SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended September 30, 2000

Commission File Number 000-23736

GUILFORD PHARMACEUTICALS INC.
(Exact name of Registrant as specified in its charter)

Delaware	**52-1841960**
(State or other jurisdiction of incorporation or organization)	*(IRS Employer Identification No.)*
6611 Tributary Street **Baltimore, Maryland** *(Address of principal executive offices)*	**21224** *(Zip Code)*

410-631-6300
(Registrant's telephone number, including area code)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes [X] No [ ]

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of the latest practicable date.

Class	Outstanding at November 10, 2000
Common Stock, $0.01 par value	23,898,401

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PART I. FINANCIAL INFORMATION

Item 1. ***Financial Statements.***

GUILFORD PHARMACEUTICALS INC.
AND SUBSIDIARIES

Consolidated Balance Sheets
(in thousands, except share data)

	September 30, 2000 (unaudited)	December 31, 1999
Assets		
Current assets:		
Cash and cash equivalents	$ 23,051	$ 14,336
Investments	74,464	108,997
Accounts and contract receivable	1,576	1,020
Inventories	1,776	1,348
Other current assets	1,022	752
Total current assets	101,889	126,453
Investments — restricted	19,615	21,385
Property and equipment, net	14,076	15,793
Other assets	1,246	611
	$ 136,826	$164,242
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,536	$ 3,085
Current portion of long-term debt	2,214	2,214
Accrued payroll related costs	2,163	2,070
Accrued contracted services	1,249	2,066
Accrued expenses and other current liabilities	1,332	1,550
Deferred income	—	1,125
Total current liabilities	10,494	12,110
Long-term debt, net of current portion	5,491	7,152
Total liabilities	15,985	19,262
Stockholders' equity:		
Preferred stock, par value $0.01 per share; authorized 4,700,000 shares, none issued	—	—
Series A junior participating preferred stock, par value $0.01 per share; authorized 300,000 shares, none issued	—	—
Common stock, par value $0.01 per share; authorized 75,000,000 shares, 23,844,845 and 23,328,313 issued at September 30, 2000 and December 31, 1999, respectively	238	233
Additional paid-in capital	239,533	232,913
Accumulated deficit	(114,116)	(82,877)
Accumulated other comprehensive loss	(1,350)	(1,838)
Note receivable from officer	(60)	(60)
Treasury stock, at cost: 267,868 and 274,880 shares at September 30, 2000 and December 31, 1999, respectively	(3,336)	(3,284)
Deferred compensation	(68)	(107)
Total stockholders' equity	120,841	144,980
	$ 136,826	$164,242

See accompanying notes to consolidated financial statements.

GUILFORD PHARMACEUTICALS INC.
AND SUBSIDIARIES

Consolidated Statements of Operations (unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2000	**1999**	**2000**	**1999**
Revenues:				
Contract revenues	$ 1,000	$ 4,500	$ 2,000	$ 4,500
Net product sales	285	565	1,492	3,432
License fees and royalties	521	542	1,622	1,785
Revenues under collaborative agreements	1,172	1,269	3,422	3,682
Total revenues	2,978	6,876	8,536	13,399
Costs and expenses:				
Cost of sales:				
Net product sales	140	303	797	1,746
Unabsorbed manufacturing overhead	455	—	455	—
Research and development	12,230	11,050	34,106	30,660
General and administrative	3,146	2,208	8,634	8,383
Merger costs	332	—	1,403	—
Total costs and expenses	16,303	13,561	45,395	40,789
Operating loss	(13,325)	(6,685)	(36,859)	(27,390)
Other income (expense):				
Investment and other income	1,902	1,642	6,030	5,584
Interest expense	(136)	(166)	(410)	(514)
Net loss	$(11,559)	$ (5,209)	$(31,239)	$(22,320)
Basic and diluted loss per common share	$ (0.49)	$ (0.26)	$ (1.33)	$ (1.14)
Weighted-average common shares outstanding	23,502	19,937	23,404	19,608

See accompanying notes to consolidated financial statements.

