-	_	_		_		_	
Dileep Bhagwat	-	_	_	_		_		_	
Earle Lockhart	_	-	56,250	_		580,500		_	
Dov Elefant	-	_	56,250	_		607,500		_	
Scott Kozak	_	-	40,000	5,000		400,000		50,000	
Oliver Wiedemann	-	-	45,000	_		468,000		_	

- (1) Based upon the assumed initial public offering price of \$12.00 per share (the midpoint of the price range set forth on the cover of this prospectus) less the exercise price per share.
- Value is determined by subtracting the exercise price of an option from an assumed \$12.00 per share (the midpoint of the price range set forth on the cover of this prospectus) fair market value of our common stock.

#### **Employment Agreements**

We have entered into employment agreements with Messrs. John V. Talley and Robert W. Cook, each dated as of October 28, 2004. Pursuant to their employment contracts, Messrs. Talley and Cook currently receive base salaries of \$275,000 and \$225,000, respectively. Upon the completion of this initial public offering of our common stock, Mr. Talley's base salary will be \$350,000 and Mr. Cook's base salary will be \$250,000. In additional, upon consummation of this offering we intend to grant stock options totalling approximately 1,000,000 shares to Mr. Talley and approximately 183,000 shares to Mr. Cook. The exercise price for these options will be the initial public offering price. These options will be subject to vesting. Each employment agreement also provides for discretionary bonuses and stock option awards and reimbursement of reasonable expenses incurred in connection with services performed under each officer's respective employment

agreement. The discretionary bonuses and stock options are based on performance standards determined by our board. Individual performance is determined based on quantitative and qualitative objectives, including our operating performance relative to budget and the achievement of certain milestones largely related to the clinical development of our products and our licensing activities. The actual objectives will be established by our board in the future. In addition, Mr. Talley's employment

agreement provides for automobile benefits and term life and long-term disability insurance coverage. Both employment agreements expire on December 31, 2006 but are automatically extended for unlimited additional one-year periods. Upon termination for any reason and in addition to any other payments disbursed in connection with termination, Mr. Talley and Mr. Cook will receive payment of his applicable base salary through the termination date, the balance of any annual, long-term or incentive award earned in any period prior to the termination date and a lump-sum payment for any accrued but unused vacation days.

If Mr. Talley dies or becomes disabled, he is entitled to (i) receive a lump-sum payment equal to (a) one-third of his base salary times (b) a fraction, the numerator being the number of days he was employed in the calendar year of termination and the denominator being the number of days in that year and (ii) have (a) 50% of outstanding stock options that are not then vested or exercisable become vested and exercisable as of the termination date; (b) the remaining outstanding stock options that are not then vested or exercisable become vested and exercisable ratably and quarterly for two years following the termination date; and (c) each outstanding stock option remain exercisable for all securities for the later of (x) the 90th day following the date that the option becomes fully vested and exercisable and (y) the first anniversary of the termination date. If Mr. Cook dies or becomes disabled, he is entitled to the same benefits as Mr. Talley, except the equation for his lump-sum payment is based on one-fourth of his base salary.

If Mr. Talley is terminated without cause or the term of his agreement is not extended pursuant to the employment agreement, he is entitled to the same benefits as if he were terminated due to death or disability and to receive a lump-sum payment equal to (a) one and one-third times (b) his base salary times (c) the number of whole and partial months remaining in the term of the agreement (but no more than 12 and no less than 6) divided by (d) 12. If Mr. Cook is terminated without cause or the term of his agreement is not extended pursuant to the employment agreement, he is entitled to the same benefits as Mr. Talley, but the equation for his lump-sum payment is based on one and one-fourth times his base salary.

If Mr. Talley is terminated after an initial public offering or in anticipation of, or within one year following, a change of control, he is entitled to: (i) receive a lump-sum payment equal to (a) one and one third times (b) his base salary times (c) the number of whole and partial months remaining in the term of the agreement (but not less than 24) divided by (d) 12 and (ii) have (a) 50% of outstanding stock options that are not then vested or exercisable become vested and exercisable as of the termination date; (b) the remaining outstanding stock options that are not then vested or exercisable become vested and exercisable ratably and monthly for the first year following the termination date; and (c) each outstanding stock option remain exercisable for all securities for the later of (x) the 90th day following the date that the option becomes fully vested and exercisable and (y) the first anniversary of the termination date. If Mr. Cook is terminated after an initial public offering or in anticipation of, or within one year following, a change of control, he is entitled to the same benefits as Mr. Talley, except his lump sum is equal to (a) one and one-fourth times (b) his base salary times (c) the number of whole and partial months remaining in the term of the agreement (but no more than 18 and no less than 12) divided by (d) 12.

#### **Stock Plans**

#### 1995 Stock Option Plan

Our 1995 Stock Option Plan, as amended, was approved by our board of directors in November 1995, and subsequently amended in April 1997, March 1999, February 2002 and June 2002. A total of 797,080 shares of our common stock were authorized for issuance under the 1995 Stock Option Plan. As of December 31, 2004, 236,943 shares were available for issuance under the 1995 Stock Option Plan.

The purpose of the 1995 Stock Option Plan is to provide us and our shareholders the benefits arising out of capital stock ownership by our employees, officers, directors, consultants and advisors and any of our subsidiaries, who are expected to contribute to our future growth and success. Our 1995 Stock Option Plan provides for the grant of non-statutory stock options to our (and our majority-owned subsidiaries')

employees, officers, directors, consultants or advisors, and for the grant of incentive stock options meeting the requirements of Section 422 of the Internal Revenue Code to our employees and employees of our majority-controlled subsidiaries.

A committee duly appointed by our board of directors administers the 1995 Stock Option Plan. The committee has the authority to (a) construe the respective option agreements and the terms of the plan; (b) prescribe, amend and rescind rules and regulations relating to the plan; (c) determine the terms and provisions of the respective option agreements, which need not be identical; (d) make all other determinations in the judgment of the committee necessary or desirable for the administration of the plan. From and after the registration of our common stock under the Securities Exchange Act of 1934, the selection of a director or an officer who is a "reporting person" under Section 16(a) of the Exchange Act as a recipient of an option, the timing of the option grant, the exercise price of the option and the number of shares subject to the option shall be determined by (a) the committee of the Board, each of which members shall be an outside director or (b) by a committee consisting of two or more directors having full authority to act in the matter, each of whom shall be an outside director.

The committee shall determine the exercise price of stock options granted under the 1995 Stock Option Plan, but with respect to all incentive stock options, the exercise price must be at least equal to the fair market value of our common stock on the date of the grant or, in the case of grants of incentive stock options to holders of more than 10% of the total combined voting power of all classes of our stock ("10% owners"), at least equal to 110% of the fair market value of our common stock on the date of the grant.

The committee shall determine the term of stock options granted under the 1995 Stock Option Plan, but such date shall not be later than 10 years after the date of the grant, except in the case of incentive stock options granted to 10% owners in which case such date shall not be later than five years after the date of the grant.

Each option granted under the 1995 Stock Option Plan is exercisable in full or in installments at such time or times and during such period as is set forth in the option agreement evidencing such option, but no option granted to a "reporting person" shall be exercisable during the first six months after the grant.

No optionee may be granted an option to purchase more than 350,000 shares in any fiscal year. In addition, no incentive stock option may be exercisable for the first time in any one calendar year for shares of common stock with an aggregate fair market value (as of the date of the grant) of more than \$100,000.

Our 1995 Stock Option Plan generally does not allow for the transfer of options and only the optionee may exercise an option during his or her lifetime.

An optionee may exercise an option at any time within three months following the termination of the optionee's employment or other relationship with us or within one year if such termination was due to the death or disability of the optionee, but except in the case of the optionee's death, in no event later than the expiration date of the option. If the termination of the optionee's employment is for cause, the option expires immediately upon termination.

Our 1995 Stock Option Plan will automatically terminate upon the earlier of November 14, 2005 or the date on which all shares available for issuance under the plan shall have been issued.

# 2005 Equity Incentive Plan

Our board of directors adopted our 2005 Equity Incentive Plan on July 13, 2004, subject to stockholder approval. Our Equity Incentive Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, stock purchase rights, restricted stock, stock appreciation rights, stock units and performance shares and cash awards to our employees, directors and consultants and our parent and subsidiary corporations' employees and consultants.

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will become effective on the day prior to the completion of this offering. No optionee may be granted an option to purchase more than 1,500,000 shares in any fiscal year.

Our board of directors or a committee of our board administers our Equity Incentive Plan. In the case of options intended to qualify as "performance-based compensation" within the meaning of Section 162(m) of the Internal Revenue Code, the committee will consist of two or more "outside directors" within the meaning of Section 162(m) of the Code. The administrator has the power to determine the terms of the awards, including the exercise price, the number of shares subject to each such award, the exercisability of the awards and the form of consideration, if any, payable upon exercise. The administrator also has the authority to institute an exchange program by which outstanding awards may be surrendered in exchange for awards with a lower exercise price.

The administrator will determine the exercise price of options granted under our Equity Incentive Plan, but with respect to nonstatutory stock options intended to qualify as "performance-based compensation" within the meaning of Section 162(m) of the Code and all incentive stock options, the exercise price must at least be equal to the fair market value of our common stock on the date of grant. The term of an incentive stock option may not exceed ten years, except that with respect to any participant who owns 10% of the voting power of all classes of our outstanding stock, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator determines the term of all other options.

Stock appreciation rights may be granted under our Equity Incentive Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. The administrator will determine the terms of stock appreciation rights, including when such rights become exercisable and whether to pay the increased appreciation in cash or with shares of our common stock, or a combination thereof.

Restricted stock may be granted under our Equity Incentive Plan. Restricted stock awards are shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee. The administrator may impose whatever conditions to vesting it determines to be appropriate. For example, the administrator may set restrictions based on the achievement of specific performance goals. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Stock units and performance shares may be granted under our Equity Incentive Plan. Stock units and performance shares are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will establish organizational or individual performance goals in its discretion, which, depending on the extent to which they are met, will determine the number and/or the value of performance units and performance shares to be paid out to participants.

Our Equity Incentive Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime.

Our Equity Incentive Plan will provide that if we experience a Change of Control (as defined), the administrator may provide at anytime prior to the Change of Control that all then outstanding stock options, stock appreciation rights and stock units and unvested cash awards shall immediately vest and become exercisable and any restrictions on restricted stock awards or stock units shall immediately lapse. In addition, the administrator may provide that all awards held by participants who are at the time of the Change of Control in our service or the service of a subsidiary or an affiliate of ours shall remain exercisable for the remainder of their terms notwithstanding any subsequent termination of a participant's service. All awards will be subject to the terms of any agreement effecting the Change of Control, which agreement may provide, without limitation, that in lieu of continuing the awards, each outstanding stock option and stock appreciation right shall terminate within a specified number of days after notice to the holder, and that such holder shall receive, with respect to each share of common stock subject to such stock option or stock appreciation right, an amount equal to the excess of the fair market value of such

shares of common stock immediately prior to the occurrence of such Change of Control over the exercise price (or base price) per share underlying such stock option or stock appreciation right with such amount payable in cash, in one or more kinds of property (including the property, if any, payable in the transaction) or in a combination thereof, as the administrator, in its discretion, shall determine. A provision like the one contained in the preceding sentence shall be inapplicable to a stock option or stock appreciation right granted within 6 months before the occurrence of a Change of Control if the holder of such stock option or stock appreciation right is subject to the reporting requirements of Section 16(a) of the Exchange Act and no exception from liability under Section 16(b) of the Exchange Act is otherwise available to such holder.

Our Equity Incentive Plan will automatically terminate ten years from the effective date, unless we terminate it sooner. In addition, our board of directors has the authority to amend, suspend or terminate the Equity Incentive Plan provided such action does not impair the rights of any participant.

#### 2005 Employee Stock Purchase Plan

Our board of directors adopted our 2005 Employee Stock Purchase Plan on July 13, 2004, subject to stockholder approval. The Employee Stock Purchase Plan will become effective on the day prior to the completion of this offering and a total of 500,000 shares of our common stock will be made available for sale.

Our board of directors or a committee of our board will administer our Employee Stock Purchase Plan. Our board of directors or the committee will have full and exclusive authority to interpret the terms of our Employee Stock Purchase Plan and determine eligibility.

All of our employees are eligible to participate if they are customarily employed by us or any participating subsidiary for at least 20 hours per week and more than five months in any calendar year. However, an employee may not be granted an option to purchase stock if such employee:

immediately after the grant owns stock possessing 5% or more of the total combined voting power or value of all classes of our capital stock, or

whose rights to purchase stock under all of our employee stock purchase plans accrues at a rate that exceeds \$25,000 worth of stock for each calendar year.

Our Employee Stock Purchase Plan is intended to qualify under Section 423 of the Internal Revenue Code and provides for consecutive, overlapping 24-month offering periods. Each offering period includes four six-month purchase periods beginning on January 1 and July 1 of each calendar year, commencing on January 1, 2006 or such other date as may be determined by the committee appointed by us to administer our Employee Stock Purchase Plan.

Our Employee Stock Purchase Plan permits participants to purchase common stock through payroll deductions from their eligible compensation, which includes a participant's base salary, wages, overtime pay, shift premium and recurring commissions, but does not include payments for incentive compensation or bonuses.

Amounts deducted and accumulated by the participant are used to purchase shares of our common stock at the end of each six-month purchase period. The price is 85% of the lower of the fair market value of our common stock at the beginning of an offering period or after a purchase period end. If the fair market value at the end of a purchase period is less than the fair market value at the beginning of the offering period, participants will be withdrawn from the current offering period following their purchase of shares on the purchase date and will be automatically re-enrolled in a new offering period. Participants may end their participation at any time during an offering period, and will be paid their payroll deductions to date. Participation ends automatically upon termination of employment with us.

A participant may not transfer rights granted under the Employee Stock Purchase Plan other than by will, the laws of descent and distribution or as otherwise provided under the Employee Stock Purchase Plan.

Our board of directors has the authority to amend or terminate our Employee Stock Purchase Plan, except that, subject to certain exceptions described in the Employee Stock Purchase Plan, no such action may adversely affect any outstanding rights to purchase stock under our Employee Stock Purchase Plan.

## 401(k) Plan

In 1998, we adopted a Retirement Savings and Investment Plan, the 401(k) Plan, covering our full-time employees located in the United States. The 401(k) Plan is intended to qualify under Section 401(k) of the Internal Revenues Code, so that contributions to the 401(k) Plan by employees or by us, and the investment earnings thereon, are not taxable to the employees until withdrawn. If our 401(k) Plan qualifies under Section 401(k) of the Internal Revenues Code, our contributions will be tax deductible by us when made. Our employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit of \$14,000 if under 50 years old and \$18,000 if over 50 years old in 2005 and to have those funds contributed to the 401(k) Plan. The 401(k) Plan permits us, but does not require us, to make additional matching contributions on behalf of all participants.

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

None of the members of our compensation committee has at any time been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the Board of Directors or compensation committee of any entity that has one or more executive officers serving on our Board of Directors or compensation committee.

#### CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

We have a policy requiring that any material transaction that we enter into with our officers, directors or principal stockholders and their affiliates be on terms no less favorable to us than reasonably could have been obtained in an arms' length transaction with independent third parties. Any other matters involving potential conflicts of interests are to be resolved on a case-by-case basis.

#### Preferred Stock

In April 1997, we sold a total of 2,330,218 shares of our Series A convertible preferred stock at a price of \$2.02 per share to TVM III Limited Partnership ("TVM III") and Alpinvest International B.V. ("Alpinvest"). Dr. Gert Caspritz, a member of our Board of Directors, is a general partner of Techno Venture Management ("TVM"), an affiliate of TVM III. In January 2000, we sold a total of 1,240,333 shares of our Series B redeemable convertible preferred stock at a price of \$1.50 per share to TVM III, Alpinvest and KB Lux Venture Capital Fund ("KB Lux"). In December 2000 and January 2001, we sold a total of 8,939,573 shares of our Series C redeemable convertible preferred stock at a price of \$1.50 per share to TVM IV GmbH & Co. KG ("TVM IV"), Alpinvest, KB Lux, The Merlin Biosciences Fund L.P. ("Merlin L.P.") and The Merlin Biosciences Fund GbR ("Merlin GbR"), Private Equity US Direct Finance (which thereafter transferred its shares to Private Equity Direct Finance) and Gold-Zack. Dr. Gert Caspritz, a member of our Board of Directors, is a general partner of TVM, an affiliate of TVM IV. Mr. Mark Docherty, a member of our Board of Directors, is a director of Merlin Biosciences Limited ("Merlin"), investment advisor to the general partner of Merlin L.P. and the managing partner of Merlin GbR. Each of these investors is a greater than 5% stockholder of EpiCept.

## Amended and Restated Registration Rights Agreement

We have entered into an agreement pursuant to which holders of our convertible preferred stock and certain other individuals have registration rights with respect to their shares of common stock following this offering. For a description of these registration rights, see "Description of Capital Stock." Concurrently with the completion of this offering, all shares of our outstanding preferred stock will be automatically converted into an equal number of shares of common stock.

#### Convertible Bridge Loan Due 2006

In November 2002, we entered into a convertible bridge loan in an aggregate amount of up to \$5,000,000. The lenders under that facility included Mr. John V. Talley, our President and Chief Executive Officer, and certain holders of our preferred stock, including TVM IV, Private Equity US Direct Finance (which thereafter transferred its notes to Private Equity Direct Finance), Merlin L.P., Merlin GbR and Gold-Zack Partners I B.V. The convertible bridge loan bears interest at 8% per annum and matures on October 30, 2006. Each of the lenders received a convertible bridge note which is, under certain circumstances, convertible into our convertible preferred stock, which in turn is convertible into our common stock. We plan to use a portion of the proceeds from this offering to repay this convertible bridge loan in full. See "Use of Proceeds." In connection with the purchase of a convertible note, each investor also received a preferred stock purchase warrant, which we refer to in this prospectus as the "bridge warrants," entitling that investor to purchase a specified amount of our preferred stock or common stock under certain specified circumstances. The bridge warrants expire upon consummation of our initial public offering. Upon a prepayment of the convertible term notes, the bridge warrants are exercisable into 3,861,464 shares of our common stock at an exercise price of \$0.628 per share.