GUILFORD PHARMACEUTICALS INC.
AND SUBSIDIARIES

Consolidated Statement of Changes in Stockholders' Equity (unaudited)
Nine Months Ended September 30, 2000
(in thousands, except share data)

	Common Stock				
	Numbers of Shares Issued	Dollar Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss
Balance, January 1, 2000	23,328,313	$233	$232,913	$ (82,877)	$(1,838)
Comprehensive loss:					
Net loss for the period				(31,239)	
Other comprehensive income:					
Unrealized gain on available-for-sale securities					488
Total comprehensive loss					
Issuances upon exercise of options	516,532	5	6,306		
Purchase of 8,285 shares of common stock					
Distribution of 15,297 shares of treasury stock to					
401(k) plan			102		
Stock option compensation			212		
Amortization of deferred compensation					
Balance, September 30, 2000	23,844,845	$238	$239,533	$(114,116)	$(1,350)

[Additional columns below]

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

	Note Receivable From Officer	Treasury Stock, at Cost	Deferred Compensation	Total Stockholders' Equity
Balance, January 1, 2000.	$(60)	$(3,284)	$(107)	$144,980
Comprehensive loss:				
Net loss for the period				(31,239)
Other comprehensive income:				
Unrealized gain on available-for-sale securities				488
Total comprehensive loss				$ (30,751)
Issuances upon exercise of options				6,311
Purchase of 8,285 shares of common stock		(237)		(237)
Distribution of 15,297 shares of treasury stock to 401(k) plan		185		287
Stock option compensation				212
Amortization of deferred compensation			39	39
Balance, September 30, 2000.	$(60)	$(3,336)	$ (68)	$120,841

See accompanying notes to consolidated financial statements.

GUILFORD PHARMACEUTICALS INC.
AND SUBSIDIARIES

Consolidated Statements of Cash Flows (unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2000	**1999**	**2000**	**1999**
Cash Flows from Operating Activities:				
Net loss	$(11,559)	$ (5,209)	$ (31,239)	$(22,320)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	1,000	1,152	2,997	3,801
Noncash compensation expense	155	638	635	995
Changes in assets and liabilities:				
Accounts and contract receivable and other assets	(1,037)	(300)	(1,471)	(695)
Inventories	107	(225)	(428)	(77)
Accounts payable	(645)	(1,422)	451	(2,158)
Accrued expenses and other current liabilities	(102)	(192)	(1,039)	855
Deferred income	(1,125)	1,125	(1,125)	—
Net cash used in operating activities	(13,206)	(4,433)	(31,219)	(19,599)
Cash Flows from Investing Activities:				
Purchases of property and equipment	(514)	(576)	(1,270)	(2,790)
Maturities of marketable securities	53,004	4,505	178,338	90,276
Purchases of marketable securities	(31,325)	(1,136)	(141,547)	(74,558)
Net cash provided by investing activities	21,165	2,793	35,521	12,928
Cash Flows from Financing Activities:				
Net proceeds from issuances of common stock	1,714	42,749	6,311	45,139
Purchase of treasury stock	(146)	—	(237)	(2,209)
Principal payments on debt	(554)	(540)	(1,661)	(1,620)
Net cash provided by financing activities	1,014	42,209	4,413	41,310
Net increase in cash and cash equivalent	8,973	40,569	8,715	34,639
Cash and Cash Equivalents at the Beginning of Period	14,078	2,550	14,336	8,480
Cash and Cash Equivalents at the End of Period	$ 23,051	$43,119	$ 23,051	$ 43,119
Supplemental disclosures of cash flow information:				
Net interest paid	$ 134	$ 161	$ 408	$ 497

See accompanying notes to consolidated financial statements.

GUILFORD PHARMACEUTICALS INC.

Notes to Consolidated Financial Statements
September 30, 2000
(unaudited)

1. Organization and Basis of Presentation

Guilford Pharmaceuticals Inc. (together with its subsidiaries, "Guilford") is a biopharmaceutical company located in Baltimore, Maryland, engaged in the development and commercialization of novel products in two principal areas: (1) targeted and controlled drug delivery systems using proprietary biodegradable polymers for the treatment of cancer and other diseases or conditions and (2) therapeutic and diagnostic products for neurological diseases and conditions.

The consolidated financial statements included herein have been prepared, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures, normally included in consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States of America, have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited financial statements and the related notes included in our annual report on Form 10-K for the year ended December 31, 1999.

In the opinion of management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, necessary to present fairly our financial position, results of operations, changes in stockholders' equity and cash flows for the three-month and nine-month periods ended September 30, 2000 as set forth in the Index. Interim results are not necessarily indicative of results for the full fiscal year.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Guilford Pharmaceuticals Inc. and its subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Earnings (Loss) Per Common Share

Basic earnings (loss) per share ("EPS") are computed by dividing earnings (loss) by the weighted-average number of shares outstanding for the period. The computation of Diluted EPS is similar to Basic EPS except that the weighted-average number of shares outstanding for the period is increased to include the number of additional shares that would have been outstanding if the dilutive potential shares had been issued. Potential common shares are excluded if the effect on earnings (loss) per share is antidilutive.

The following table sets forth the computation our basic and diluted net loss per share (in thousands, except per share amount):

	Three Months Ended September 30,		Nine months Ended September 30,	
	2000	1999	2000	1999
Net loss	$(11,559)	$ (5,209)	$(31,239)	$(22,320)
Weighted-average common shares outstanding	23,502	19,937	23,404	19,608
Basic and diluted loss per common share	$ (0.49)	$ (0.26)	$ (1.33)	$ (1.14)

Recently Issued Accounting Pronouncements

In December 1999, the staff of the SEC issued Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements (“SAB 101”). SAB 101 summarizes certain of the staff’s views in applying generally accepted accounting principles to revenue recognition in the financial statements, including recognition of non-refundable fees received upon entering into arrangements. In June 2000, the SEC issued Staff Accounting Bulletin No. 101B which delays the implementation date of SAB 101 until no later than the fourth fiscal quarter for the fiscal years beginning after December 15, 1999. Accordingly, we are evaluating SAB 101 and the effect it will have on our consolidated financial statements including the effect, if any, on previously recognized transactions with Amgen and Aventis.

Reclassifications

Certain prior year amounts have been reclassified to conform with current year presentation.

3. Inventories and Cost of Sales

	September 30, 2000	December 31, 1999
(in thousands)		
Raw materials	$ 314	$ 280
Work in process	713	416
Finished goods	749	652
	$1,776	$1,348

Inventories are net of applicable reserves and allowances. Inventories include finished goods and raw materials that may be available for sale, consumed in production or consumed internally in our development activities. Inventories identified for development activities are expensed in the period in which such inventories are designated for such use.

As a result of the reacquisition of GLIADEL ® Wafer, we did not manufacture GLIADEL ® Wafer during the three-month period ended September 30, 2000. Therefore, the fixed costs associated with our manufacturing capabilities were shown in our Consolidated Statments of Operations as "Cost of Sales — unabsorbed manufacturing overhead".

4. Termination of Proposed Merger with Gliatech Inc.

On August 28, 2000, we announced that we agreed with Gliatech Inc. (“Gliatech”) to terminate our Agreement and Plan of Merger (the “Merger Agreement”) entered into on May 29, 2000. Under the Merger Agreement, a wholly-owned subsidiary of ours would have acquired all of the outstanding shares of Gliatech in a tax-free transaction intended to be accounted for as a pooling of interests.

Related to the proposed merger, in June 2000, Cartech Company, LTD, (“Cartech”) filed a lawsuit against Gliatech and Guilford alleging breach of and interference with Gliatech’s build-to-suit lease with Cartech. The parties subsequently entered into a settlement agreement to resolve the litigation. Due to the termination of the Merger Agreement on August 28, 2000, we have no payment obligations under the terms of the settlement agreement.

We incurred costs related to the proposed merger transaction of $0.3 million and $1.4 million for the three and nine-month periods ended September 30, 2000, respectively.

5. Investment in ProQuest Pharmaceuticals Inc.

In March 2000, we acquired from ProQuest Pharmaceuticals Inc. ("ProQuest") an exclusive worldwide license to a pro-drug of propofol, a novel pro-drug of a widely used anesthetic agent. Pursuant to this transaction, we paid approximately $0.7 million for 133,333 shares of common stock of ProQuest. In addition, we paid approximately $0.3 million for in process research and development that was charged to earnings during the three-month period ended March 31, 2000. Under the terms of the agreement, we are obligated to make milestone payments based on clinical development and royalties on any product sales. ProQuest is a privately held pharmaceutical company based in Lawrence, Kansas. Because our investment in ProQuest is less than 20% of the outstanding common stock of ProQuest, we have accounted for our investment under the cost method.

6. Related Party Transaction

A note receivable on common stock of $60,000 at September 30, 2000 and December 31, 1999, represents an

amount due from an officer of Guilford related to the officer’s purchase of shares of our common stock. The note bears interest at the rate of 5.34% per

annum and is due and payable on February 14, 2002. This amount is reflected as a reduction of stockholders' equity in the accompanying balance sheets.