#### Senior Notes due 2006

In March 2005, we completed the private placement of \$4.0 million aggregate principal amount of 8% Senior Notes due 2006. The purchasers of our Senior Notes included Sanders Opportunity Fund, L.P.,

Sanders Opportunity Fund (Institutional), L.P. and certain holders of our preferred stock, including TVM IV, Private Equity Direct Finance, Merlin L.P. and Merlin GbR. The Senior Notes mature on October 30, 2006. We may prepay the Senior Notes, including all accrued and unpaid interest, at any time without premium or penalty. We are required to repurchase the Senior Notes upon the completion of this offering. Each of the purchasers also purchased stock purchase warrants exercisable into an amount of shares of common stock equal to 35% of the principal amount of such purchaser's senior notes divided by the initial public offering price of our common stock or an aggregate of 116,667 shares of our common stock (based on an assumed offering price of \$12.00, the midpoint of the price range set forth on the cover of this prospectus). The exercise price for the warrants will be 75% of the initial public offering price. Assuming an initial public offering price of \$12.00 per share (the midpoint of the price range set forth on the cover of this prospectus), the exercise price would be \$9.00 per share. The warrants are exercisable by the purchaser at any time before the earlier to occur of (a) March 3, 2008 or (b) a merger, consolidation, share exchange sale of our company, certain change of control events, and events of liquidation. If our initial public offering has not been consummated by March 3, 2006, the expiration date of the warrants will be extended until March 3, 2009. We intend to use the proceeds from the sale of the Senior Notes for general working capital.

#### tbg Loans

In August 1997 and February 1998, our German subsidiary entered into two 10-year non-amortizing loans with tbg, one of our greater than 5% stockholders. For a description of these loans, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

#### **Employment Agreements**

As described under "Executive Compensation – Employment Agreements," we have employment agreements with Mr. John V. Talley, our President and Chief Executive Officer, and Mr. Robert Cook, our Chief Financial Officer.

#### PRINCIPAL STOCKHOLDERS

The following table sets forth information known to us with respect to the beneficial ownership of our common stock as of March 31, 2005 as adjusted to reflect the sale of common stock offered hereby by:

each stockholder known by us to own beneficially more than five percent of our common stock;

each of the named executive officers;

each of our directors; and

all of our directors and the named executive officers as a group.

Except as indicated by footnote, and subject to community property laws where applicable, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them. Unless otherwise indicated, the principal address of each of the stockholders below is in care of EpiCept Corporation, 270 Sylvan Avenue, Englewood Cliffs, New Jersey 07632.

		Percent of Shares Beneficially Owned(1)(2)		
	<b>Number of Shares</b>			
	<b>Beneficially Owned</b>			
	Prior to the	Before	After	
Name and Address of Beneficial Owner	Offering	Offering	Offering	
5% Stockholders				
TVM Techno Venture Management(3)	3,852,522	32.2%	22.0%	
Merlin General Partner II Limited(4)	1,808,660	15.2	10.4	
Private Equity Direct Finance(5)	1,622,756	13.3	9.2	
GZ Paul Partners B.V.(6)	835,500	7.0	4.8	
IKB Private Equity GmbH(7)	712,730	6.0	4.1	
Dr. Rainer Liedtke(8)	1,073,547	9.1	6.2	
Technologie-Beteiligungs Gesellschaft mbH(9)	597,562	5.0	3.4	
<b>Executive Officers and Directors</b>				
John V. Talley(10)	248,367	2.1	1.4	
Robert W. Cook	_	_	_	
Dov Elefant(11)	56,250	*	*	
Dr. Earle Lockhart(11)	56,250	*	*	
Scott B. Kozak(12)	45,000	*	*	
Dr. Oliver Wiedemann(12)	45,000	*	*	
Dr. Dileep Bhagwat	_	_	_	
Robert G. Savage	_	_	_	
Prof. Ernst-Günter Afting(13)	22,185	*	*	
Dr. Gert Caspritz(3)	3,852,522	32.2	22.0	
Mark Docherty(4)	1,808,660	15.2	10.4	
Guy Jackson	_	_	_	
Dr. Reiner Ponschab(14)	17,625	*	*	
Dr. Thorlef Spickschen	37,625	*	*	

All directors and named executive officers as a group			
(14 persons)(15)	6,189,484	50.0	34.6

- \* Represents beneficial ownership of less than one percent (1%) of the outstanding shares of our common stock.
- (1) Beneficial ownership is determined with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Shares of common stock

(3)

**(4)** 

subject to stock options and warrants currently exercisable or exercisable within 60 days are deemed to be outstanding for computing the percentage ownership of the person holding such options and the percentage ownership of any group of which the holder is a member, but are not deemed outstanding for computing the percentage of any other person. Except as indicated by footnote, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown beneficially owned by them.

Percentage ownership is based on 11,851,451 shares of common stock outstanding on March 31, 2005, after giving effect to the conversion of all of our preferred stock into shares of our common stock, the exercise of the bridge warrants and the conversion of the tbg convertible loan.

Includes 102,520 shares of common stock held by TVM III, 1,018,329 shares issuable upon the conversion of 2,666,667 shares of

Series C redeemable convertible preferred stock and 1,592,356 shares issuable upon the exercise of the bridge warrants held by TVM IV. Includes 1,000,377 shares issuable upon the conversion of 1,538,389 shares of Series A convertible preferred stock, 333,333 shares of Series B redeemable convertible preferred stock and 490,731 shares of Series C redeemable convertible preferred stock held by TVM III. Also includes 120,816 shares of common stock issuable upon the exercise of warrants that are exercisable within 60 days held by TVM III and TVM IV, respectively. For a description of these warrants, see "Description of Capital Stock – Warrants." Includes 6,042 shares of common stock held by Dr. Gert Caspritz, one of our directors, who is a general partner of TVM, which is the general partner of each of TVM III and TVM IV, and an aggregate of 12,082 shares of common stock held by Friedrich Bornikoel, Christian Claussen, John J. Di Bello, Alexandra Goll, Helmut Schühsler and Bernd Seibel who are individual Partners of Techno Venture Management (such entities collectively with TVM III and TVM IV, "TVM"). TVM Techno Venture Management No. III, L.P. ("TVM III Management") is the General Partner and the investment committee of TVM III. TVM IV Management GmbH & Co. KG ("TVM IV Management") is the Managing Limited Partner and investment committee of TVM IV. The investment committees, composed of certain Managing Limited Partners of TVM, have voting and dispositive authority over the shares held by each of these entities and therefore beneficially owns such shares. Decisions of the investment committees are made by a majority vote of their members and, as a result, no single member of the investment committees has voting or dispositive authority over the shares.

Friedrich Bornikoel, John J. Di Bello, Alexandra Goll, Christian Claussen, Bernd Seibel and Helmut Schühsler are the members of the investment committee of TVM III Management. They, along with Gert Caspritz, John Chapman and Hans G. Schreck are the members of the investment committee of TVM IV Management. Friedrich Bornikoel, John J. DiBello, Alexandra Goll, Christian Claussen, Bernd Seibel and Helmut Schühsler each disclaim beneficial ownership of the shares held by TVM III and TVM IV except to the extent any individual has a pecuniary interest therein. Gert Caspritz, John Chapman and Hans G. Schreck each disclaim beneficial ownership of the shares held by TVM IV except to the extent any individual has a pecuniary interest therein. The address of TVM III Management and TVM IV Management is 101 Arch Street, Suite 1950, Boston, MA 02110.

Includes 8,781 shares of common stock, 509,164 shares issuable upon the conversion of 1,333,333 shares of Series C redeemable convertible preferred stock and 1,194,267 shares issuable upon the exercise of the bridge warrants beneficially owned by Merlin L.P. and Merlin GbR and held by Merlin. Also includes 29,167 shares of common stock issuable upon the exercise of warrants that are exercisable within 60 days beneficially owned by Merlin L.P. and Merlin GbR and held by Merlin. Includes 1,875 shares of common stock issuable upon the exercise of stock options that are exercisable within 60 days held by Mr. Mark Docherty, one of our directors, who is a director of Merlin, which is investment advisor to the general partner of each of Merlin L.P. and Merlin GbR. Includes 16,802 shares issuable upon the conversion of 44,000 shares of Series B redeemable convertible preferred stock and 48,604 shares of common stock held by Dr. Hellmut Kirchner, who is a director of Merlin. The Merlin Biosciences Fund is comprised of two entities: Merlin L.P. and Merlin GbR. Both are controlled by the board of directors of Merlin General

(6)

Partner II Limited, a Jersey-based limited liability company, which is owned by Merlin. Merlin has agreed not to exercise its voting rights to change or replace the board of directors of Merlin General Partner II Limited. The board of directors of Merlin General Partner II Limited, effectively controls Merlin L.P. and Merlin GbR because it is General Partner of Merlin L.P. and Managing Partner of Merlin GbR. Investment decisions are made with a majority of the board of directors of Merlin General Partner II Limited, no single person has control. The directors of Merlin General Partner II Limited are as follows: Dr Max Link (Chairman), William Edge, Sir Christopher Evans OBE, Robin Herbert CBE, Professor Trevor Jones, Dr. Hellmut Kirchner, Mark Clement, Denzil Boschat, Alison Creed and Jeff Iliffe. Some of the directors hold small limited partnership interests in the Fund but none of these are individually or collectively able to influence the Fund. The registered office is at La Motte Chambers, St Helier, Jersey JE1 1BJ, UK. Mr. Docherty and Dr. Kirchner each disclaim beneficial ownership of the shares held by Merlin, Merlin L.P. and Merlin GbR except to the extent any such individual has a pecuniary interest therein. The address of Mr. Docherty, Merlin, Merlin L.P. and Merlin GbR is c/o Merlin Biosciences Limited, 33 King Street, St. James' s, London, SW1Y 6RJ, United Kingdom.

Includes 511,006 shares of common stock issuable upon conversion of 1,338,155 shares of our Series C redeemable convertible preferred stock, 796,178 shares issuable upon the exercise of the bridge warrants and 315,572 shares of common stock issuable upon the exercise of warrants that are exercisable within 60 days. For a description of these warrants, see "Description of Capital Stock – Warrants." Private Equity Direct Finance is a Cayman Islands exempted limited company and a wholly-owned subsidiary of Private Equity Holding Cayman, itself a Cayman Islands exempted limited company, and a wholly-owned subsidiary of Private Equity Holding Ltd. Private Equity Holding Ltd. is a Swiss corporation with registered office at Innere Güterstrasse 4, 6300 Zug,

- (5) Switzerland, and listed on the SWX Swiss Exchange. The discretion for divestments by Private Equity Direct Finance rests with ALPHA Associates (Cayman), L.P., as investment manager. The members of the board of directors of the general partner of ALPHA Associates (Cayman), L.P. are the same persons as the members of the board of directors of Private Equity Direct Finance: Rick Gorter, Gwendolyn McLaughlin and Andrew Tyson. A meeting of the directors at which a quorum is present is competent to exercise all or any of the powers and discretions. The quorum necessary for the transaction of business at a meeting of the directors may be fixed by the directors and, unless so fixed at any other number, is two. The address of Private Equity Direct Finance is One Capital Place, P.O. Box 847, George Town, Grand Cayman, Cayman Islands.
  - Includes 636,456 shares of common stock issuable upon conversion of 1,666,667 shares of our Series C redeemable convertible preferred stock and 199,044 shares issuable upon the exercise of the bridge warrants. Mr. Helmut A. Krueger and Mr. Florus Mouthaan are managing directors of GZ Paul Partners B.V., whereby each managing director is individually authorized to represent GZ Paul Partners B.V. Through its managing directors, GZ Paul Partners B.V. has voting and dispositive authority over the shares held by GZ Paul Partners B.V. Messrs. Krueger and Mouthaan each disclaim beneficial ownership of the shares held by GZ Paul Partners B.V. The address of GZ Paul Partners B.V. is c/o GZ Paul Management Services GmbH, Lindenstrasse 43, D-60325 Frankfurt, Germany.
  - Includes 712,730 shares issuable upon the conversion of 1,866,403 shares of Series B redeemable convertible preferred stock. Voting rights can be executed by any designated authority to whom a power of attorney has been granted by IKB. Two signatures are required for a power of attorney. These can originate from any of the following persons: Roland Eschmann (Managing Director), Rolf Brobeck (Managing Director), Thomas Stratmann (Risk Manager), Dr. Kerstin Waterloh (Team Leader LifeSciences), Dr. Marcus
- (7) Huhmann (internal legal counsel) and Helmut Taubert (internal legal counsel). Disposition decisions are made by the Anlageausschu*B*, or investment committee, based on a proposal by the Project Manager and Team Leader LifeSciences, in this case Dr. Kerstin Waterloh and the Exit Manager, Olaf Wilms, and approved by Managing Directors Roland Eschmann and Rolf Brobeck. The investment committee is represented by Dr. Markus Guthoff (CEO of IKB Bank and responsible for the 100% affiliate IKB Private

Equity). The External Disposition Order is signed by two of the following three persons: Roland Eschmann, Rolf Brobeck, Thomas Stratmann. The address of IKB is Wilhelm-Bötzkes-Strasse 1, 40002 Düsseldorf, Germany.

Includes 692,652 shares of common stock held by Dr. Liedtke, 271,517 shares of common stock held by Ms. Hanne Liedtke, his spouse, and 25,000 shares of common stock held by Dr. Liedtke's children. Also includes 69,104 shares of common stock issuable upon conversion of our Series A convertible preferred stock and 15,274 shares of common stock issuable upon conversion of our

- (8) Series C redeemable convertible preferred stock, each held by pharmed Holding GmbH, which is an entity controlled by Dr. Liedtke. Dr. Liedtke disclaims beneficial ownership of the shares held by his wife, his children and pharmed Holding GmbH except to the extent of his pecuniary interest therein. The address of Dr. Liedtke, his wife, his children and pharmed Holding GmbH is c/o pharmed Holding GmbH, P.O. Box 1306, 82027 Grünwald/ München, Germany.
- Includes 369,902 shares of common stock issuable upon conversion of 829,901 shares of Series A convertible stock. Pursuant to the terms of the convertible loan described under "Certain Relationships and Related Party Transactions," tbg will receive an additional 227,660 shares of common stock. The address of tbg is c/o Technologie-Beteiligungs-Gesellschaft mbH, Ludwig-Erhard-Platz 1, 5319 Bonn, Germany.
- (10) Includes 250 shares of common stock, 79,617 shares issuable upon exercise of the bridge warrants and 168,500 shares exercisable upon the exercise of options that are exercisable within 60 days.
- (11) Includes 56,250 shares exercisable upon the exercise of options that are exercisable within 60 days.
- (12) Includes 45,000 shares exercisable upon the exercise of options that are exercisable within 60 days.
- Includes 6,250 shares of common stock, 10,310 shares of common stock issuable upon the conversion of 27,000 shares of Series B convertible stock and 5,625 shares of common stock issuable upon the exercise of options that are exercisable within 60 days.
- Includes 16,875 shares of common stock held by Dr. Ponschab and 750 shares of common stock held by Dr. Ponschab's wife.

  (14) Dr. Ponschab disclaims beneficial ownership of the shares of stock held by his wife except to the extent of his pecuniary interest therein.
- (15) Includes an aggregate of 378,500 shares issuable upon exercise of options and 149,983 shares issuable upon the exercise of warrants.

#### DESCRIPTION OF CAPITAL STOCK

#### General

After the completion of this offering, our restated certificate of incorporation will authorize 50,000,000 shares of common stock, \$0.0001 par value, and 5,000,000 shares of undesignated preferred stock, \$0.0001 par value. The foregoing and the following description of capital stock give effect to the restated certificate of incorporation and is subject to and qualified by our restated certificate of incorporation and bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part, and by the provisions of the applicable Delaware law.

#### Common Stock

Assuming the conversion of all of our preferred stock, the exercise of the bridge warrants and the conversion of the tbg convertible term loan into 10,152,455 shares of common stock at the closing of this offering, as of March 31, 2005 we would have had 11,851,451 shares of common stock outstanding that were held of record by approximately 70 stockholders.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders. Subject to preferences that may be applicable to any outstanding preferred stock, the holders of common stock are entitled to receive ratably any dividends that may be declared from time to time by the board of directors out of funds legally available for that purpose. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock then outstanding. The common stock has no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and nonassessable, and the shares of common stock to be issued upon the closing of this offering will be fully paid and nonassessable.

#### **Preferred Stock**

Upon the closing of this offering, our board of directors will have the authority, without action by our stockholders, to designate and issue up to 5,000,000 shares of preferred stock in one or more series. The board of directors may also designate the rights, preferences and privileges of each series of preferred stock; any or all of which may be greater than the rights of the common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock upon the rights of holders of the common stock until the board of directors determines the specific rights of the holders of the preferred stock. However, these effects might include:

restricting dividends on the common stock;

diluting the voting power of the common stock;

impairing the liquidation rights of the common stock; and

delaying or preventing a change in control of our company without further action by the stockholders.

We have no present plans to issue any shares of preferred stock.

#### Warrants

As of March 31, 2005, the following warrants were outstanding:

In August 2000, in connection with the issuance of convertible term notes, we issued two warrants to purchase an aggregate of 333,333 shares of our Series B redeemable convertible preferred stock at an exercise price of \$1.50 per share to Alpinvest International B.V. and TVM Techno Ventures Enterprises No. III Limited Partnership (now known as TVM III Limited Partnership). The

expiration date of these warrants is August 15, 2010. Upon automatic conversion of our Series B redeemable convertible preferred stock in connection with our initial public offering, these warrants will represent the right to purchase 127,291 shares of common stock at an exercise price of \$3.93. The exercise price and the number of shares of common stock issuable upon exercise of the warrant are subject to adjustment upon the occurrence of certain anti-dilution events.

In November 2000, in connection with the issuance of a convertible term note, we issued a warrants to purchase an aggregate of 750,000 shares of our Series C redeemable convertible preferred stock at an exercise price of \$1.50 per share to Private Equity US Direct Finance (which thereafter transferred its warrants to Private Equity Direct Finance). The expiration date of these warrants is November 30, 2010. Upon automatic conversion of our Series C redeemable convertible preferred stock in connection with our initial public offering, these warrants will represent the right to purchase 286,405 shares of common stock at an exercise price of \$3.93. The exercise price and the number of shares of common stock issuable upon exercise of the warrants are subject to adjustment upon the occurrence of certain anti-dilution events.

In November 2002, in connection with the bridge financing, we issued stock purchase warrants to the lenders thereunder entitling them to purchase a number of shares of common stock equal to 50% of the greatest principal amount outstanding under the convertible bridge loan, divided by the applicable exercise price as defined in the warrant. The warrants are exercisable into preferred stock or common stock at any time through November 2012 and possess certain anti-dilutive rights. Upon consummation of our initial public offering, the warrants will be exercisable into 3,861,464 shares of common stock at an exercise price of \$0.628 per share.

In March 2005, in connection with the issuance of the senior notes due 2006, each of the purchasers also purchased stock purchase warrants exercisable into an amount of shares of common stock equal to 35% of the principal amount of such purchaser's senior notes divided by the initial public offering price of our common stock or an aggregate of 116,667 shares of our common stock (based on an assumed offering price of \$12.00, the midpoint of the price range set forth on the cover of this prospectus). The exercise price for the warrants will be 75% of the initial public offering price. Assuming an initial public offering price of \$12.00 per share (the midpoint of the price range set forth on the cover of this prospectus), the exercise price would be \$9.00 per share. The warrants are exercisable by the purchaser at any time before the earlier to occur of (a) March 3, 2008 or (b) a merger, consolidation, share exchange sale of our company, certain change of control events, and events of liquidation. If our initial public offering has not been consummated by March 3, 2006, the expiration date of the warrants will be extended until March 3, 2009.