7. Subsequent Event — Reacquisition of Commercial Rights to GLIADEL® Wafer

In June 1996, we entered into certain agreements (as amended from time to time, the "Aventis Agreements") with Rhone-Poulenc Rorer Pharmaceuticals Inc. ("RPR," Aventis Pharmaceuticals Inc. ("Aventis") is the successor by merger to RPR as a result of the merger of RPR and Hoescht AG in December 1999) for the worldwide sale, marketing and distribution of GLIADEL® Wafer (except in Scandinavia and Japan).

On October 23, 2000, we entered into a Rights Reversion Agreement (the "Rights Reversion Agreement") with Aventis, pursuant to which we reacquired the rights to sell, market and distribute GLIADEL® Wafer held by Aventis pursuant to the Aventis Agreements (sometimes referred to as the GLIADEL® Wafer Repurchase"). In consideration for the reacquisition of these rights, we issued to Aventis 300,000 shares of the Company's common stock, valued at approximately $8.0 million and granted Aventis certain registration rights with respect to such stock. In accordance with the terms of the Rights Reversion Agreement, after the conclusion of a transition period ending December 31, 2000, we will be responsible for all aspects of the worldwide sale, marketing and distribution of GLIADEL® Wafer (except in Scandinavia where GLIADEL® Wafer will continue to be distributed by Orion Pharma). We intend to continue marketing GLIADEL® Wafer in the United States and Europe (except for Scandinavia) and in other countries to the extent permitted by local laws. Until December 31, 2000, we and Aventis will generally continue to operate under the Aventis Agreements except that Aventis is no longer obligated to make additional milestone payments resulting from GLIADEL® Wafer receiving additional regulatory approvals, nor is it required to make an equity investment in us upon the approval of the use of GLIADEL® Wafer in first surgeries for glioblastoma multiforme. Additionally, we no longer have the right to borrow from Aventis up to $7.5 million, as provided under the Aventis Agreements.

Item 2. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

Cautionary Note

In this quarterly report we make statements that reflect our current expectations regarding our future results of operations, economic performance, and financial condition, as well as other matters that may affect our business. In general, we try to identify these forward-looking statements by using words such as:

- "anticipate,"
- "believe,"
- "expect,"
- "estimate," and similar expressions.

While these statements reflect our current plans and expectations, and we base the statements on information currently available to us, we cannot be sure that we will be able to implement these plans successfully. We may not realize our expectations in whole or in part in the future.

The forward-looking statements contained in this quarterly report may cover, but are not necessarily limited to, the following topics:

- the consequences of our reacquisition from Aventis of the worldwide sale, marketing and distribution rights to GLIADEL® Wafer;

- our efforts to market, sell and distribute GLIADEL® Wafer;
- our efforts to expand the labeled uses for GLIADEL® Wafer, including our efforts to obtain additional U.S. and international regulatory clearances for such uses;
- our efforts to develop polymer drug delivery product line extensions and new polymer drug delivery products;
- our research programs related to our FKBP neuroimmunophilin ligand technology partnered with Amgen Inc. ("Amgen"), as well as our NAALADase inhibition, PARP inhibition, polymer drug delivery and other technologies;
- our clinical development activities, including the commencement and conducting of clinical trials, related to our polymer-based drug delivery products and product candidates (including GLIADEL® Wafer, PACLIMER™ Microspheres and LIDOMER™ Microspheres) and our pharmaceutical product candidates (including lead compounds in our FKBP neuroimmunophilin ligand, NAALADase and propofol pro-drug programs and any future lead compounds in our PARP program);
- our efforts to scale-up product candidates from laboratory bench quantities to commercial quantities;
- our efforts to secure adequate supply of the active pharmaceutical ingredients for clinical development and commercialization;
- our efforts to manufacture drug candidates for clinical development and eventual commercial supply;
- our strategic plans;
- anticipated expenditures and the potential need for additional funds; and
- specific guidance we give in the section entitled "Outlook" below, regarding our current expectations of our future operating results.

All of these items involve significant risks and uncertainties.

Any of the statements we make in this quarterly report that are forward-looking are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We wish to caution you that our actual results may differ materially from the results we discuss in the forward-looking statements.

We discuss factors that could cause or contribute to such differences elsewhere in this quarterly report, as well as in our filings with the SEC. Our SEC filings include our annual report on Form 10-K for the year ended December 31, 1999. For convenience, we refer to this document as the "1999 Form 10-K" in the discussion set forth below. In addition, any forward-looking statements we make in this document speak only as of the date of this document, and, except for our ongoing obligations to disclose material developments as required by the federal securities laws, we do not intend to update or alter any such forward-looking statements to reflect events or circumstances that occur after the date of this report.

Introduction

In the following sections of this Management's Discussion and Analysis of Financial Condition and Results of Operations, we explain the general financial condition and the results of operations for Guilford and its subsidiaries, including:

- what factors affect our business;
- what our revenues and expenses were in the periods presented;
- why our revenues and expenses changed between periods;
- where our revenues came from;
- how all of the foregoing affect our overall financial condition; and

- what our expenditures for capital projects were in the periods presented.

As you read the Management's Discussion and Analysis, you may find it helpful to refer to our consolidated financial statements beginning on page 3 of this quarterly report. These consolidated financial statements present the results of our operations for the three-month and nine-month periods ended September 30, 2000 and 1999, as well as our financial position at September 30, 2000 and December 31, 1999. We analyze and explain the changes in certain line items set forth in the section of our consolidated financial statements titled "Consolidated Statements of Operations". Our analysis may be important to you in making decisions about your investment in Guilford.

General

Guilford is a biopharmaceutical company located in Baltimore, Maryland, engaged in the development and commercialization of novel products in two principal areas:

- targeted and controlled drug delivery systems using proprietary biodegradable polymers for the treatment of cancer and other diseases or conditions and

- therapeutic and diagnostic products for neurological diseases and conditions.

In February 1997, we commercially launched our first product, GLIADEL ® Wafer, in the United States through Aventis. GLIADEL® Wafer is a proprietary polymer product for the treatment of certain types of brain cancer. This product dissolves over time and releases an anti-cancer drug known as "BCNU" (or carmustine) directly to the tumor site. Until October 23, 2000, Aventis was our exclusive worldwide marketing partner (except in Scandinavia and Japan) for GLIADEL® Wafer. On October 23, 2000, we reacquired from Aventis its sales, marketing and distribution rights to GLIADEL® Wafer in consideration for the issuance to Aventis of 300,000 shares of our common stock. Aventis will continue to sell, market and distribute GLIADEL® Wafer during a transition period ending December 31, 2000, after which we will assume responsibility for all aspects of sales, marketing and distribution of GLIADEL® Wafer worldwide (except in Scandinavia, where our Scandinavian distributor and marketing partner, Orion Pharma, will continue to distribute our product).

We have also licensed from others and internally developed on our own:

- technologies that may be useful in preventing and treating certain neurological diseases and conditions;

- a novel pro-drug of propofol, a widely-used anesthetic; and

- a new class of biodegradable polymers different from the type used in GLIADEL ® Wafer, including PACLIMER™ Microspheres and LIDOMER™ Microspheres, which we are using for the targeted and controlled delivery of cancer chemotherapeutics and other drugs, including drugs for pain management.

For the nine-month period ended September 30, 2000, our revenues came primarily from the following sources:

- sales of GLIADEL® Wafer to Aventis and Orion Pharma;

- royalties from Aventis related to its sales of GLIADEL® Wafer to third parties; and/or

- one-time rights, milestone, and other payments from corporate partners under our current collaborative agreements.

As we discuss in greater detail below, if compounds which are the subject of our collaboration with Amgen attain certain regulatory and/or development objectives, we are eligible to receive certain milestone and other payments from Amgen. We view these potential payments as significant future revenue and/or capital raising opportunities. As we discuss here and in the 1999 Form 10-K, we cannot be sure that Amgen will achieve the designated milestones and that we will receive any or all of the milestone payments for which we are eligible

under our existing collaboration with Amgen. We also cannot be sure that we will be able to enter into collaborations in the future with others for the research, development, and/or commercialization of our technologies.

Because we have not marketed, sold and distributed a drug before, we cannot be certain of the level of revenue we will be able to achieve from our commercialization of GLIADEL® Wafer following our assumption of these activities as of January 1, 2001. Additionally, prior to the GLIADEL® Wafer Repurchase, we had received milestone and other payments from Aventis; for example, in March and September 2000, we earned non-refundable milestone payments of $1.0 million each from Aventis upon receipt of approval to market and sell GLIADEL® Wafer for the recurrent surgery indication in Spain and the U.K. After the GLIADEL® Wafer Repurchase, we will not be receiving such payments from Aventis.