## **Registration Rights**

Upon completion of this offering, under our amended and restated registration rights agreement, the holders of 7,371,457 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended. These rights include demand, piggyback and Form S-3 registration rights.

**Demand Registration Rights.** Demand registration rights are rights that entitle holders to require us to register some or all of their shares of our common stock under the Securities Act at such holder's election. Generally, the following groups of holders may require us to register their shares pursuant to these demand registration rights, subject to applicable minimum thresholds to be included in the requested registration:

holders of at least 25% of the then outstanding common stock issued upon conversion of our Series C Preferred Stock;

holders of at least 25% of the then outstanding common stock issued upon conversion of our Series B Preferred Stock;

holders of at least 50% of the then outstanding common stock issued upon conversion of our Series A Preferred Stock; and

holders of at least 50% of the then outstanding common stock issuable upon exercise of the warrants issued in connection with the senior notes due 2006.

Collectively, there are a total of 6,407,288 shares of common stock that are subject to these demand registration rights. We are not obligated to effect more than two registrations on behalf of any of the aforementioned groups pursuant to their demand registration rights. We have the right, under various circumstances, to delay the registration of the requesting holders' shares for a limited time period. We generally must pay all expenses, except for underwriters' discounts and commissions, incurred in connection with the exercise of these demand registration rights.

*Piggyback Registration Rights.* Piggyback registration rights are rights that entitle holders to require us to register some or all of their shares of our common stock under the Securities Act if we register any securities for public sale, subject to specified exceptions. The underwriters of any underwritten offering may have the right to limit the number of shares registered by these holders due to marketing conditions. There are a total of 7,371,457 shares of common stock that are subject to these piggyback registration rights. We generally must pay all expenses, except for underwriters' discounts and commissions, incurred in connection with the exercise of these piggyback registration rights. All of the holders of registration rights in connection with this offering have waived their piggyback rights with respect to this offering.

Form S-3 Registration Rights. If we are eligible to file a registration statement on Form S-3, holders of at least 25% of the shares of our common stock issued upon conversion of our series A convertible preferred stock, series B convertible preferred stock, series C convertible preferred stock, or upon exercise of the warrants issued in connection with our senior notes due 2006, as applicable, can request that we register their shares under the Securities Act on Form S-3, provided that the total proceeds of the shares of common stock offered to the public is at least \$250,000. We generally must pay all expenses, except for underwriters' discounts and commissions, incurred in connection with the exercise of these Form S-3 registration rights.

#### **Anti-Takeover Provisions**

Provisions of Delaware law and our amended and restated certificate of incorporation and amended bylaws to be in effect upon the closing of this offering could make the acquisition of our company through a tender offer, a proxy contest or other means more difficult and could make the removal of incumbent officers and directors more difficult. We expect these provisions to discourage coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of our company to first negotiate with our board of directors. We believe that the benefits provided by our ability to negotiate with the proponent of an unfriendly or unsolicited proposal outweigh the disadvantages of discouraging these proposals. We believe the negotiation of an unfriendly or unsolicited proposal could result in an improvement of its terms.

Effects of Some Provisions of Delaware Law. Upon the closing of this offering, we will be subject to Section 203 of the Delaware General Corporation Law, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date the person became an interested stockholder, unless:

prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

the stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers, and (b) shares owned by employee stock plans in which employee participants do not have the right to determine

confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a "business combination" for these purposes includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" for these purposes is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting securities. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Anti-Takeover Effects of Provisions of Our Charter Documents. Our amended and restated certificate of incorporation to be in effect upon the closing of this offering provides for our board of directors to be divided into three classes serving staggered terms. Approximately one-third of the board of directors will be elected each year. The provision for a classified board could prevent a party who acquires control of a majority of the outstanding voting stock from obtaining control of the board of directors until the second annual stockholders meeting following the date the acquiring party obtains the controlling stock interest. The classified board provision could discourage a potential acquiror from making a tender offer or otherwise attempting to obtain control of our company and could increase the likelihood that incumbent directors will retain their positions. Our amended and restated certificate of incorporation to be in effect upon the closing of this offering also provides that directors may be removed with cause by the affirmative vote of the holders of the outstanding shares of common stock.

Our amended and restated bylaws to be in effect upon the closing of this offering establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. At an annual meeting, stockholders may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors. Stockholders may also consider a proposal or nomination by a person who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given to our Secretary timely written notice, in proper form, of his or her intention to bring that business before the meeting. The amended bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting of the stockholders. However, our bylaws may have the effect of precluding the conduct of business at a meeting if the proper procedures are not followed. These provisions may also discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company.

Under Delaware law, a special meeting of stockholders may be called by the board of directors or by any other person authorized to do so in the amended and restated certificate of incorporation or the amended and restated bylaws. Our amended and restated bylaws authorize a majority of our board of directors, the chairman of the board or the chief executive officer to call a special meeting of stockholders. Because our stockholders do not have the right to call a special meeting, a stockholder could not force stockholder consideration of a proposal over the opposition of the board of directors by calling a special meeting of stockholders prior to such time as a majority of the board of directors believed or the chief executive officer believed the matter should be considered or until the next annual meeting provided that the requestor met the notice requirements. The restriction on the ability of stockholders to call a special meeting means that a proposal to replace the board also could be delayed until the next annual meeting.

Delaware law provides that stockholders may execute an action by written consent in lieu of a stockholder meeting. However, Delaware law also allows us to eliminate stockholder actions by written consent. Elimination of written consents of stockholders may lengthen the amount of time required to take stockholder actions since actions by written consent are not subject to the minimum notice requirement of a stockholder's meeting. However, we believe that the elimination of stockholders' written consents may deter hostile takeover attempts. Without the availability of stockholders' actions by written consent, a holder controlling a majority of our capital stock would not be able to amend our bylaws or remove directors without holding a stockholders meeting. The holder would have to obtain the consent of a majority of the board of directors, the chairman of the board or the chief executive officer to call a stockholders meeting and satisfy the notice periods determined by the board of directors. Our amended and restated certificate of incorporation to be in effect upon the closing of this offering provides for the elimination of actions by written consent of stockholders upon the closing of this offering.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Wachovia Bank, N.A., located at 1525 W. WT Harris Blvd., 3C3, Charlotte, North Carolina 28288-1153.

#### Nasdaq Stock Market Listing

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

#### SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our stock. Future sales of substantial amounts of our common stock in the public market following this offering or the possibility of these sales occurring could adversely affect prevailing market prices for our common stock or could impair our ability to raise capital through an offering of equity securities.

Upon the closing of this offering, 17,339,576 shares of our common stock will be outstanding, based on the number of shares outstanding on December 31, 2004. All of the shares sold in this offering will be freely tradable without restriction under the Securities Act except for any shares purchased by our affiliates as that term is defined in Rule 144 under the Securities Act. The remaining 11,839,576 shares of common stock held by existing stockholders as of December 31, 2004 are restricted shares as that term is defined in Rule 144 under the Securities Act or if they qualify for an exemption from registration, such as the exemptions provided under Rule 144 or 701 under the Securities Act, which are summarized below.

### **Rule 144**

*Sales by Affiliates.* After the expiration of the lock-up agreements, described below under "Lock-up Agreements," the holders of 6,250,385 shares of our common stock will be eligible to sell their shares under Rule 144. All shares of our common stock held by our affiliates, other than shares eligible for resale under Rule 701, have Rule 144 holding periods that exceed one year. As a result, under Rule 144, our affiliates will be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

One percent of the number of shares of common stock then outstanding, which will equal approximately 173,395 shares immediately after the offering; or

The average weekly trading volume of our common stock during the four calendar weeks preceding the date on which notice of the sale is filed.

Sales under Rule 144 are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Sales by Non-affiliates. Subject to the lock-up agreements described below, Rule 144(k) is available immediately upon effectiveness of the offering for any person, other than a person deemed to have been an affiliate of our company at any time during the three months preceding a sale, who is selling shares that have a Rule 144 holding period that exceeds two years. As of December 31, 2004, all of the outstanding shares held by non-affiliates have a Rule 144 holding period that exceeds two years, other than shares that are eligible for resale under Rule 701. As a result, our non-affiliates may sell these shares under Rule 144(k) without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144.

#### **Rule 701**

Subject to the lock-up agreements described below, all sales of our common stock effected under Rule 701 may be made beginning 90 days after the effectiveness of this offering. Rule 701 applies to shares of our common stock outstanding before the effectiveness of this offering that were acquired pursuant to our stock plans. These shares may be resold without compliance with Rule 144's one-year holding period:

By persons other than affiliates, subject only to the manner-of-sale provisions of Rule 144; and

By affiliates, subject to the manner-of-sale, current public information and filing requirements of Rule 144.

### Form S-8 Registration Statements

Shortly after the effectiveness of the offering, we intend to file a registration statement on Form S-8 under the Securities Act to register an aggregate of 4,736,943 shares of common stock reserved for issuance under our 1995 Stock Option Plan, 2005 Equity Incentive Plan and our 2005 Employee Stock Purchase Plan. Shares of common stock issued upon exercise of options under the Form S-8 will be available for sale in the public market, subject to Rule 144 volume limitations applicable to affiliates and subject to the lock-up agreements described below.

## **Lock-up Agreements**

Our directors, executive officers and certain of our stockholders, who will, after the offering, collectively hold an aggregate of 12,837,238 shares have agreed to enter into lock-up agreements with us or the underwriters in connection with this offering. These lock-up agreements will provide that, with limited exceptions, these persons and entities will not offer, sell, contract to sell, grant any option to purchase or otherwise dispose of any of our shares for a period of 180 days after the effective date of this offering. Wachovia Capital Markets, LLC may, in its sole discretion and at any time without prior notice, release all or any portion of the shares subject to these lock-up agreements. We have also entered into an agreement with Wachovia Capital Markets, LLC that, with certain exceptions, we will not offer, sell or otherwise dispose of our common stock until 180 days after the date of this prospectus.

### MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

#### General

The following is a general discussion of the material U.S. federal income and estate tax consequences of the ownership and disposition of common stock that may be relevant to you if you are a non-U.S. Holder. For purposes of this discussion, a "non-U.S. Holder" is any person or entity that is, for U.S. federal income tax purposes, a foreign corporation, a nonresident alien individual, a foreign estate or a foreign trust. This discussion is based on current law, which is subject to change, possibly with retroactive effect, or different interpretations. This discussion is limited to non-U.S. Holders who hold shares of common stock as capital assets. Moreover, this discussion is for general information only and does not address all the tax consequences that may be relevant to you in light of your personal circumstances. In particular, this discussion does not address the U.S. federal income tax consequences to certain holders that are subject to special treatment (such as holders who are broker dealers, insurance companies, tax-exempt organizations, banks, financial institutions, or "financial services entities"); holders of our common stock held as part of a "straddle," "hedge," "constructive sale" or "conversion transaction" with other investments; holders who received our common stock as compensation; holders who have elected mark-to-market accounting; and certain expatriates or former long-term residents of the United States. Additionally, the discussion does not consider the tax treatment of holders who are partnerships or pass-through entities for U.S. federal income tax purposes, or persons who hold our common stock through a partnership or other pass-through entity. If a partnership holds shares of the common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner and the activities of the partnership. In addition, this discussion does not consider any aspect of state, local or non-U.S. tax laws.

If you are an individual, you may, in many cases, be deemed to be a resident alien, as opposed to a nonresident alien, by virtue of being present in the United States for at least 31 days in the calendar year and for an aggregate of at least 183 days during a three-year period ending in the current calendar year. For these purposes all the days present in the current year, one-third of the days present in the immediately preceding year, and one-sixth of the days present in the second preceding year are counted. Resident aliens are subject to U.S. federal income tax as if they were U.S. citizens. Because U.S. federal tax law uses different tests to determine whether an individual is a non-resident alien for income tax purposes, some individuals may be "non-U.S. Holders" for purposes of the U.S. federal income tax discussion, but not for the purpose of the U.S. federal estate tax discussion and vice versa.

EACH PROSPECTIVE PURCHASER OF COMMON STOCK IS ADVISED TO CONSULT A TAX ADVISOR WITH RESPECT TO CURRENT AND POSSIBLE FUTURE TAX CONSEQUENCES OF PURCHASING, OWNING AND DISPOSING OF OUR COMMON STOCK AS WELL AS ANY TAX CONSEQUENCES THAT MAY ARISE UNDER THE LAWS OF ANY U.S. STATE, MUNICIPALITY OR OTHER TAXING JURISDICTION.

### **Dividends**

In the event that distributions are paid by us, such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). If the amount of a distribution exceeds our current and accumulated earnings and profits, such excess first will be treated as a tax-free return of capital to the extent of your tax basis in the common stock, and thereafter will be treated as capital gain, as discussed below under "Dispositions of Common Stock." If dividends for U.S. federal income tax purposes are paid, as a non-U.S. Holder, you will be subject to U.S. federal withholding tax at a 30% rate or a lower rate as may be specified by an applicable income tax treaty. To claim the benefit of a lower rate under an income tax treaty, you must properly file with the payor an Internal Revenue Service Form W-8BEN, or successor form, claiming an exemption from or reduction in withholding under the applicable tax treaty. If dividends are considered effectively connected with the conduct of a trade or business by you within the United States and, where a tax treaty applies, are attributable to a

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U.S. permanent establishment those dividends will be subject to U.S. federal income tax on a net basis at regular U.S. federal income tax rates in the same manner as a U.S. person but will not be subject to U.S. federal withholding tax, provided an Internal Revenue Service Form W-8ECI, or successor form, is filed with the payor. If you are a foreign corporation, any effectively connected dividends may, under certain circumstances, be subject to an additional "branch profits tax" at a rate of 30% or a lower rate as may be specified by an applicable income tax treaty.

You must comply with the certification procedures described above, or, in the case of payments made outside the United States with respect to an offshore account, certain documentary evidence procedures, directly or under certain circumstances through an intermediary, to obtain the benefits of a reduced rate under an income tax treaty with respect to dividends paid with respect to your common stock. In addition, if you are required to provide an Internal Revenue Service Form W-8ECI or successor form, as discussed above, you must also provide your tax identification number.

If you are eligible for a reduced rate of U.S. federal withholding tax pursuant to an income tax treaty, you may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for refund with the Internal Revenue Service.

### **Dispositions of Common Stock**

As a non-U.S. Holder, you generally will not be subject to U.S. federal income or withholding tax on any gain recognized on the sale or other disposition of common stock unless:

the gain is considered effectively connected with the conduct of a trade or business by you within the United States and, where a tax treaty applies, is attributable to a U.S. permanent establishment (and, in which case, if you are a foreign corporation, you may be subject to an additional branch profits tax equal to 30% or a lower rate as may be specified by an applicable income tax treaty);

you are an individual who holds the common stock as a capital asset and are present in the United States for 183 or more days in the taxable year of the sale or other disposition and other conditions are met; or

we are or become a U.S. Real Property Holding Corporation (USRPHC). In general, a corporation is a USRPHC if the fair market value of its "U.S. real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests and its other assets used or held for use in a trade or business. We believe that we are not currently, and are not likely not to become, a USRPHC. If we were to become a USRPHC, then gain on the sale or other disposition of common stock by you generally would not be subject to U.S. federal income tax provided:

the common stock was "regularly traded on an established securities market"; and

you do not actually or constructively own more than 5% of the common stock during the shorter of (i) the five-year period preceding the disposition or (ii) your holding period.

No assurance can be given that we will not be a USRPHC, or that our common stock will be considered regularly traded, when you sell your shares of common stock.

# **Federal Estate Tax**

If you are an individual, common stock held at the time of your death will be included in your gross estate for U.S. federal estate tax purposes, and may be subject to U.S. federal estate tax, unless an applicable estate tax treaty provides otherwise.

Information Reporting and Backup Withholding Tax

We must report annually to the Internal Revenue Service and to each of you the amount of dividends paid to you and the tax withheld with respect to those dividends, regardless of whether withholding was					
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required. Copies of the information returns reporting those dividends and withholding amounts may also be made available to the tax authorities in the country in which you reside under the provisions of an applicable income tax treaty or other applicable agreements.

Backup withholding is generally imposed at a current rate of 28% on certain payments to persons that fail to furnish the necessary identifying information to the payor. You generally will be subject to backup withholding tax (currently 28%) with respect to dividends paid on your common stock unless you certify your non-U.S. status on Internal Revenue Service Form W-8BEN (or successor form) or otherwise establish an exemption.

The payment of proceeds of a sale of common stock effected by or through a U.S. office of a broker is subject to both backup withholding and information reporting unless you provide the payor with your name and address and you certify your non-U.S. status or you otherwise establish an exemption. In general, backup withholding and information reporting will not apply to the payment of the proceeds of a sale of common stock by or through a foreign office of a broker. If, however, such broker is, for U.S. federal income tax purposes, a U.S. person, a controlled foreign corporation, a foreign person that derives 50% or more of its gross income for certain periods from the conduct of a trade or business in the United States or a foreign partnership that at any time during its tax year either is engaged in the conduct of a trade or business in the United States or has as partners one or more U.S. persons that, in the aggregate, hold more than 50% of the income or capital interest in the partnership, backup withholding will not apply, but such payments will be subject to information reporting, unless such broker has documentary evidence in its records that you are a non-U.S. Holder and certain other conditions are met or you otherwise establish an exemption.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against your U.S. federal income tax liability provided the required information is furnished in a timely manner to the Internal Revenue Service.

#### UNDERWRITING

Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters named below and the underwriters have severally agreed to purchase from us, the number of shares of common stock appearing opposite their names below.

Wachovia Capital Markets, LLC
C.E. Unterberg, Towbin, LLC
Jefferies & Company, Inc.
Total

The underwriters have agreed to purchase all of the shares shown in the above table if any of those shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriter may be increased or the underwriting agreement may be terminated.

The shares of common stock are offered by the underwriters, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by counsel for the underwriters and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers' certificates and legal opinions.

The underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

#### Commissions and Discounts

The underwriters have advised us that they propose to offer the shares of our common stock to the public at the public offering price falling within the range listed on the cover page of this prospectus and to certain dealers at that price less a concession of not more than \$ per share, of which \$ may be reallowed to other dealers. After completion of this initial public offering, the public offering price, concession and reallowance to dealers may be changed.

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us on a per share basis and in total, assuming either no exercise or full exercise by the underwriters of their over-allotment option.

		Tot	al
	Per Share	Without Option	With Option
Public offering price	\$	\$	\$
Underwriting discount	\$	\$	\$
Proceeds to us (before expenses)	\$	\$	\$

We estimate that the expenses of this offering, not including the underwriting discount, will be approximately \$2.1 million and are payable by us.