In order to assist us in selling and marketing GLIADEL® Wafer, we have entered into an agreement with Cardinal Health Sales and Marketing Services, a division of Redkey, Inc. ("Cardinal"). Under the agreement with Cardinal, Cardinal will hire and train sales representatives to market and sell GLIADEL® Wafer to potential customers.

Since the commercial launch of GLIADEL® Wafer in the United States in February 1997 through September 30, 2000, we have recognized an aggregate of $23.7 million in product sales and royalties. Of this amount, $15.5 million represents revenues from sales of GLIADEL® Wafer to Aventis and to Orion Pharma. The additional $8.2 million are royalties paid to us from Aventis on its sales of GLIADEL® Wafer to third parties, such as hospitals.

As we discuss below and in the 1999 Form 10-K, a number of factors subject our future sales of GLIADEL® Wafer to significant risk and uncertainty. We cannot be sure our sales of GLIADEL® Wafer will increase over time or even continue at the current rate. Until the GLIADEL® Wafer Repurchase, we have not had responsibility for the sales, marketing and distribution of GLIADEL® Wafer. Increasing sales of the GLIADEL® Wafer are contingent upon, among other things, the following:

- developing internally or outsourcing a sales, marketing and distribution network for GLIADEL® Wafer;
- making certain international regulatory filings and obtaining clearances to market GLIADEL® Wafer for the recurrent surgery indication or the first surgery indication pursuant to such filings;
- obtaining authorization from the U.S. Food and Drug Administration ("FDA") and international health regulatory authorities to expand the labeled indications for GLIADEL® Wafer; and
- obtaining permission to sell GLIADEL® Wafer in those countries that require pricing approval at prices that are acceptable to those countries and to us.

Additionally, we cannot control the timing and extent of governmental clearances, nor can we be sure that we will attain any of these regulatory objectives. We also cannot be certain of the degree of acceptance of GLIADEL® Wafer by neurosurgeons, payors and patients in the U.S. and internationally, based on previously available clinical data, data from the recently announced Phase III first surgery trial and actual clinical experience with the marketed drug. Even if the market were to increasingly accept the product, we cannot be certain that our sales, marketing and distribution efforts will be successful.

In August 1997, we entered into a collaboration with Amgen to research, develop, and commercialize our FKBP neuroimmunophilin compound technology. Under our agreement with Amgen, Amgen paid us $35 million in 1997. Of this amount, $15 million was in the form of a one-time, non-refundable rights fee upon signing the agreement. Amgen paid us the remaining $20 million for the purchase of 640,095 shares of our common stock and warrants to purchase up to an additional 700,000 shares of our common stock. These warrants are exercisable for five years and have an exercise price of $35.15 per share. We also granted to Amgen certain rights to register shares of our common stock with the SEC for sale in the public markets.

As part of this collaboration, Amgen agreed to fund up to a total of $13.5 million to support our research relating to the FKBP neuroimmunophilin ligand technology. This research funding began on October 1, 1997 and was payable quarterly over three years, with the last quarterly payment received July 1, 2000. As of September 30, 2000, we had recognized an aggregate of $13.5 million in research support from Amgen under our collaboration arrangement.

Our agreement also requires that Amgen make milestone payments to us if Amgen achieves specified regulatory and product development milestones. If Amgen is able to meet all of these milestones for each of 10 different specified clinical indications (i.e., uses), then these payments could total up to an additional $386 million in the aggregate. Amgen is also required to pay us royalties on its sales to third parties of any product(s) that result from

our collaboration.

As we discuss below and in the 1999 Form 10-K, we cannot be sure that Amgen will be successful in its efforts to develop one or more FKBP neuroimmunophilin compounds into products that the FDA and international regulatory authorities will approve as safe and effective drugs for neurological or other uses. Consequently, we cannot be sure that we will earn any of the milestone payments related to these regulatory and product development activities.