# **Over-allotment Option**

We have granted to the underwriters an option, exercisable during the 30-day period after the date of this prospectus, to purchase up to a total of 825,000 additional shares of common stock at the public offering price per share less the underwriting discounts and commissions per share shown on the cover page of this prospectus. To the extent that the underwriters exercise this option, each of the underwriters will have a

firm commitment, subject to conditions, to purchase approximately the same percentage of the additional shares that the number of shares of
common stock to be purchased by that underwriter as shown in the above table represents as a percentage of the total number of shares sho
in that table.

## **Indemnity**

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

### Lock-up Agreements

Our directors and officers and the holders of approximately 12,837,238 of the shares of our common stock outstanding as of March 31, 2005 have agreed, with limited exceptions, for a period of 180 days after the date of this prospectus, they will not, without the prior written consent of Wachovia Capital Markets, LLC, offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or other capital stock or any securities convertible into, or exercisable or exchangeable for, shares of our common or our other capital stock, except that such directors, officers and stockholders will be permitted to transfer any of these securities by gift, will or intestate succession (so long as any recipient of those securities enters into a similar lock-up agreement), the selling stockholders will be permitted to distribute securities to their partners (so long as any recipient of those securities enters into a similar lock-up agreement).

In addition, we have agreed that, for a period of 180 days after the date of this prospectus, we will not, without the prior written consent of Wachovia Capital Markets, LLC, offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or other capital stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock or other capital stock, except for:

the shares of common stock being sold by us in this offering;

the issuance of shares of common stock and stock options pursuant to our stock option plans as in effect on the date of this prospectus; and

the issuance of shares of common stock upon the exercise of stock options.

Wachovia Capital Markets, LLC may, in its sole discretion and at any time or from time to time, without notice, release all or any portion of the shares or other securities subject to the lock-up agreements listed above.

### Stabilization

The representatives have advised us that, pursuant to Regulation M under the Securities Exchange Act of 1934, certain persons participating in this offering may engage in transactions, including stabilizing bids, syndicate covering transactions or the imposition of penalty bids, which may have the effect of stabilizing or maintaining the market price of our common stock at a level above that which might otherwise prevail in the open market.

A "stabilizing bid" is a bid for or the purchase of the common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock.

A "syndicate covering transaction" is a bid for or the purchase of the common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with this offering.

A "penalty bid" is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to an underwriter or selling group member in connection with this offering if the common stock originally sold by that underwriter or selling group member is purchased by the underwriters in a syndicate covering transaction and has therefore not been effectively placed by that underwriter or selling group member.

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The underwriters have advised us that these transactions may be effected on the Nasdaq National Market or otherwise. Neither we nor any of the underwriters makes any representation that the underwriters will engage in any of the transactions described above, and these transactions, if commenced, may be discontinued without notice. Neither we nor any of the underwriters makes any representation or prediction as to the direction or magnitude of the effect that the transactions described above, if commenced, may have on the market price of our common stock.

# Other Relationships

C.E. Unterberg, Towbin, LLC has performed investment banking and advisory services for us from time to time for which they received customary fees and expenses. Wachovia Bank, N.A. is acting as transfer agent and registrar for our common stock for which it receives customary fees and expenses. The underwriters may, from time to time, engage in transactions with and perform services for us in the ordinary course of business.

# **Pricing of this Offering**

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

prevailing market conditions;

our results of operations and financial condition;

financial and operating information and market valuations with respect to other companies that we and the representatives of the underwriters believe to be comparable to us;

the present state of our business; and

our future prospects.

An active trading market for our common stock may not develop. It is possible that the market price of our common stock after this offering may be less than the initial public offering price. In addition, the estimated initial public offering price range appearing on the cover of this preliminary prospectus is subject to change as a result of market conditions or other factors.

### **Quotation on the Nasdaq National Market**

We have filed an application for our common stock to be quoted on the Nasdaq National Market under the symbol "EPCT."

### **Electronic Prospectus**

In connection with this offering, certain of the underwriters or securities dealers may distribute this prospectus electronically.

# **VALIDITY OF SECURITIES**

Weil, Gotshal & Manges LLP, New York, New York has passed upon the validity of the common stock offered hereby on behalf of us. Shearman & Sterling LLP, New York, New York has passed upon the validity of the common stock offered hereby on behalf of the underwriters.

#### **EXPERTS**

The consolidated financial statements included in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein and elsewhere in the registration statement (which report expresses an unqualified opinion on the consolidated financial statements and includes explanatory paragraphs referring to the Company's ability to continue as a going concern as referred to in Note 1 and the restatement referred to in Note 11), and have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

#### CHANGE IN INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Our consolidated balance sheets as of December 31, 2001 and 2000 and the related consolidated statements of operations, stockholders' (deficiency) equity and cash flows for the years then ended and the period from March 9, 1993 (inception) through December 31, 2001 were previously audited by Ernst & Young LLP, an independent registered public accounting firm. On May 10, 2004, Ernst & Young LLP resigned.

On July 13, 2004, our board of directors approved the appointment of Deloitte & Touche LLP to serve as our independent registered public accounting firm. We engaged Deloitte & Touche LLP to audit our consolidated financial statements as of December 31, 2003 and 2002, and for the years then ended, and to re-audit our consolidated financial statements for the year ended December 31, 2001.

In connection with the audits of our consolidated financial statements for the years ended December 31, 2000 and 2001 and in the interim period through May 10, 2004, there were no disagreements with Ernst & Young LLP on any matters of accounting principles or practices, financial statement disclosure or auditing scope and procedures, which if not resolved to the satisfaction of Ernst & Young LLP would have caused Ernst & Young LLP to make reference to the matter in their report. Further during the same periods, there were no "reportable events" as that term is described in Item 304(a)(1)(v) of Regulation S-K. Except for a paragraph relating to a going concern uncertainty, the audit report of Ernst & Young LLP on our consolidated financial statements described above did not contain any adverse opinion or disclaimer of opinion, nor was it qualified or modified as to uncertainty, audit scope or accounting principles.

As a result of the reaudit of our consolidated financial statements for the year ended December 31, 2001, we determined that a restatement was required for certain items as disclosed in Note 11 to those financial statements, and we informed Ernst & Young LLP about these matters.

We have requested Ernst & Young LLP to furnish a letter addressed to the Securities and Exchange Commission stating whether it agrees with the above statements. A copy of that letter confirming its agreement, dated March 29, 2005, is filed as Exhibit 16.1.

### WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the common stock offered hereby. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. For further information with respect to EpiCept Corporation and the common stock offered hereby, you should refer to the registration statement and to the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits and schedules therewith may be inspected without charge at the public reference room maintained by the SEC located at 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of all or any portion of the

registration statement may be obtained from such offices upon payment of prescribed fees. The public may obtain information on the
operation of the public reference room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website at www.sec.gov that contains
reports, proxy and information statements and other information regarding registrants that file electronically with the SEC.

# CONSOLIDATED FINANCIAL STATEMENTS

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# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

EpiCept Corporation and subsidiary:

We have audited the accompanying consolidated balance sheets of EpiCept Corporation and subsidiary (the "Company") as of December 31, 2004 and 2003, and the related consolidated statements of operations, preferred stock and stockholders' deficit, and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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, such consolidated financial statements present fairly, in all material respects, the financial position of EpiCept Corporation and subsidiary as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's recurring losses from operations and stockholders' deficit raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 11, the accompanying 2003 consolidated financial statements have been restated.

DELOITTE & TOUCHE LLP

Parsippany, New Jersey

March 29, 2005 (April 15, 2005 as to the effects of the reverse stock split described in Note 13)

# CONSOLIDATED BALANCE SHEETS

				Pro Forma
				Liabilities and
				Stockholders'
	Dec		Deficit	
			_	December 31,
	 2004	 2003		2004 (Note 2)
		(As Restated		(Unaudited)
		See Note 11)		
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 1,253,507	\$ 8,007,187		
Prepaid expenses and other current assets	47,616	36,285		
Total current assets	1,301,123	8,043,472		
Property and equipment, net	109,033	110,135		
Deferred financing and initial public offering costs	1,197,888	28,552		
Other assets	18,748	13,345		
Total assets	\$ 2,626,792	\$ 8,195,504		
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$ 1,622,382	\$ 387,230		
Accrued research contract costs	162,183	114,537		
Accrued interest	806,714	419,597		
Other accrued liabilities	445,714	478,490		
Notes and loans payable, current portion	817,260	1,010,400		
Deferred revenue, current portion	2,399,679	1,115,089		
Total current liabilities	6,253,932	3,525,343		
Notes and loans payable	11,572,628	10,272,177	\$	8,786,905
Deferred revenue	6,108,657	8,508,336		
Accrued interest	413,467	343,654		
Contingent interest	706,065	483,173		
Deferred rent and other noncurrent liabilities	13,534	31,578		
Total long term liabilities	18,814,351	19,638,918		16,028,628
Total liabilities	25,068,283	23,164,261		22,282,560

Commitments (Note 7)

Series B Redeemable Convertible Preferred Stock, \$0.0001 par value; authorized 3,440,069 shares; issued and outstanding 3,106,736 shares (\$9,320,208 liquidation preference at December 31, 2004 and 2003)	6,748,052	6,421,845	_
protection at 2000 moor 21, 2001 and 2000)			
Series C Redeemable Convertible Preferred Stock,			
\$0.0001 par value; authorized 12,769,573 shares; issued and			
outstanding 8,839,573 shares (\$26,518,719 liquidation			
preference at December 31, 2004 and 2003)	18,605,762	17,677,607	_
Warrants	4,583,974	4,583,974	-
Stockholders' Deficit:			
Series A Convertible Preferred Stock, \$0.0001 par value;			
authorized 3,422,620 shares, issued and outstanding			
3,368,385 and 3,315,160 shares at December 31, 2004 and			
2003; (liquidation preference of \$6,804,138 and \$6,696,623			
at December 31, 2004 and 2003)	8,225,806	8,191,840	-
Common stock, \$0.0001 par value; authorized			
60,000,000 shares; issued 1,699,620 and 1,650,839 shares at			
December 31, 2004 and 2003 and 6,577,125 shares pro			
forma at December 31, 2004	170	165	658
Additional paid-in capital	150,510	34,461	25,900,045
Deferred stock compensation	(24,444 )	(394,972 )	(24,444 )
Accumulated deficit	(59,291,948)	(50,410,962)	(59,291,948)
Accumulated other comprehensive loss	(1,364,373)	(997,715 )	(1,364,373 )
Treasury stock, at cost (12,500 shares)	(75,000 )	(75,000 )	(75,000 )
Total stockholders' deficit	(52,379,279)	(43,652,183)	(34,855,062)
Total liabilities and stockholders' deficit	\$ 2,626,792	\$ 8,195,504	

See accompanying notes.

# CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,					
		2004		2003		2002
				(As Restated		
				See Note 11)		
Revenue	\$	1,115,089	\$	376,575	\$	-
Operating expenses:						
General and administrative		4,407,702		3,406,648		3,492,928
Research and development		1,784,451		1,640,955		4,873,999
		6,192,153		5,047,603		8,366,927
Loss from operations		(5,077,064)		(4,671,028)		(8,366,927)
Other income (expense):						
Interest income		39,828		_		41,978
Foreign exchange loss		(175,693 )		(770,777 )		(728,167)
Interest expense		(2,670,364)		(4,593,180)		(823,389 )
Other expense, net		(2,806,229)		(5,363,957)		(1,509,578)
				<u> </u>		<u> </u>
Loss before benefit for income taxes		(7,883,293)		(10,034,985)		(9,876,505)
Benefit for income taxes		274,886		74,454		225,343
Net loss		(7,608,407)		(9,960,531)		(9,651,162)
Deemed dividend and redeemable convertible						
preferred stock dividends		(1,404,362)		(1,254,362)		(1,288,328)
Loss attributable to common stockholders	\$	(9,012,769)	\$	(11,214,893)	\$	(10,939,490)
Basic and diluted loss per common share	\$	(5.35)	\$	(6.79)	\$	(6.63)
Weighted average shares outstanding	Ψ	1,683,199	Ψ	1,650,717	Ψ	1,649,409
Unaudited pro forma basic and diluted loss per		-,000,100		-,~~,,,,,,		-,0 .,, .,
common share (Note 2)	\$	(0.73)				
Shares used in computing unaudited pro forma basic	4	(2				
and diluted loss per common share (Note 2)		10,422,171				

See accompanying notes.

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# CONSOLIDATED STATEMENTS OF PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

### For the Years Ended December 31, 2002, 2003 and 2004

Series B Redeemable Series C Redeemable **Convertible Preferred Convertible Preferred** Series A Convertible Stock Stock Preferred Stock **Common Stock** Shares Amount Shares Amount Warrants Shares Amount Shares Amount Balance at January 1, 2002 3,106,736 5,148,084 8,839,573 14,053,383 949,957 3,315,160 7,274,762 1,643,192 164 Exercise of stock options 7,147 1 Accretion of preferred stock dividends 326,207 928,155 Issuance of Series A Convertible Preferred Stock warrants to investor Series A Convertible Preferred Stock deemed dividend Deferred stock compensation related to employee stock options Amortization of deferred stock compensation Stock-based compensation to third parties Sale of warrants 1,677,380 Foreign currency

translation									
adjustment									
Net loss									
Net ioss									
Dalamas at									
Balance at									
December 31,									
2002	3,106,736	5,474,291	8,839,573	14,981,538	2,627,337	3,315,160	7,274,762	1,650,339	165
Exercise of									
stock options	-	-	-	_	-	-	-	500	-
Accretion of									
preferred									
stock									
dividends	-	326,207	_	928,155	_	_	_	_	-
Beneficial									
conversion									
feature									
related to									
preferred									
stock	-	621,347	-	1,767,914	-	_	917,078	_	-
Deferred stock									
compensation									
related to									
employee									
stock options	-	-	-	_	-	-	-	-	-
Amortization of									
deferred									
stock									
compensation	-	-	-	-	=	-	=	-	=
Stock-based									
compensation									
to third									
parties	-	-	-	-	-	-	-	-	-
Sale of warrants	-	-	-	_	1,956,637	-	=	-	-
Beneficial									
conversion									
feature									
related to									
convertible									
term notes	-	-	-	-	-	-	-	-	-
Foreign									
currency									
translation									
adjustment	_	-	-	-	-	-	-	-	-
Net loss as									
restated,									
see Note 11	-	=	_	=	=	_	=	=	=
Balance at									
December 31,									
2003 as	3,106,736	6,421,845	8,839,573	17,677,607	4,583,974	3,315,160	8,191,840	1,650,839	165

# CONSOLIDATED STATEMENTS OF PREFERRED STOCK AND STOCKHOLDERS' DEFICIT - (Continued)

Series B Redeemable Convertible Preferred Series C Redeemable Convertible Preferred

Exercise of stock options		Stock		Stock					
Exercise of  stock options	-		Stock	Amount		Stock		_	Warrants
stock options	Exercise of								
Exercise of Series A Convertible Preferred Stock warrants		_		_	_		_		_
Series A Convertible Preferred Stock warrants	Exercise of								
Convertible Preferred Stock warrants	Series A								
Preferred Stock warrants									
Warrants									
Beneficial conversion feature related to Series A Convertible Preferred Stock warrant exercise   -   -   -   -   -   Accretion of preferred stock dividends   -   326,207   -   928,155   -   Amortization of deferred stock compensation   -   -   -   -   -   Stock-based compensation to third parties   -   -   -   -   -   Foreign currency translation adjustment   -   -   -   -   Net loss   -   -   Net loss   -   -   -   Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -   Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -   Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -     Net loss   -	Stock								
conversion feature related to Series A Convertible Preferred Stock warrant exercise	warrants	_		_	_		_		_
feature related to Series A Convertible Preferred Stock warrant exercise	Beneficial								
related to Series A  Convertible Preferred Stock warrant exercise	conversion								
Series A  Convertible Preferred Stock warrant exercise	feature								
Convertible Preferred Stock warrant exercise	related to								
Preferred Stock warrant exercise	Series A								
Stock warrant   exercise	Convertible								
exercise	Preferred								
Accretion of preferred stock dividends	Stock warrant								
preferred stock dividends	exercise	_		_	_		_		-
stock dividends	Accretion of								
dividends - 326,207 - 928,155 -  Amortization of deferred stock compensation  Stock-based compensation to third parties  Foreign currency translation adjustment  Net loss	preferred								
Amortization of deferred stock compensation	stock								
of deferred stock compensation Stock-based compensation to third parties	dividends	-		326,207	-		928,155		-
stock compensation	Amortization								
compensation       -       -       -       -       -         Stock-based       compensation       -	of deferred								
Stock-based         compensation         to third         parties       -	stock								
compensation         to third         parties       -       -       -       -         Foreign         currency       translation       -       -       -       -         Met loss       -       -       -       -       -       -		-		-	-		-		-
to third parties Foreign currency translation adjustment	Stock-based								
parties									
Foreign									
currency         translation         adjustment       -       -       -       -       -         Net loss       -       -       -       -       -       -       -       -		_		-	-		_		-
translation  adjustment									
adjustment       -       -       -       -       -       -         Net loss       -									
Net loss – – – – – – – – – – – – – – – – – –									
		-		-	_		_		_
	Net loss	_		_	_		_		_
	D.1								
	Balance at								
December 31,		2.106.726	Φ	(749.053	0.020.572	Ф	10 (05 7(2)	Ф	4 502 074
2004 3,106,736 \$ 6,748,052 8,839,573 \$ 18,605,762 \$ 4,583,974	2004	3,106,736	\$	6,748,052	8,839,573	\$	18,605,762	\$	4,583,974

# [Continued from above table, first column(s) repeated]

# Series A Convertible

	Prefer	red Stock	Common Stock		Additional Paid-In	Deferred Stock
	Shares	Amount	Shares	Amount	Capital	Compensation
Exercise of stock						
options	-	-	48,781	5	69,033	-
Exercise of						
Series A						
Convertible						
Preferred Stock						
warrants	53,225	33,966	_	-	(33,966)	_
Beneficial .						
conversion feature related						
to Series A						
Convertible						
Preferred Stock						
warrant exercise	_	_	_	_	150,000	_
Accretion of					,	
preferred stock						
dividends	_	_	_	_	(131,783)	_
Amortization of						
deferred stock						
compensation	-	_	-	-	_	370,528
Stock-based						
compensation to						
third parties	_	_	_	-	62,765	_
Foreign currency						
translation						
adjustment Net loss	_	_	_	_	_	_
Net 1088				_		
Balance at						
December 31,						
2004	3,368,385	\$ 8,225,806	1,699,620	\$ 170	\$ 150,510	\$ (24,444)

[Additional columns below]

# [Continued from above table, first column(s) repeated]

	Accumulated			
	Other		Total	
Accumulated	Comprehensive	Treasury	Stockholders'	Comprehensive
Deficit	(Loss)	Stock	Deficit	Loss

Exercise of stock options	_		_		_		69,038		_
Exercise of							09,038		
Series A									
Convertible									
Preferred									
Stock									
warrants	_		_		_		_		-
Beneficial									
conversion									
feature									
related to									
Series A									
Convertible									
Preferred									
Stock warrant	(150,000								
exercise Accretion of	(150,000 )		_		-		_		_
preferred									
stock	(1.122.570.)						(1.254.262.)		
dividends Amortization	(1,122,579)		_		_		(1,254,362)		_
of deferred									
stock							270.520		
compensation Stock-based	_		_		_		370,528		_
compensation to third									
							62.765		
parties	_		_		_		62,765		_
Foreign									
currency translation									
adjustment			(366,658)				(366,658)	\$	(366,658)
Net loss	(7,608,407)		(300,038 )		_		(7,608,407)	Ф	
1101 1088	(7,000,407)						(7,000,407)		(7,608,407)
Balance at									
December 31,									
2004 \$	(59,291,948)	\$	(1,364,373)	\$	(75,000)	\$	(52,379,279)	\$	(7,975,065)
200 <del>1</del>	(37,271,770)	Ψ	(1,304,373)	Ψ	(75,000)	Ψ	(32,317,217)	Ψ	(1,713,003)

See accompanying notes.

# CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,					
		2004		2003		2002
				(As Restated		
				See Note 11)		
Cash flows from operating activities:						
Net loss	\$	(7,608,407)	\$	(9,960,531)	\$	(9,651,162)
Adjustments to reconcile net loss to net cash provided						
by (used in) operating activities:						
Depreciation and amortization		57,627		78,424		97,143
Gain on disposal of assets		(1,895)		_		_
Foreign exchange loss		175,693		770,777		728,167
Stock-based compensation expense		433,293		768,876		906,020
Amortization of deferred financing costs		28,552		85,657		14,276
Accretion of discount on loans		1,316,563		3,356,400		177,057
Change in operating assets and liabilities –						
(Increase) decrease in prepaid expenses and other						
current assets		(11,331 )		453		(1,324)
(Increase) in other assets		(5,403)		(2,513)		(2,041)
Increase (decrease) in accounts payable		1,235,152		(155,725)		377,733
Increase (decrease) in accrued research contract costs		47,646		(469,806)		277,887
Increase in accrued interest – current		387,117		377,268		22,051
(Decrease) increase in other accrued liabilities		(32,776)		58,594		109,624
Increase in deferred revenue		_		10,000,000		_
Amortization of deferred revenue		(1,115,089)		(376,575)		_
Increase in accrued interest		69,813		64,093		53,425
Increase in contingent interest		222,892		183,246		111,442
Decrease in other liabilities		(18,044 )		(11,637)		(8,433)
Net cash (used in) provided by operating activities		(4,818,597)		4,767,001		(6,788,135)
Cash flows from investing activities:						
Purchase of property and equipment		(50,054)		(17,357)		(9,933)
Proceeds from sale of property and equipment		999		_		_
Net cash used in investing activities		(49,055)		(17,357)		(9,933)
Cash flows from financing activities:						
Issuance of common stock		69,038		600		8,578
Proceeds from bridge loans and warrants		_		2,654,546		2,195,454
Repayment of loan		(729,340 )		_		_
Deferred financing and initial public offering costs		(1,197,888)		_		(128,485 )
Net cash (used in) provided by financing activities		(1,858,190)		2,655,146		2,075,547
		-				

Net increase (decrease) in cash and cash equivalents	(6,725,842)	7,404,790	(4,722,521)
Effect of exchange rate changes on cash	(27,838 )	(17,155 )	(14,371 )
Cash and cash equivalents at beginning of period	8,007,187	619,552	5,356,444
Cash and cash equivalents at end of period	\$ 1,253,507	\$ 8,007,187	\$ 619,552
Supplemental disclosure of cash flow information			
Cash paid for interest	\$ 709,493	\$ 493,579	\$ 453,333
Supplemental disclosure of non-cash investing and			
financing activities			
Deemed dividend and redeemable convertible preferred			
stock dividends	\$ 1,254,362	\$ 1,254,362	\$ 1,288,328
Beneficial conversion feature related to preferred stock			
or warrant exercise	\$ 150,000	\$ 3,306,339	\$ _
Beneficial conversion feature related to convertible			
term notes	\$ _	\$ 1,215,983	\$ _
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### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### Years Ended December 31, 2004, 2003 and 2002

### 1. Organization and Description of Business

EpiCept Corporation ("EpiCept" or the "Company") is a specialty pharmaceutical company focused on the development and commercialization of topically delivered prescription pain management therapeutics. The Company has six product candidates in clinical development, three of which are in late-stage clinical development and ready to enter, or which have entered, Phase IIb or Phase III clinical trials. EpiCept's product candidates target moderate-to-severe pain that is influenced, or mediated, by nerve receptors located just beneath the skin's surface. The Company's product candidates utilize several proprietary formulations and topical delivery technologies to administer established, FDA-approved pain management therapeutics, or analgesics.

The Company's late stage product candidates are EpiCept NP-1, a prescription topical analgesic cream designed to provide effective long-term relief of peripheral neuropathies; LidoPAIN SP, a sterile prescription analgesic patch designed to provide sustained topical delivery of lidocaine to a post-surgical or post-traumatic sutured wound while also providing a sterile protective covering for the wound; and LidoPAIN BP, a prescription analgesic non-sterile patch designed to provide sustained topical delivery of lidocaine for the treatment of acute or recurrent lower back pain.

The Company has yet to generate product revenues from any of its product candidates in development. During 2003, the Company entered into two strategic alliances, the first in July 2003 with Adolor Corporation ("Adolor") for the development and commercialization of certain products, including LidoPAIN SP in North America, and the second in December 2003 with Endo Pharmaceuticals, Inc. ("Endo") for the worldwide commercialization of LidoPAIN BP. The Company received a total of \$10.0 million in upfront non-refundable license fees upon the closing of these license agreements. Under these relationships, the Company is eligible to receive an additional \$102.5 million in milestone payments and, upon receipt of appropriate regulatory approvals, the Company will earn royalties based on net sales of products. There is no assurance that any of these milestones will be earned or any royalties paid. The Company's ability to generate additional revenue in the future will depend on its ability to meet development or regulatory milestones under its existing license agreements that trigger additional payments, to enter into new license agreements for other products or territories, and to receive regulatory approvals for, and successfully commercialize, its product candidates either directly or through commercial partners.

The Company is subject to a number of risks associated with companies in the specialty pharmaceutical industry. Principal among these are risks associated with the Company's dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with the U.S. Food and Drug Administration and other governmental regulations and approval requirements, as well as the ability to grow the Company's business and the need to obtain adequate financing to fund this growth.

The Company has prepared its financial statements under the assumption that it is a going concern. The Company has devoted substantially all of its cash resources to research and development programs and general and administrative expenses, and to date it has not generated any meaningful revenues from the sale of products and does not expect to generate any such revenues for a number of years, if at all. As a result, the Company has incurred an accumulated deficit of \$59.3 and \$50.4 million as of December 31, 2004 and 2003, respectively, and expects to incur operating losses, potentially greater than losses in prior years, for a number of years. The Company's recurring losses from operations and the accumulated deficit raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company has financed its operations through the proceeds from the sales of common and preferred equity securities,

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

debt, proceeds from collaborative relationships, investment income earned on cash balances and short-term investments and the sales of a portion of its New Jersey net operating loss carryforwards.

The Company expects to utilize its cash and cash equivalents to fund its operations, including research and development of its product candidates, primarily for clinical trials. Based upon the projected spending levels for the Company, the Company does not currently have adequate cash and cash equivalents to complete the trials and therefore will require additional funding. As a result, the Company intends to monitor its liquidity position and the status of its clinical trials and to continue to actively pursue fund-raising possibilities through the sale of its equity securities. If the Company is unsuccessful in its efforts to raise additional funds through the sale of its equity securities or achievement of development milestones, it may be required to significantly reduce or curtail its research and development activities and other operations if its level of cash and cash equivalents falls below pre-determined levels. As more fully described in Note 12, the Company completed a senior note financing with stock warrants in March 2005 generating gross proceeds of \$4.0 million. The Company believes that its existing cash and cash equivalent plus the proceeds of this financing will be sufficient to fund our operations through the third quarter of 2005.

The Company will require, over the long-term, substantial new funding to pursue development and commercialization of its product candidates and continue its operations. The Company believes that satisfying these capital requirements over the long-term will require successful commercialization of its product candidates. However, it is uncertain whether any products will be approved or will be commercially successful. The amount of the Company's future capital requirements will depend on numerous factors, including the progress of its research and development programs, the conduct of pre-clinical tests and clinical trials, the development of regulatory submissions, the costs associated with protecting patents and other proprietary rights, the development of marketing and sales capabilities and the availability of third-party funding.

There can be no assurance that such funding will be available at all or on terms acceptable to the Company. If the Company obtains funds through arrangements with collaborative partners or others, the Company may be required to relinquish rights to certain of its technologies or product candidates.

The Company was incorporated in Delaware in March 1993. A 100%-owned subsidiary, EpiCept GmbH, organized in Munich, Germany, is engaged in research and development activities on behalf of the Company.

### 2. Summary of Significant Accounting Policies

### Consolidation

The accompanying consolidated financial statements include the accounts of EpiCept Corporation and the Company's 100%-owned subsidiary, EpiCept GmbH. All significant intercompany transactions and balances have been eliminated.

# Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

### Revenue Recognition

The Company recognizes revenue relating to its collaboration agreements in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force ("EITF") Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. Revenue under collaborative arrangements may result from license fees, milestone payments, research and development payments and royalty payments.

The Company's application of these standards requires subjective determinations and requires management to make judgments about value of the individual elements and whether they are separable from the other aspects of the contractual relationship. The Company evaluates its collaboration agreements to determine units of accounting for revenue recognition purposes. To date, the Company has determined that its upfront non-refundable license fees cannot be separated from its ongoing collaborative research and development activities and, accordingly, do not treat them as a separate element. The Company recognizes revenue from non-refundable, upfront licenses and related payments, not specifically tied to a separate earnings process, either on the proportional performance method or ratably over the development period in which the Company is obligated to participate on a continuing and substantial basis in the research and development activities outlined in the contract. Ratable revenue recognition is only utilized if the research and development services are performed systematically over the development period. Proportional performance is measured based on costs incurred compared to total estimated costs to be incurred over the development period which approximates the proportion of the value of the services provided compared to the total estimated value over the development period. The Company periodically reviews its estimates of cost and the length of the development period and, to the extent such estimates change, the impact of the change is recorded at that time.

The Company recognizes milestone payments as revenue upon achievement of the milestone only if (1) it represents a separate unit of accounting as defined in EITF Issue No. 00-21; (2) the milestone payment is nonrefundable; (3) substantive effort is involved in achieving the milestone; and (4) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with the achievement of the milestone. If any of these conditions is not met, the Company recognizes milestones as revenue in accordance with the accounting policy in effect for the respective contract. At the time of a milestone payment receipt, the Company would recognize revenue based upon the portion of the development services that are completed to date and defer the remaining portion and recognize it over the remainder of the development services on the proportional or ratable method, whichever is applicable. To date, the Company has not recognized revenue from any milestone payment. When payments are specifically tied to a separate earnings process, revenue will be recognized when the specific performance obligation associated with the payment has been satisfied.

Deferred revenue represents the excess of cash received compared to revenue recognized to date under licensing agreements.

## Foreign Currency Translation

The financial statements of the Company's foreign subsidiary are translated into U.S. dollars using the year-end exchange rate for all balance sheet accounts and the average exchange rates for expenses. Adjustments resulting from translation have been reported in other comprehensive loss.

Gains or losses from foreign currency transactions relating to intercompany debt are recorded in the consolidated statements of operations in other income (expense).

Stock-Based Compensation

As permitted by Statement of Financial Accounting Standards ("SFAS") No. 123, Accounting for Stock-Based Compensation
("SFAS 123"), the Company accounts for employee stock-based compensation in accordance with Accounting Principles Board ("APB")
Opinion No. 25, Accounting for Stock

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

Issued to Employees ("APB 25"), using intrinsic values with appropriate disclosures using the fair value based method.

Pro forma information regarding net loss is required by SFAS 123, as amended by SFAS No. 148 *Accounting for Stock-Based Compensation, Transition and Disclosure* ("SFAS 148"), and has been determined as if the Company had accounted for its employee stock options under the fair value method. As allowed by SFAS 123 and SFAS 148, the Company has elected to continue to apply the intrinsic-value-based method of accounting for employee stock options described above, and has adopted only the disclosure requirements of SFAS 123. The following table illustrates the effect on earnings as if the Company applied the fair value method of accounting for stock-based employee compensation under SFAS 123:

	Year Ended December 31,					
		2004		2003		2002
Net loss	\$	(7,608,407)	\$	(9,960,531)	\$	(9,651,162)
Add back: Total stock-based employee compensation expense under the APB 25 intrinsic						
value method		370,528		590,318		858,908
Deduct: Total stock-based employee compensation						
expense determined under fair value based method		(378,569)		(634,148)		(869,844)
Net loss – pro forma		(7,616,448)		(10,004,361)		(9,662,098)
Deemed dividend and redeemable convertible						
preferred stock dividends		(1,404,362)		(1,254,362)		(1,288,328)
Pro forma loss attributable to common stockholders	\$	(9,020,810)	\$	(11,258,723)	\$	(10,950,426)
Basic and diluted loss per common share						
As reported	\$	(5.35)	\$	(6.79)	\$	(6.63)
Pro forma	\$	(5.36)	\$	(6.82)	\$	(6.64)

The pro forma net loss may not be representative of pro forma net loss in future years because the pro forma results include the impact of previous grants and related vesting, while subsequent years will include additional grants and vesting.

The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model. The following weighted average assumptions were used for grants in 2003 and 2002: dividend yield of 0%, risk free interest rate of 2.87% and 3.81%-4.65%, volatility of 0% and expected life of 4 years. No options were granted in 2004. The weighted-average fair value of options granted was \$4.20 and \$4.68 for the years ended December 31, 2003 and 2002, respectively.

Options issued to non-employees are valued using the fair value method (Black-Scholes option pricing model) under SFAS 123 and EITF Issue 96-18, *Accounting for Equity Investments that are Issued to Other than Employees for Acquiring or in Conjunction with Selling Goods or Services* ("EITF 96-18"). The value of such options is periodically remeasured and income or expense is recognized during the vesting terms.

Income Taxes

The Company accounts for its income taxes under the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized based upon the differences arising from carrying amounts of the Company's assets and liabilities for tax and financial reporting purposes using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect on the deferred tax assets and liabilities of a change in tax rates is recognized in the period when the change in tax rates is enacted. A valuation allowance is established when it is determined that it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of December 31, 2004 and

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

2003, a full valuation allowance has been applied against the Company's deferred tax assets (See Note 10).

### Loss Per Share

Basic and diluted loss per share is computed by dividing loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted weighted average shares outstanding excludes shares underlying the Series A convertible preferred stock, the Series B redeemable convertible preferred stock and the Series C redeemable convertible preferred stock (collectively the "Preferred Stock"), stock options and warrants, since the effects would be anti-dilutive. Accordingly, basic and diluted loss per share is the same. Such excluded shares are summarized as follows:

	For the Year Ended December 31,				
	2004	2003	2002		
Common stock options	466,625	515,406	643,660		
Warrants	6,374,999	6,400,321	6,400,321		
Series A Convertible Preferred Stock	1,148,571	1,130,422	1,130,422		
Redeemable convertible preferred stock					
Series B	896,173	896,173	896,173		
Series C	2,549,876	2,549,876	2,549,876		
Total shares excluded from calculation	11,436,244	11,492,198	11,620,452		

### Unaudited Pro Forma Loss Per Share

Unaudited pro forma loss per share is computed using the weighted average number of shares of common stock outstanding, including the pro forma effects of the conversion of the Company's Preferred Stock, conversion of the Company's ten-year non-amortizing convertible loan and the exercise of the bridge warrants (Note 9) into shares of the Company's common stock effective upon the assumed closing of the Company's proposed initial public offering, as if such conversion had occurred at January 1, 2004. The following table reconciles the loss attributable to common stockholders used in the computation of basic and diluted loss per share to the unaudited pro forma loss attributable to common stockholders:

		Year Ended
		December 31, 2004
Loss attributable to common stockholders, as reported	\$	(9,012,769)
Reversal of deemed and preferred dividends		1,404,362
Unaudited are forme loss attributable to common steeliholders	¢	(7,609,407)
Unaudited pro forma loss attributable to common stockholders	Φ	(7,608,407)

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

The following table reconciles the weighted average number of common shares used in the computation of basic and diluted weighted average common shares outstanding to the unaudited pro forma basic and diluted weighted average number of common shares outstanding:

	Year Ended
_	December 31, 2004
Basic and diluted weighted average number of common shares	
outstanding	1,683,199
Weighted average number of common shares assuming the conversion of the Preferred Stock, conversion of the Company's ten-year non-amortizing convertible loan and exercise of bridge warrants at January 1, 2004	8,738,972
	<u> </u>
Unaudited pro forma basic and diluted weighted average common	
shares outstanding	10,422,171

### Unaudited Pro Forma Liabilities and Stockholders' Deficit

The pro forma liabilities and stockholders' deficit as of December 31, 2004 assumes the automatic conversion of the Preferred Stock effective upon the assumed close of the Company's proposed initial public offering of common stock and the conversion of the Company's ten-year non-amortizing convertible loan, as if such conversion had occurred as of December 31, 2004 and the reclassification of the warrant value into additional paid-in capital. At the time of the proposed initial public offering of common stock, the warrants are only exercisable into common stock of the Company (see Note 9).

### Cash Equivalents

Cash equivalents consist of money market mutual funds, which invest in U.S. government securities and bank deposits. The Company considers all highly liquid instruments which have maturity of three months or less when acquired to be cash equivalents.

## Deferred Financing and Initial Public Offering Costs

At December 31, 2003, deferred financing costs represent legal and other costs and fees incurred to negotiate and obtain financing. These costs are capitalized and amortized on a straight-line basis (which approximates the effective interest method) over the life of the applicable financing. As of December 31, 2004, deferred financing and initial public offering costs includes approximately \$1.2 million of costs incurred relating to the Company's proposed initial public offering of common stock. Such amount will be reclassified against the proceeds received from the proposed initial public offering at closing.

## Property and Equipment

Property and equipment consists of office furniture and equipment, laboratory equipment and leasehold improvements stated at cost. Furniture and equipment are depreciated on a straight-line basis over their estimated useful lives ranging from five to seven years. Leasehold

improvements are amortized on a straight-line basis over the shorter of the lease term or the estimated useful life of the asset. Mainten	ance and
repairs are charged to expense as incurred.	

# Impairment of Long-Lived Assets

The Company performs impairment tests on its long-lived assets when circumstances indicate that their carrying amounts may not be recoverable. If required, recoverability is tested by comparing the

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

estimated future undiscounted cash flows of the asset or asset group to its carrying value. If the carrying value is not recoverable, the asset or asset group is written down to fair value. No such impairments have been identified with respect to the Company's long-lived assets, which consist primarily of property and equipment.

#### Derivatives

The Company accounts for its derivative instruments in accordance with SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities," as amended by SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities ("SFAS 133"). SFAS 133 establishes accounting and reporting standards requiring that derivative instruments, including derivative instruments embedded in other contracts, be recorded on the balance sheet as either an asset or liability measured at its fair value. SFAS 133 also requires that changes in the fair value of derivative instruments be recognized currently in results of operations unless specific hedge accounting criteria are met. The Company does not enter into hedging activities. As a result of certain financings (see Note 6), derivative instruments were created that are measured at fair value and marked to market at each reporting period. Changes in the derivative value are recorded as interest expense.

## Comprehensive Loss

The Company's only element of comprehensive loss other than net loss is foreign currency translation adjustments.

### Fair Value of Financial Instruments

The following methods and assumptions were used to estimate the fair value of each class of financial instruments for which it is practicable to estimate that value:

*Cash and Cash Equivalents.* The estimated fair value of cash and cash equivalents approximates its carrying value due to the short-term nature of these instruments.

*Non-Convertible Loans.* The estimated fair value of non-convertible loans is based on the present value of their cash flows discounted at a rate that approximates current market returns for issues of similar risk.

Convertible Loans and Redeemable Convertible Preferred Stock. The fair value of the convertible loan, the convertible bridge loans, and the two series of redeemable convertible preferred stock is estimated based on the Company's estimated fair value of its common stock of \$16.00 per share into which such instruments are convertible.

The estimated fair values of the Company's financial instruments are as follows:

	At Dece	mber 31,	
2	004	2	2003
Carrying		Carrying	
Amount	Fair Value	Amount	Fair Value
Amount		Amount	Fair v

Cash and cash equivalents	\$ 1.3	\$ 1.3	\$ 8.0	\$ 8.0
Non-convertible loans	4.8	5.4	5.2	5.4
Convertible bridge loans	7.6	31.5	7.4	31.1
Redeemable Convertible Preferred Stock	25.4	55.1	24.1	55.1

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

## Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 153, *Exchanges of Nonmonetary Assets* ("SFAS 153"). SFAS 153 amends Accounting Principles Board ("APB") Opinion No. 29 ("APB 29"), *Accounting for Nonmonetary Transactions*, which requires that exchanges of nonmonetary assets be measured based on the fair value of the assets exchanged, but which includes certain exceptions to that principle. SFAS 153 eliminates the exception in APB 29 for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have a commercial substance. SFAS 153 is effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of SFAS 153 is not expected to have a material impact on the Company's consolidated financial position or results of operations.

In December 2004, the FASB issued SFAS No. 123 (revised), *Share-Based Payment* ("SFAS 123R"). SFAS 123R replaces SFAS 123 and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions and is effective as of the beginning of the fiscal year that begins after June 15, 2005 for public entities that do not file as small business issuers. The Company has illustrated the impact on its earnings as if it had adopted the minimum value approach to a fair value method of accounting for stock-based compensation under SFAS 123 in Note 2 to the Consolidated Financial Statements for the years ended December 31, 2002, 2003, and 2004. At this time, the Company is unable to determine the future impact of the adoption of SFAS 123R on its consolidated financial position or results of operations.

In May 2003, SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity ("SFAS 150") was issued. This statement establishes how a company classifies and measures certain financial instruments with characteristics of both liabilities and equity, including redeemable convertible preferred stock. This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise effective at the beginning of the interim period commencing July 1, 2003, except for mandatorily redeemable financial instruments of nonpublic companies. The Financial Accounting Standards Board ("FASB") has indefinitely deferred implementation of certain provisions of SFAS 150. The Company's Series B redeemable convertible preferred stock and Series C redeemable convertible preferred stock are redeemable at the option of the investor ratably on each of December 31, 2006, 2007 and 2008, or in any amount thereafter at a price of \$1.50 per share and are automatically converted into common stock of the Company upon an initial public offering. The adoption of SFAS 150 did not have a significant impact on the Company's consolidated financial position or results of operations.

## 3. License Agreements

# Adolor Corporation

In July 2003, the Company entered into a license agreement with Adolor under which it granted Adolor the exclusive right to commercialize a sterile topical patch containing an analgesic alone or, in combination, including without limitation, LidoPAIN SP throughout North America. Upon the execution of the Adolor agreement, the Company received a non-refundable payment of \$2.5 million, which has been deferred and is being recognized as revenue ratably over the estimated product development period. Under the Adolor agreement, Adolor is obligated to pay the Company additional non-refundable amounts of up to \$15.0 million upon the achievement of various milestones relating to product development and regulatory approval, and is also obligated to pay royalties to the Company based on the net sales of licensed products in North America on a country-by-country basis until the last patent covering the

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

licensed product expires or the tenth anniversary of the first commercial sale of licensed product, whichever is later. Adolor is also obligated to pay the Company a one-time bonus payment of up to \$5.0 million upon the achievement of specified net sales milestones of licensed product. The total amount of upfront and milestone payments the Company is eligible to receive from Adolor is \$22.5 million.

Under the terms of the agreement, Adolor is responsible for conducting further clinical trials and completing the approval process in North America. At Adolor's option, the Company may be required to supply or to obtain supply of the clinical products necessary to complete clinical trials. Alternatively, Adolor may choose to subcontract these responsibilities to a third party. In North America, Adolor is responsible for the supply and manufacture of LidoPAIN SP for commercial use or, at its option, may subcontract these responsibilities to third parties.

The Company has the option to negotiate a co-promotion arrangement with Adolor for LidoPAIN SP or similar product in any country in which a New Drug Application ("NDA") (or foreign equivalent) filing has been made within thirty days of such filing. However, neither EpiCept nor Adolor is under any obligation to enter into any such agreement.

#### Endo Pharmaceuticals Inc.

In December 2003, the Company entered into a license agreement with Endo under which it granted Endo (and its affiliates) the exclusive (including as to the Company and its affiliates) worldwide right to commercialize LidoPAIN BP. The Company also granted Endo worldwide rights to use certain of its patents for the development of certain other non-sterile, topical lidocaine containing patches, including Lidoderm, Endo's topical lidocaine-containing patch for the treatment of chronic lower back pain. Upon the execution of the Endo agreement, the Company received a non-refundable payment of \$7.5 million, which has been deferred and is being recognized as revenue on the proportional performance method, and the Company may receive payments of up to \$52.5 million upon the achievement of various milestones relating to product development and regulatory approval for both the Company's LidoPAIN BP product and licensed Endo products, including Lidoderm, Endo's own back pain product candidate, so long as, in the case of Endo's product candidate, the Company's patents provide protection thereof. The Company will also receive royalties from Endo based on the net sales of LidoPAIN BP. These royalties are payable until generic equivalents to the LidoPAIN BP product are available or until expiration of the patents covering LidoPAIN BP, whichever is sooner. The Company is also eligible to receive milestone payments from Endo of up to approximately \$30.0 million upon the achievement of specified net sales milestones for licensed Endo products, including Lidoderm, Endo's chronic lower back pain product candidate, so long as our patents provide protection thereof. The total amount of upfront and milestone payments the Company is eligible to receive under the Endo agreement is \$90.0 million.

The Company is responsible for continuing and completing the development of LidoPAIN BP, including the conduct of all clinical trials and the supply of the clinical products necessary for those trials and the preparation and submission of the NDA in order to obtain regulatory approval for LidoPAIN BP. It may subcontract with third parties for the manufacture and supply of LidoPAIN BP. Endo remains responsible for continuing and completing the development of Lidoderm for the treatment of chronic lower back pain, including the conduct of all clinical trials and the supply of the clinical products necessary for those trials.

The Company has the option to negotiate a co-promotion arrangement with Endo for LidoPAIN BP or similar product in any country in which an NDA (or foreign equivalent) filing has been made within thirty days of such filing. The Company also has the right to terminate its license to Endo with respect to any territory in which Endo has failed to commercialize LidoPAIN BP within three years of the receipt of regulatory approval permitting such commercialization.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

#### Cassel

In October 1999, the Company acquired from Dr. R. Douglas Cassel certain patent applications relating to technology for the treatment of surgical incision pain. On July 16, 2003, this royalty agreement was amended. Pursuant to the agreement, the Company is obligated to pay Dr. Cassel a fee of \$4,000 per month until July 2006 and is also obligated to pay Dr. Cassel royalties based on the net sales of any of the licensed products for the treatment of pain associated with surgically closed wounds. The \$4,000 per month fee will be credited towards these royalty payments. The royalty obligations will terminate upon the expiration of the last to expire acquired patent. As part of the royalty arrangement, the Company has engaged Dr. Cassel as a consultant, for which he is paid on a per diem basis.

## **Epitome**

In August 1999, the Company entered into a sublicense agreement with Epitome Pharmaceuticals Limited under which the Company was granted an exclusive license to certain patents for the topical use of tricyclic anti-depressants and NMDA antagonists as topical analgesics for neuralgia. This technology has been incorporated into EpiCept NP-1. The Company has been granted worldwide rights to make, use, develop, sell and market products utilizing the licensed technology in connection with passive dermal applications. The Company is obligated to make payments to Epitome upon achievement of specified milestones and to pay royalties based on annual net sales derived from the products incorporating the licensed technology. At the end of each year in which there has been no commercially sold products, the Company is obligated to pay Epitome a maintenance fee that is equal to twice the fee paid in the previous year, or Epitome will have the option to terminate the contract. In October 2004, the Company paid Epitome a \$0.1 million maintenance fee. The sublicense terminates upon the expiration of the last to expire licensed patent. The sublicense may be terminated earlier under specified circumstances, such as breaches, lack of commercial feasibility and regulatory issues.

## 4. Property and Equipment

Property and equipment consist of the following:

	December 31,			
		2004		2003
Furniture, office and laboratory equipment	\$	501,356	\$	500,125
Leasehold improvements		125,834		125,834
		627,190		625,959
Less accumulated depreciation		(518,157)		(515,824)
	\$	109,033	\$	110,135

Depreciation expense was approximately \$0.1 million for each of the years ended December 31, 2004, 2003 and 2002, respectively.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

## 5. Other Accrued Liabilities

Other accrued liabilities consist of the following:

		December 31,		
	2004	2003		
Accrued professional fees	\$ 314,941	\$ 242,865		
Income taxes	34,679	145,417		
Other	96,094	90,208		
	\$ 445,714	\$ 478,490		

## 6. Notes, Loans and Financings

The Company is a party to several loan agreements, the amounts, terms and descriptions of which are as follows:

		December 31,			
	2004			2003	
Ten-year, non-amortizing loan due December 31,					
2007(A)	\$	2,089,292	\$	1,937,285	
Ten-year, non-amortizing convertible loan due					
December 31, 2007(B)		2,785,723		2,583,047	
Term loan due June 30, 2007(C)		2,664,873		3,228,808	
Convertible bridge loans due October 30, 2006(D)		4,850,000		4,850,000	
Total notes and loans payable, before debt discount		12,389,888		12,599,140	
Less: debt discount(D)		_		1,316,563	
Total notes and loans payable		12,389,888		11,282,577	
Less: Notes and loans payable, current portion		817,260		1,010,400	
Notes and loans payable, long-term	\$	11,572,628	\$	10,272,177	

(A) In August 1997, EpiCept GmbH entered into a ten-year non-amortizing loan in the amount of 1.5 million with Technologie-Beteiligungs Gesellschaft mbH der Deutschen Ausgleichsbank ("tbg"). Proceeds must be directed toward research, development, production and distribution of pharmaceutical products. The loan bears interest at 6% per annum. The lender also receives additional compensation equal to 9% of the annual surplus (income before taxes, as defined in the agreement) of EpiCept GmbH, reduced by any other compensation received from EpiCept GmbH by virtue of other loans to or investments in EpiCept GmbH provided that tbg is an equity investor in EpiCept GmbH during that time period. To date, EpiCept GmbH has had no annual surplus. The Company considers

the additional compensation element based on the surplus of EpiCept GmbH to be a derivative. The Company has assigned no value to the derivative at each reporting period as no surplus of EpiCept GmbH is anticipated over the term of the agreement.

At the demand of tbg, additional amounts may be due at the end of the loan term up to 30% of the loan amount, plus 6% of the principal balance of the note for each year after the expiration of the fifth complete year of the loan period, such payments to be offset by the cumulative amount of all payments made to the lender from the annual surplus of EpiCept GmbH. The Company is accruing these additional amounts as additional interest up to the maximum amount due over the term of the loan. Accrued interest attributable to these additional amounts totaled \$0.4 and \$0.3 million at December 31, 2004 and 2003, respectively. The effective rate of interest of this loan is 9.7%.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

- (B) In February 1998, EpiCept GmbH entered into a ten-year non-amortizing convertible term loan in the amount of 2.0 million with tbg. The loan is non-interest bearing; however, the loan agreement provides for potential future annual payments from surplus of EpiCept GmbH up to 6% of the outstanding loan principal balance, not to exceed 9% of all payments made from surplus of EpiCept GmbH and limited to 7% of the total financing from tbg. To date, EpiCept GmbH has had no annual surplus. The Company considers the additional compensation element based on the surplus of EpiCept GmbH to be a derivative. The Company has assigned no value to the derivative at each reporting period as no surplus of EpiCept GmbH is anticipated over the term of the agreement.
  - The loan is convertible into shares of the Company's common stock at any time by the holder at a conversion price of \$28.28 per share. The Company can require conversion upon a defined triggering event (such as a sale of substantially all assets of the Company, a public offering of the Company's securities, a sale of more than 50% in voting power of outstanding equity securities of the Company, a merger, etc.) at a calculated conversion price ranging between \$8.08 and \$28.28 based on provisions pertaining to the applicable triggering event. Shares issuable upon conversion of this loan range from 80,824 to 282,885 shares.
- (C) In March 1998, EpiCept GmbH entered into a term loan in the amount of 2.6 million with IKB Private Equity GmbH ("IKB"), guaranteed by the Company. The interest rate on the loan varies and was 10.5% per annum from August 1, 2000 through March 31, 2001, 15% per annum through June 30, 2003 and 20% per annum thereafter. The loan was amended in November 2002 by extending the maturity to December 31, 2006 and incorporating a principal repayment schedule, which commenced April 30, 2004. Quarterly principal payments are 0.2 million (approximately \$0.3 million as of December 31, 2004) except for the payment due December 31, 2006, which will be approximately 0.4 million (approximately \$0.5 million as of December 31, 2004). The loan agreement provides for contingent interest of 4% per annum of the principal balance, becoming due only upon the Company's realization of a profit, as defined in the agreement. The Company has not realized a profit through December 31, 2004. The Company values the contingent interest as a derivative using the fair value method in accordance with SFAS 133. Changes in the fair value of the contingent interest are recorded as an adjustment to interest expense. The fair value of the contingent interest was approximately \$0.7 and \$0.5 as of December 31, 2004 and 2003, respectively. The repayment schedule in effect December 31, 2004 was deferred until June 30, 2005 when repayments in accordance with the schedule will resume. Payments due December 31, 2004 and March 31, 2005 have been deferred until March 31, 2007 and June 30, 2007, respectively. As a result of the deferral, the maturity date has been extended until June 30, 2007. Payment of accrued interest during the period of October 1, 2004 through March 31, 2005 has been deferred until June 30, 2005 although interest continues to accrue in accordance with the terms of the agreement.
- (D) In November 2002, the Company entered into convertible bridge loans with several of its stockholders, in an aggregate amount of up to \$5.0 million. At December 31, 2004 and 2003, the Company had borrowings outstanding of \$4.8 million. The convertible bridge loans bear interest at 8% per annum. The convertible bridge loans are convertible into the next round of preferred stock financing, and also have provisions for optional conversion into preferred stock or common stock. The conversion rate is equal to the lowest price per share paid by any purchaser in a financing of the next round of preferred stock, or at anti-dilutive conversion rates for optional conversion into preferred stock or common stock based upon the achievement of certain milestones. In addition, warrants to purchase preferred stock were issued to the lenders in connection with the convertible bridge loans (see Note 9). Such warrants were valued utilizing the Black-Scholes options pricing model and resulted in recording warrants at \$3.6 million and a discount of \$3.6 million to the convertible bridge loans. The discount is being accreted over the term of the loan. During the years ended December 31, 2004 and 2003, the Company recognized approximately \$0.9 and \$2.5 million, respectively, of non-

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

cash interest expense related to the accretion of the debt discount. The term of the convertible bridge loans have been extended from April 30, 2004 until October 30, 2006.

Emerging Issues Task Force Issue No. 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios, as supplemented by EITF 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments, requires the Company to compute the beneficial conversion feature ("BCF"). The Company computed the BCF of the convertible bridge loan as of the commitment date and accounted for it when certain clinical trial results became available in 2003 that determined the appropriate conversion rate. The BCF is being amortized as additional interest expense through the debt's redemption date. For these convertible bridge loans, the BCF was recorded in April 2003 at approximately \$1.2 million. For the year ended December 31, 2004 and 2003, approximately \$0.4 and \$0.8 million of the BCF was amortized and included as interest expense, respectively.

Investors in the Company's common stock and Preferred Stock hold all of the Company's notes, loans and financings. For the years ended December 31, 2004, 2003 and 2002, the interest expense related to these notes, loans and financings was \$1.4, \$1.2 and \$0.6 million, respectively. The above loans are unsecured. Accretion of the discount of the loans approximated \$1.3, \$3.4 and \$0.2 million for the years ended December 31, 2004, 2003 and 2002, respectively. Such amounts are included in interest expense in the accompanying consolidated statements of operations.

At December 31, 2004 principal payments due on long-term debt are as follows:

Year Ending	
2005	\$ 817,260
2006	6,152,773
2007	5,419,855
Total	\$ 12,389,888

#### 7. Commitments

The Company leases facilities and certain equipment under agreements through 2007 accounted for as operating leases. The leases generally contain renewal options and require the Company to pay all executory costs such as maintenance and insurance. Rent expense was \$0.3 million for each of the years ended December 31, 2004, 2003 and 2002, respectively.

Future minimum rental payments under non-cancelable operating leases as of December 31, 2004 are as follows:

	Year Ending	
2005		\$ 223,000
2006		76,000
2007		45,000
		\$ 344,000

The Company maintains a 401(k) plan covering substantially all employees. The Company is not obligated to make matching contributions to the plan. In 2003, the Company made a contribution of approximately \$35,000 to employees participating in the 401(k) plan for plan year 2002 in order to comply with the top-heavy provisions of Section 416 of the Internal Revenue Code. No contributions were made in 2004 or 2002.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

The Company is a party to a number of research, consulting, and license agreements, which require the Company to make payments to the other party to the agreement upon the other party attaining certain milestones as defined in the agreements. The Company paid approximately \$0.8 million in 2004, the majority of which was in connection with milestones relating to preclinical and clinical trials and manufacturing. As of December 31, 2004 the Company may be required to make future milestone payments, totaling approximately \$5.0 million, under these agreements, of which approximately \$1.5 million is payable during 2005 and approximately \$0.8, \$1.2, \$0.5, and \$1.0 million from 2006 through 2009. In 2004, the Company entered into a clinical research agreement for approximately \$1.2 million with a contract research organization to conduct a clinical trial of our LidoPAIN SP product in Germany. The terms of the agreement require payment upon reaching certain milestones, including patient recruitment. If the contract is cancelled for any reason, the Company is subject to a 15% penalty for any offered but unperformed services. The Company has paid the contract research organization approximately \$0.1 million for services in 2004. The Company is also obligated to make future royalty payments to two of its collaborators under existing license agreements, one based on net sales of EpiCept NP-1 and the other based on net sales of LidoPAIN SP, to the extent revenues on such products are realized. Under its agreement with Epitome Pharmaceuticals, the Company is obligated to pay a maintenance fee annually that is equal to twice the fee paid in the previous year so long as no commercial product sales have occurred and the Company desires to maintain its rights under the license agreement. A maintenance fee payment of \$0.1 million was paid in October 2004.

The Company's Board of Directors ratified the employment agreements between the Company and its chief executive officer and chief financial officer dated as of October 28, 2004. The employment agreements cover an initial term through December 31, 2006, but may be extended for unlimited additional one-year periods, and provide for base salary, discretionary compensation, stock option awards, and reimbursement of reasonable expenses in connection with services performed under the employment agreements. The agreements also compensate such officers in the event of their death or disability, termination without cause, or termination within one year of an initial public offering or a change of control, as defined in the respective employment agreements.

A compensation plan for directors was approved by the Board of Directors. This plan contemplates the payment of annual retainers, meeting fees and the granting of stock options and will be effective upon the consummation of the initial public offering.

#### 8. Preferred Stock and Stockholders' Deficit

The Company is currently authorized to issue two classes of stock: common stock and preferred stock. Pursuant to the Company's Amended Restated Certificate of Incorporation (the "Certificate"), preferred stockholders and common stockholders vote together as a class on all matters presented to the stockholders. Preferred stockholders have the right to the number of votes equal to the number of shares of common stock into which each such share of preferred stock held by such holder could be converted on the date for determination of stockholders entitled to vote. Pursuant to the terms of a voting agreement, the preferred stockholders also have the right, separately from the common stockholders, to elect three directors to the Company's Board of Directors. The voting agreement also fixes the number of directors to be at least seven but no more than eight directors.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

## Preferred Stock

The Company has issued Preferred Stock, as of December 31, 2004, as follows:

				Common
	Shares	Shares	Liquidation	Shares as if
Preferred Stock Series	Authorized	Outstanding	Preference	Converted
A	3,422,620	3,368,385	\$ 6,804,138	1,148,571
В	3,440,069	3,106,736	9,320,208	896,173
C	12,769,573	8,839,573	26,518,719	2,549,876
	19,632,262	15,314,694	\$ 42,643,065	4,594,620

A summary of the rights, preferences, and privileges of the Preferred Stock is as follows:

## Liquidation Preference

In the event of any liquidation, dissolution or winding up of the affairs of the Company, whether voluntary or involuntary, the holders of Series C redeemable convertible preferred stock ("Series C Preferred") are entitled to be ratably paid first out of the assets of the Company available for distribution an amount equal to \$3.00 per share, plus all dividends accrued or declared thereon but unpaid. The holders of Series B redeemable convertible preferred stock ("Series B Preferred") are entitled to be ratably paid next in an amount equal to \$3.00 per share, plus all dividends accrued or declared thereon but unpaid. The holders of Series A convertible preferred stock ("Series A Preferred") are entitled then to be ratably paid in an amount equal to \$2.02 per share, plus all dividends accrued or declared thereon but unpaid. No payment shall be made with respect to any series of preferred stock unless and until full payment has been made to the holders of the series of convertible preferred stock with preferential rights of the amounts that they are entitled to receive. After the payment in full of the Series A Preferred, the remaining assets and funds of the Company legally available for distribution, if any, are distributable ratably among the holders of common stock and the Preferred Stock in proportion to the number of shares of common stock then held by them or issuable to them upon conversion of the Preferred Stock then held by them.

## Conversion Rights

Each share of Preferred Stock is convertible, without the payment of any additional consideration by the holder thereof, at the option of the holder, subject to future adjustments for stock splits, stock dividends, recapitalizations or other similar events, as well as future dilutive issuances of common stock. Future dilutive issuances of common stock or Preferred Stock may result in additional beneficial conversion features.

Each share of Preferred Stock will automatically be converted into shares of common stock upon the closing of a firm commitment for an underwritten public offering pursuant to an effective registration statement covering the offer and the sale of the common stock at an offering price per share of not less than \$1.00 and with gross proceeds to the Company of not less than \$15 million. The holders of Preferred Stock have registration rights, under an amended and restated registration rights agreement, which requires the Company, upon request, to register

25% of the "Registrable Securities" as defined in the registration rights agreement at any time after the earlier of April 28, 2002 or the dat
that is six months after the closing of the Company's first public offering of securities. In addition, the holders of the Preferred Stock are
entitled to "piggy back" registration rights in conjunction with a public offering of the Company's common stock.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

#### Dividends

The holders of Series B Preferred and Series C Preferred are entitled to receive, when and as declared by the Board of Directors, preferential cumulative dividends in cash at the rate of 7% per annum of the preferred stock's stated value of \$1.50 per share, subject to adjustment as defined in the Certificate. Such dividends accrue from the original issue date, as defined, of each of the Series B Preferred and Series C Preferred. Dividends are payable to the holders of Series B Preferred only to the extent that holders of Series C Preferred first receive the dividend payment to which they are entitled. The Company's Board of Directors has not declared any dividend payment on any class of preferred stock or common stock. Dividends are being recorded as an addition to the preferred stock carrying value through the earliest redemption date (see "Redemption" below). The total amount of accreted dividends was approximately \$5.3 and \$4.1 million as of December 31, 2004 and 2003, respectively.

#### Redemption

Each holder of Series B Preferred and Series C Preferred may request the Company to redeem for cash such holder's preferred stock, ratably on each of December 31, 2006, 2007 and 2008, or in any amount thereafter at \$1.50 per share plus all dividends accrued but unpaid, and any and all other amounts owing with respect to the holder's shares of such preferred stock. The redemption price for each share of Series B Preferred or Series C Preferred is subject to adjustment to take account of any stock splits, stock dividend, combination of shares, or other similar event.

#### Other

In connection with the convertible bridge loans (see Note 6), the Company recorded BCF's related to adjustments made to the conversion ratios of the Preferred Stock. The adjustments to the conversion ratios entitled the Preferred Stockholders to additional shares of common stock upon conversion. The BCF approximated \$3.3 million, increasing the carrying value of the Preferred Stock with a related charge to additional paid-in capital, to the extent available, and to accumulated deficit in 2003.

## Common Stock

In 1999, the Company repurchased 12,500 shares of its common stock at a cost of \$75,000, which has been recorded as treasury stock for accounting purposes.

## 9. Stock Options and Warrants

## Stock Options

The EpiCept Corporation 1995 Stock Option Plan as amended in 1997 and 1999 (the "Plan") provides for the granting of incentive stock options and non-qualified stock options to purchase the Company's stock through the year 2005. A total of approximately 0.8 million shares of the Company's common stock are authorized under the Plan. As of December 31, 2004, the number of shares of common stock available for grant under the Plan is 236,942 shares. Options are to be granted and vest as determined by the Board of Directors, generally over a three-year period.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

Stock option activity under the Plan is as follows:

			Weighted
	Under		Average
	Option	1	Exercise Price
Options outstanding at December 31, 2001	579,597	\$	1.56
Options granted	161,667	\$	1.56
Options canceled/expired	(90,456)	\$	1.20
Options exercised	(7,148 )	\$	1.20
Options outstanding at December 31, 2002	643,660	\$	1.52
Options granted	11,250	\$	2.00
Options canceled/expired	(139,003)	\$	1.84
Options exercised	(500 )	\$	1.20
Options outstanding at December 31, 2003	515,407	\$	1.44
Options exercised	(48,782)	\$	1.40
Options outstanding at December 31, 2004	466,625	\$	1.48
Options exercisable at December 31, 2002	387,701	\$	1.64
Options exercisable at December 31, 2003	416,463	\$	1.44
Options exercisable at December 31, 2004	459,793	\$	1.44

The following table summarizes information about stock options outstanding at December 31, 2004:

	Options Outstanding			Options Exercisable		
	Options	Weighted-	Weighted-	Veighted- Shares		
	Outstanding at	Average	ge Average Exercisable at		Average	
Range of	December 31,	Remaining	Exercise	December 31,	Exercise	
 <b>Exercise Price</b>	2004	Contractual Life Price		2003	Price	
\$ 1.20	358,500	6.3 years	\$ 1.20	358,424	\$ 1.20	
2.00	71,875	7.4 years	2.00	65,119	2.00	
3.00	36,250	4.5 years	3.00	36,250	3.00	
	466,625		1.48	459,793	1.44	

During 2004, the Company granted no options to employees. However, the Company's Board of Directors approved the grant of stock options to two of the Company's employees, subject to consummation of the Company's proposed initial public offering. The options enable

such employees to purchase 131,250 shares of the Company's common stock in the aggregate. The exercise price of the grants will be equal to the initial public offering price. One half of the options will vest on the grant date and the remainder will vest ratably on a monthly basis over a two-year period.

During 2003, the Company granted options to employees to purchase an aggregate of 11,250 shares of common stock at exercise prices that were considered to be below the deemed fair value at the date of grant for financial reporting purposes resulting in deferred stock compensation of \$45,000. Such amount is being amortized over the option vesting period. The Company adjusted the deferred stock compensation by \$0.1 million for stock option forfeitures during the year.

During 2002, the Company granted options to employees to purchase an aggregate of 161,667 shares of common stock at exercise prices, which were considered to be below the deemed fair value at the date of grant for financial reporting purposes resulting in deferred stock compensation of approximately

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

\$0.7 million. Such amount is being amortized over the option vesting period. The Company adjusted the deferred stock compensation by \$0.1 million for stock option forfeitures during the year.

Amortization of deferred stock compensation approximated \$0.4, \$0.6 and \$0.9 million for the years ended December 31, 2004, 2003, and 2002, respectively.

The fair value of the Company's common stock for options granted during 2003 and 2002 was determined contemporaneously at the time of the grant by the board of directors, with input from management. Prior to the completion of the Adolor license agreement in July 2003, the Company utilized the value paid for each of its series of preferred stock as an estimate of the fair value of its common stock. The majority of the Company's historical stock option grants contained exercise prices below the estimated fair value of the underlying shares at the time of grant.

During 2004, the Company's Board of Directors approved the establishment of a stock option pool under the Company's 2004 Stock Option Plan (which will be implemented upon consummation of the proposed initial public offering), initially equal to 2% of the fully-diluted outstanding common stock of the Company immediately following the consummation of the Company's proposed initial public offering. The options in the pool vest within four years of the date of the applicable grant, and their exercise price will be equal to the initial offering price. Options to employees under the pool were approved for issuance upon successful completion of the initial public offering.

#### Warrants

In connection with the issuance of the convertible bridge loans discussed in Note 6, the Company issued warrants in 2003 and 2002 entitling the lenders, subject to adjustments as defined, to purchase a number of shares equal to 50% of the greatest principal amount outstanding under the loan divided by the applicable exercise price as described in the warrant. The warrants are exercisable into preferred stock or common stock, at any time through November 2012 and possess certain anti-dilutive rights, as defined in the warrant. In the event of an initial public offering of the Company's common stock, the warrants are exercisable into 3,861,464 shares of common stock at an exercise price of \$0.628 per share, however, such warrants will expire on the first business day following the date of the consummation of an initial public offering. The fair value ascribed to the warrants was \$1.9 million in 2003 and \$1.7 million in 2002 and was determined utilizing the Black-Scholes option pricing model. The following assumptions were used: dividend yield of zero (0%) percent; risk free interest rate of 4.53%; volatility of 101%; and expected life of 4 years.

The value of these warrants of \$3.6 million has been recorded as temporary equity as the warrants are potentially exercisable into redeemable preferred stock.

The following table summarizes shares issuable upon exercise of warrants outstanding at December 31, 2004:

				Common
Expiration Date	<b>Shares Issuable Upon Exercise</b>	Ex	tercise Price	Shares Issuable
August 2010	333,333 Series B Preferred	\$	1.30	96,153
November 2012	750,000 Series C Preferred	\$	1.30	216,346
November 2012	6,062,500 Common	\$	0.40	6,062,500
	August 2010  November 2012	August 2010 333,333 Series B Preferred  November 2012 750,000 Series C Preferred	August 2010 333,333 Series B Preferred \$  November 2012 750,000 Series C Preferred \$	August 2010       333,333 Series B Preferred       \$ 1.30         November 2012       750,000 Series C Preferred       \$ 1.30

Total 6,374,999

The number of shares issuable upon the exercise of the warrants is subject to adjustment to take account of any stock splits, stock dividend, combination of shares, or other similar event. In April 2002, warrants to purchase 24,753 shares of Series A Preferred expired unexercised. In April 2004, 74,259 warrants issued in April 1997 were exercised via a net share issuance of 53,225 shares of Series A

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

Preferred. A BCF charge of \$0.2 million was recorded to reflect a dividend deemed to be paid at the exercise date.

#### Third Party Stock-Based Compensation

During 2002 and 2001, the Company granted options to purchase the Company's common stock to third party consultants in connection with service agreements. Compensation expense relating to third party stock-based compensation was approximately \$0.1 million, \$0.2 million and \$47,000 for the years ended December 31, 2004, 2003 and 2002, respectively. The Company values these options utilizing the Black-Scholes option pricing model and remeasures them during the vesting period.

#### 10. Income Taxes

The Company has deferred tax assets of \$19.5 and \$16.9 million as of December 31, 2004 and 2003, respectively, for items including: net operating loss carryforwards ("NOLs"), stock-based compensation, deferred revenue, patent costs and accrued liabilities. As of December 31, 2004 and 2003, the Company has federal, state, and foreign NOLs of approximately \$60.4 and \$44.6 million, respectively, available to reduce future taxable income. The Company's federal and state NOLs expire in various intervals through 2024. In the event of certain ownership changes, the Company's ability to utilize the tax benefits from NOLs could be substantially limited. In accordance with SFAS 109, *Accounting for Income Taxes*, the Company has provided a valuation allowance for the full amount of its net deferred tax assets because it is not more likely than not that the Company will realize future benefits associated with deductible temporary differences and NOLs at December 31, 2004 and 2003.

The valuation allowance at December 31, 2004 and 2003 was approximately \$19.5 and \$16.9 million, respectively. For the years ended December 31, 2004, 2003 and 2002, the valuation allowance increased by \$2.6, \$3.4 and \$3.6 million, respectively.

A reconciliation of the federal statutory tax rate and the effective tax rates for the years ended December 31, 2004, 2003, and 2002 is as follows:

	11	For the Tear Ended			
		December 31,			
	2004	2003	2002		
Statutory tax rate	(34.0)%	(34.0)%	(34.0)%		
State income taxes, net of federal benefit	(3.4)	(0.6)	(1.5)		
Nondeductible expenses	1.8	2.8	_		
Change in valuation allowance	32.2	31.2	33.2		
Effective tax rate	(3.4)%	(0.6)%	(2.3)%		
	_				

For the Year Ended

The principal differences between the U.S. statutory tax benefit rate of 34% and the Company's effective tax benefit rates of 3.4%, 0.6%, and 2.3% for the years ended December 31, 2004, 2003 and 2002, respectively, are primarily due to the state income tax benefit from the sale of state NOLs and the Company not recognizing the benefit of its NOLs incurred during the year.

Federal income tax expense for the years ended December 31, 2004 and 2003 was \$0 and \$31,000, respectively. Federal income tax expense for 2003 was comprised of current alternative minimum tax. State income benefit for the years ended December 31, 2004 and 2003 was \$(0.3) and \$(0.1) million, respectively. The 2004 and 2002 state income tax benefit resulted from the sale of some state NOLs of \$0.3 and \$0.2 million, respectively. The 2003 state income tax benefit was comprised of state income tax expense of \$0.1 million offset by a state income tax benefit resulting from the sale of some state NOLs of \$0.2 million.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

During the years ended December 31, 2004, 2003 and 2002, the Company sold a portion of its state NOLs resulting in a state tax benefit of approximately \$0.3 million in each of those years. The sales of cumulative NOLs are a result of a New Jersey state law enacted January 1, 1999 allowing emerging technology and biotechnology companies to transfer or "sell" their unused New Jersey NOLs and New Jersey research and development tax credits to any profitable New Jersey company qualified to purchase them for cash. The Company received approval from the State of New Jersey to sell NOLs in November of each year and entered into a contract with a third party to sell the NOLs at a discount for approximately \$0.3, \$.02 and \$0.2 million in December of each year. Accordingly, the valuation allowance was reduced by the gross amount of \$0.3 million each as of December 31, 2004, 2003 and 2002.

The principal components of deferred tax assets, liabilities and the valuation allowance are as follows:

	 December 31,		
	 2004		2003
Deferred tax assets:			
Patent costs	\$ 544,000	\$	623,000
Stock-based compensation	1,495,000		1,321,000
Accrued liabilities	590,000		818,000
Amortization of discount	_		167,000
Deferred revenue	2,828,000		3,124,000
Other assets	53,000		64,000
Net operating loss carryforwards	14,014,000		10,767,000
Total deferred tax assets	19,524,000		16,884,000
Valuation allowance	(19,524,000)		(16,884,000)
Net deferred tax asset	\$ -	\$	-

## 11. Restatement of December 31, 2003 Consolidated Financial Statements

In connection with the review of our revenue recognition policy and subsequent to the issuance of the Company's December 31, 2003 consolidated financial statements, the Company determined such statements contained an error relating to the accounting treatment that had been applied to the recognition of revenue under the Endo license agreement, which was signed in December 2003.

The Company had previously recognized revenue from the non-refundable, upfront license fee received from Endo ratably over the estimated development period in which the Company is obligated to participate on a continuing and substantial basis in the research and development activities as outlined in the contract. The Company subsequently determined that such revenue should be recognized on the proportional performance method based on research and development costs incurred compared to total estimated costs to be incurred over the development period which approximates the proportion of value of the services provided compared to the total estimated value over the development period. As costs are weighted to the latter part of the development period, revenue is recognized more slowly using this method than under the ratable revenue recognition method. As a result, the accompanying December 31, 2003

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

consolidated financial statements have been restated from the amounts previously reported to correct the accounting for this item. The following is a summary of the effects of the restatement:

	As Previously	
	 Reported	As Restated
For the year ended December 31, 2003:		
Revenue	\$ 433,810	\$ 376,575
Net loss	(9,903,296)	(9,960,531)
Basic and diluted loss per common share	(6.00)	(6.79)
As of December 31, 2003:		
Deferred revenue, current portion	\$ 2,500,508	\$ 1,115,089
Deferred revenue	7,065,682	8,508,336
Accumulated deficit	(50,353,727)	(50,410,962)
Stockholders' deficit	(43,594,948)	(43,652,183)

### 12. Subsequent Event

In March 2005, the Company completed a private placement of 8% Senior Notes due in 2006 in the aggregate principal amount of \$4.0 million. Each of the purchasers also purchased warrants exercisable for a specified amount of shares of the Company's common stock or preferred in certain specified circumstances. The Senior Notes mature on October 30, 2006 and the warrants expire on March 3, 2008. The Company may prepay the Senior Notes, including all accrued and unpaid interest, at any time without premium or penalty. The Company is required to repurchase the Senior Notes upon the completion of any public sale of its debt or equity securities.

The Company will allocate the proceeds between the Senior Notes and the detachable warrants based on their relative fair market values and record a debt discount. The warrants are exercisable by the purchaser at any time before the earlier to occur of (a) March 3, 2008 or (b) a merger, consolidation, share exchange sale of the Company, certain change of control events and events of liquidation. If the Company's initial public offering has not been consummated by March 3, 2006, the expiration date of the warrants will be extended until March 3, 2009. Upon the consummation of an initial public offering by the Company, the warrant share number will equal 35% of the principal amount of the purchaser's Senior Note divided by the initial public offering price, and the exercise price of the warrant shares will be 75% of the initial public offering price.

The warrants issued in connection with the March 2005 private placement meet the requirements of and will be accounted for as a liability in accordance with EITF 00-19 as the number and price of the warrant shares are unknown at the time of financing. The number and price of the warrant shares will be determined by the price of the common stock issued in an initial public offering or the next preferred stock transaction. The value of the warrant shares will be marked to market each reporting period as a derivative gain or loss until exercised or expiration. As of March 31, 2005, the warrants had a fair market value of \$908,000. The fair value of the warrants was determined utilizing the Black-Scholes option-pricing model utilizing the following assumptions: dividend yield of 0%, risk free interest rate of 3.76%, volatility of 90% and an expected life of three years.

## 13. Reverse Stock Split

On April 15, 2005, the Company's stockholders approved a 1 for 4 reverse stock split of its common stock. The accompanying consolidated financial statements have been retroactively adjusted to reflect the reverse stock split.

5,500,000 Shares



<b>Common Stock</b>
PROSPECTUS
, 2005

Wachovia Securities

C.E. Unterberg, Towbin Jefferies & Company, Inc.

Until , 2005 (25 days after the commencement of this offering), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

#### PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

## Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses, other than the underwriting discounts, payable by the Registrant in connection with the sale of the securities being registered. All amounts are estimates except the SEC registration fee, the NASD filing fee and The Nasdaq National Market listing fee.

SEC Registration Fee	\$ 8,827.50
NASD Filing Fee	9,145.00
Nasdaq National Market Listing Fee	130,000.00
Printing costs	400,000.00
Legal fees and expenses	800,000.00
Accounting fees and expenses	750,000.00
Blue Sky fees and expenses	2,000.00
Transfer Agent and Registrar fees	5,000.00
Miscellaneous	18,027.50
Total	\$ 2,123,000.00

#### Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law ("Section 145") permits indemnification of officers and directors of the Company under certain conditions and subject to certain limitations. Section 145 also provides that a corporation has the power to maintain insurance on behalf of its officers and directors against any liability asserted against such person and incurred by him or her in such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify him or her against such liability under the provisions of Section 145.

Article 6, Section 1, of the Registrant's Amended and Restated Certificate of Incorporation provides for mandatory indemnification of its directors and officers and permissible indemnification of employees and other agents to the maximum extent not prohibited by the Delaware General Corporation Law. The rights to indemnity thereunder continue as to a person who has ceased to be a director, officer, employee or agent and inure to the benefit of the heirs, executors and administrators of the person. In addition, expenses incurred by a director or executive officer in defending any civil, criminal, administrative or investigative action, suit or proceeding by reason of the fact that he or she is or was a director or officer of the Registrant (or was serving at the Registrant's request as a director or officer of another corporation) shall be paid by the Registrant in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that he or she is not entitled to be indemnified by the Registrant as authorized by the relevant section of the Delaware General Corporation Law.

As permitted by Section 102(b)(7) of the Delaware General Corporation Law, the Registrant's Certificate of Incorporation provides that, pursuant to Delaware law, its directors shall not be personally liable for monetary damages for breach of the directors' fiduciary duty as directors to the Registrant and its stockholders. This provision in the Certificate of Incorporation does not eliminate the directors' fiduciary duty, 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 omission not in good faith or involving international misconduct, for knowing violations of law, for actions leading to improper

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also does not affect a director's responsibilities under any other law, such as the federal securities laws or state or federal environmental laws.

The Registrant intends to enter into indemnification agreements with each of its directors and executive officers and to purchase directors' and officers' liability insurance. Generally, the indemnification agreements attempt to provide the maximum protection permitted by Delaware law as it may be amended from time to time. Moreover, the indemnification agreements provide for certain additional indemnification. Under such additional indemnification provisions, an individual will receive indemnification for expenses, judgments, fines and amounts paid in settlement if he or she is found to have acted in good faith and in a manner reasonably believed to be in, or not opposed to, the best interests of the Registrant, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. Notwithstanding anything to the contrary in the indemnification agreement, the Registrant shall not indemnify any such director or executive officer seeking indemnification in connection with any action, suit, proceeding, claim or counterclaim, or part thereof, initiated by such person unless the initiation thereof was authorized in the specific case by the Board of Directors of the Registrant. The indemnification agreements provide for the Registrant to advance to the individual any and all expenses (including attorneys' fees) incurred in defending any proceeding in advance of the final disposition thereof. In order to receive an advance of expenses, the individual must submit to the Registrant copies of invoices presented to him or her for such expenses. Also, the individual must repay such advances upon a final judicial decision that he or she is not entitled to indemnification.

In addition to the foregoing, the Underwriting Agreement contains certain provisions by which the Underwriters have agreed to indemnify the Registrant, each person, if any, who controls the Registrant within the meaning of Section 15 of the Securities Act, each director of the Registrant, each officer of the Registrant who signs the Registration Statement, with respect to information furnished in writing by or on behalf of the Underwriters for use in the Registration Statement.

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

## Item 15. Recent Sales of Unregistered Securities.

Since December 31, 2000, we have sold and issued the following securities:

## **Preferred Stock and Debt Financings**

- (1) In 2002, we granted options to Mr. John V. Talley, our President and Chief Executive Officer, and Mr. Scott Kozak, our Vice President, Business Development, and current directors Afting, Caspritz, Ponschab and Spickshen along with former directors Mr. Mark Clement and Mr. Erik Hornnaess, to purchase an aggregate of 141,666 shares of our common stock under our 1995 Stock Option Plan at a weighted average exercise price of \$1.20 per share.
- (2) In November 2002, we entered into a convertible bridge loan arrangement in an aggregate amount of up to \$5,000,000. The lenders under that convertible bridge loan arrangement included Mr. John V. Talley, our President and Chief Executive Officer, and certain holders of our preferred stock, including TVM IV GmbH & Co. KG, Private Equity US Direct Finance (which thereafter transferred its notes to Private Equity Direct Finance), The Merlin Biosciences Fund L.P., The Merlin Biosciences Fund GbR and Gold-Zack Partners I B.V (collectively, the "2002 Bridge Investors"). At December 31, 2003, we had received \$4,850,000. The loan bears interest at 8% per annum and matures on October 30, 2006. The loan is convertible into the next round of preferred stock, and also has provisions for optional conversion preferred stock or common stock. Such conversion shall occur at the lowest price per share paid by any purchaser in the qualifying financing of the next round of preferred stock, or at anti-dilutive conversion rates for optional conversion preferred stock or common stock based upon the results of certain milestones.

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- (3) In connection with the issuance of the convertible bridge loan, in November 2002, we also issued warrants to the 2002 Bridge Investors to purchase 6,062,500 shares of common stock entitling the 2002 Bridge Investors, subject to adjustments as defined, to purchase a number of shares equal to 50% of the greatest principal amount that has been outstanding under such holder's note divided by the applicable exercise price as described in the agreement. The warrants are convertible into the next round of preferred stock, optional conversion preferred stock or common stock. The warrants are exercisable at any time through November 2012 and possess certain anti-dilutive rights as defined in the agreement.
- (4) In 2003, we granted options to current directors Afting, Caspritz, Docherty, Ponschab and Spickschen and former director Hornnaess to purchase an aggregate of 11,250 shares of our common stock under our 1995 Stock Option Plan at a weighted average exercise price of \$2.00 per share.
- (5) In March 2005, we completed the private placement of \$4.0 million aggregate principal amount of our senior notes due 2006. The purchasers of our senior notes included Sanders Opportunity Fund, L.P. and Sanders Opportunity Fund (Institutional), L.P. (collectively, the "Sanders Investors") and certain holders of our preferred stock, including TVM Techno Venture Management ("TVM"), Private Equity Direct Finance and Merlin General Partner II Limited (collectively with the Sanders Investors, the "2005 Investors"). The Sanders Investors are "accredited investors" as that term is defined in Regulation D of the Securities Act. TVM is a "qualified institutional buyer" within the meaning of Rule 144A under the Securities Act. Both Private Equity Direct Finance and Merlin General Partner II Limited are non-U.S. Persons within the meaning of Regulation S under the Securities Act and sales to them were made in accordance with Regulation S and the rules thereunder. The notes bear interest at 8% per annum and mature on October 30, 2006. In the event this initial public offering is not completed, the notes are convertible at the option of the holder into the next round of preferred stock. Such conversion shall occur at the lowest price per share paid by any purchaser in the qualifying financing of the next round of preferred stock.
- (6) In connection with the issuance of the senior notes due 2006, in March 2005, we also issued warrants to the 2005 Investors to purchase common stock or next round preferred stock, entitling the 2005 Investors, subject to adjustments as defined, to purchase a number of shares of common stock equal to 35% of the original principal amount of the senior notes divided by the applicable public offering price as defined in the warrant. The warrants are convertible, under certain specified circumstances, for common stock or the next round of preferred stock. The warrants are exercisable at any time through March 3, 2008 and possess certain anti-dilutive rights as set forth in the warrant.

The sales of the above securities were deemed to be exempt from registration in reliance on Section 4(2) of the Securities Act or Regulation D or Regulation S promulgated thereunder as transactions by an issuer not involving any public offering. All recipients were either accredited, sophisticated investors or non-U.S. persons, as those terms are defined in the Securities Act and the regulations promulgated thereunder. The recipients of securities in each such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and other instruments issued in such transactions. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

## **Stock Options and Stock Purchase Rights**

(1) During 2002, we granted options to employees to purchase an aggregate of 20,000 shares of our common stock under our 1995 Stock Option Plan at a weighted average exercise price of \$1.56 per share. In 2002, 7,147 stock options were exercised.

The sales of the above securities were deemed to be exempt from registration in reliance on Rule 701 promulgated under Section 3(b) under the Securities Act as transactions pursuant to a compensatory benefit plan or a written contract relating to compensation.

## Item 16. Exhibits and Financial Statement Schedules

Exhibit	
Number	Description
†1.1	Form of Underwriting Agreement.
†3.1	Amended and Restated Certificate of Incorporation of the Registrant.
†3.2	Form of Certificate of Incorporation of the Registrant to be in effect after the closing of the offering made under
	this Registration Statement.
†3.3	Second Amended and Restated Bylaws of the Registrant.
†3.4	Form of Bylaws of the Registrant to be in effect after the closing of the offering made under this Registration
	Statement.
†4.1	Specimen Common Stock Certificate.
†4.2	First Amendment to the Amended and Restated Registration Rights Agreement, dated as of December 28, 2000,
	among the Series A Investors, the Series B Investors, the Series C Investors, the Founders and the Registrant.
†4.3	Form of Third Amended and Restated Convertible Term Note.
†4.4	Form of Third Amended and Restated Stock Purchase Warrant.
†4.5	Warrant for the purchase of Series C Convertible Preferred Stock, dated November 30, 2000, issued by EpiCept
	Corporation to Private Equity US Direct Finance.
†4.6	Warrant for the purchase of Series B Convertible Preferred Stock, dated August 14, 2000, issued by EpiCept
	Corporation to Alpinvest International B.V.
†4.7	Warrant for the purchase of Series B Convertible Preferred Stock, dated August 9, 2000, issued by EpiCept
	Corporation to TVM Techno Ventures Enterprises No. III Limited Partnership.
†5.1	Opinion of Weil, Gotshal & Manges LLP.
†10.1	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.
†10.2	1995 Stock Option Plan.
†10.3	2005 Equity Incentive Plan.
†10.4	2005 Employee Stock Purchase Plan.
†10.5	Employment Agreement, dated as of October 28, 2004, between the Registrant and John V. Talley.
†10.6	Employment Agreement, dated as of October 28, 2004, between the Registrant and Robert Cook.
†10.7(1)	License Agreement, dated as of July 23, 2003, between Adolor Corporation and the Registrant.
†10.8	Amendment No. 1 to License Agreement, dated as of October 21, 2004, between Adolor Corporation and the
	Registrant.
†10.9(1)	License Agreement, dated as of December 18, 2003, between Endo Pharmaceuticals Inc. and the Registrant.
†10.10(1)	Royalty Agreement, dated as of July 16, 2003, between the Registrant and R. Douglas Cassel, M.D.
†10.11(1)	Sublicense Agreement, dated as of August 27, 1999, between Epitome Pharmaceuticals Limited and American
	Pharmed Labs, Inc.
†10.12	Lease Agreement between Connecticut General Life Insurance Company, as Landlord, and American Pharmed
	Labs, Inc., as Tenant, dated July 31, 1997.
†10.13	Cooperation Agreement between APL American Pharmed Labs, Inc. and Technologie-Beteiligungs-Gesellschaft
	mbH, dated August 1997.
†10.14	Investment Agreement between Pharmed Labs GmbH and Technologie-Beteiligungs-Gesellschaft mbH, dated
	August 1997.
†10.15	Investment Agreement among Pharmed Labs GmbH, American Pharmed Labs, Inc. and Technologie-
	Beteiligungs-Gesellschaft mbH, dated February 17, 1998.

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Exhibit				
Number	Description			
†10.16	Letter Agreement, dated March 31, 1998, between Pharmed Labs GmbH and IKB Nachrangkapital GmbH.			
†10.17	Limited Guaranty, dated April 27, 1998, by American Pharmed Labs, Inc. for the benefit of IKB Nachrangkaptial GmbH.			
†10.18	Note Purchase Agreement (the "Note Purchase Agreement"), dated as of March 3, 2005, by and among EpiCept			
	Corporation and the Purchasers named on the signature pages thereto.			
†10.19	Form of Note issued pursuant to the Note Purchase Agreement.			
†10.20	Form of Warrant issued pursuant to the Note Purchase Agreement.			
†10.21	Second Amended and Restated Registration Rights Agreement, dated as of March 4, 2005, among the Series A			
	Investors, the Series B Investors, the Series C Investors, the Founders, the New Warrant Holders and the			
	Registrant.			
†10.22	First Exchange Option Agreement, dated as of December 31, 1997, by and between American Pharmed Labs, Inc.			
	and tbg Technologie-Beteiligungs-Gesellschaft mbg der Deutschen Ausgleichsbank.			
†10.23	Second Exchange Option Agreement, dated as of February 17, 1998, by and between American Pharmed Labs,			
	Inc. and tbg Technologie-Beteiligungs-Gesellschaft mbh der Deutschen Ausgleichsbank.			
†11.1	Statement Regarding Computation of Per Share Earnings (incorporated by reference to the Notes to Consolidated			
	Financial Statements included in Part I of this Registration Statement).			
†16.1	Letter Regarding Change in Certifying Accountant.			
†21.1	List of Subsidiaries.			
23.1	Consent of Deloitte & Touche LLP.			
†23.2	Consent of Weil, Gotshal & Manges LLP (included in Exhibit 5.1).			
†24.1	Power of Attorney.			

## † Previously filed.

Pursuant to a request for confidential treatment, portions of the Exhibit have been redacted from the publicly filed document and have been furnished separately to the SEC as required by Rule 406 under the Securities Act.

## (b) Financial Statement Schedules

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

## Item 17. Undertakings.

The undersigned 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 Securities 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

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jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities 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.
- (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

## **SIGNATURES**

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this Amendment No. 5 to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Englewood Cliffs, state of New Jersey, on May 2, 2005.

EPICEPT CORPORATION	EPICEPT	CORPOR	ATION
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By:	*	

John V. Talley
President and Chief Executive Officer

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

Signature	Title	Date
* John V. Talley	Director, President and Chief Executive Officer (Principal Executive Officer)	May 2, 2005
Robert W. Cook	Chief Financial Officer (Principal Financial and Accounting Officer)	May 2, 2005
* Robert G. Savage	Director	May 2, 2005
* Gert Caspritz	Director	May 2, 2005
* Ernst-Günter Afting	Director	May 2, 2005
* Mark Docherty	Director	May 2, 2005
* Reiner Ponschab	Director	May 2, 2005
* Thorlef Spickschen	Director	May 2, 2005
* Guy C. Jackson	Director	May 2, 2005
Robert W. Cook	Attorney-in-Fact	May 2, 2005

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<sup>†</sup> Previously filed.

Pursuant to a request for confidential treatment, portions of the Exhibit have been redacted from the publicly filed document and have been furnished separately to the SEC as required by Rule 406 under the Securities Act.

## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Amendment No. 5 to the Registration Statement No. 333-121938 of our report dated March 29, 2005, April 15, 2005 as to the effects of Note 13 (which report expresses an unqualified opinion and includes explanatory paragraphs referring to the Company's ability to continue as a going concern referred to in Note 1 and the restatement of the 2003 financial statements referred to in Note 11) relating to the financial statements of EpiCept Corporation appearing in the Prospectus, which is part of this Registration Statement.

We also consent to the reference to us under the headings "Experts" and "Change in Independent Public Accounting Firm" in such Prospectus.

DELOITTE & TOUCHE LLP

Parsippany, New Jersey May 2, 2005