In addition to revenues related to net product sales and royalties from GLIADEL ® Wafer, the only other significant revenues we recognized for the nine-month period ended September 30, 2000 consisted of:

- non-refundable milestone payments of $1.0 million each from Aventis in March and September 2000, based upon Aventis' receipt of specified regulatory approval to market and sell GLIADEL ® Wafer for the recurrent surgery indication in Spain and the U.K.; and

- $3.4 million relating to research support for the FKBP neuroimmunophilin ligand technology from Amgen.

As a result of our recent reacquisition of the marketing rights for GLIADEL ® Wafer, we will not be receiving any future milestone payments from Aventis. As we discuss below and in greater detail in the 1999 Form 10-K, whether Amgen will ever make milestone or royalty payments to us in the future is subject to significant risk and uncertainty. We cannot be sure that we will recognize any significant revenues from Amgen in the future.

For the three- and nine-month periods ended September 30, 2000, we incurred a net loss of $11.6 million and $31.2 million, respectively. Since inception through September 30, 2000, we have an accumulated deficit of $114.1 million. Our accumulated deficit is equal to the sum of our cumulative profits and losses since inception in July 1993.

We do not expect 2000 to be profitable. We cannot be sure that we will ever achieve or sustain profitability in the future. Furthermore, our revenues and expenses have fluctuated significantly in the past because of the nature and timing of their sources. We expect fluctuations in our revenues and expenses to continue, and thus our operating results should also vary significantly from quarter-to-quarter and year-to-year. A variety of factors cause these fluctuations, including:

- the timing and amount of sales of GLIADEL ® Wafer;

- the timing and realization of milestone and other payments from our corporate partners;

- the timing and amount of expenses relating to our research and development, product development, and manufacturing activities;

- the extent and timing of costs related to our activities to obtain, extend, enforce and/or defend our patent and other rights to our intellectual property; and

- the cost of developing a sales, marketing and distribution network for our GLIADEL ® Wafer product.

We expect that expenses in all areas of our business will continue to increase. These areas include research and product development, pre-clinical testing, human clinical trials, regulatory affairs, operations, manufacturing, and sales general and administrative activities. In addition, we expect the number of employees working at our company to continue to increase. At September 30, 2000, we had 245 full-time employees, which compares to 228 at December 31, 1999.

Our ability to achieve consistent profitability in the future will depend on many factors, including:

- the level of future sales of GLIADEL ® Wafer;

- our ability to arrange for sales, marketing and distribution of GLIADEL ® Wafer in the U.S. and internationally, either by ourselves or through outsourcing such activities to third party vendors such as Cardinal;

- our ability, either alone or with others, to develop our product candidates successfully, including NIL-A with Amgen, PACLIMER™ Microspheres, LIDOMER™ Microspheres and any other product candidates;

- the extent of any human clinical trials and related costs necessary to develop our product candidates;

- our ability, either alone or with others, to obtain required regulatory approvals to market our product candidates;
- our ability and that of our corporate partners to manufacture products at reasonable cost;
- our ability and that of our collaborators to market, sell and distribute products successfully;
- our ability to enter into acceptable collaborative arrangements for our technologies and license agreements for new technologies of others in the future; and
- our ability to invent or acquire new technologies and/or in-license new technologies from others and to obtain, acquire, defend, and/or enforce patents on new and existing technologies.

Future product sales of GLIADEL® Wafer are subject to many risks and uncertainties including the following:

- we have never marketed or sold our products directly before and we may not be successful in our efforts to market, sell and distribute GLIADEL® Wafer through Cardinal, or otherwise.
- neurosurgeons and their patients may not accept GLIADEL® Wafer for a number of reasons, including the fact that GLIADEL® Wafer represents a relatively new and unfamiliar approach to the treatment of brain cancer and their possible assessment that benefits of this therapy do not outweigh its costs.
- we may not be successful in our attempts to obtain any additional regulatory and marketing approvals to market GLIADEL® Wafer and sell GLIADEL® Wafer at acceptable prices.
- BCNU, the chemotherapeutic agent we use in GLIADEL® Wafer, is currently only available from two suppliers, and thus this material may not be available for GLIADEL® Wafer manufacture.
- our current manufacturing plants for GLIADEL® Wafer are located in close proximity to each other in Baltimore, Maryland, and thus, are subject to the risk that natural disasters or other factors may adversely affect their operation and interrupt GLIADEL® Wafer manufacture.

For a discussion of these and other risks, you should read the “Risk Factors” section included in this quarterly report, particularly those paragraphs specifically addressing the risks we note above.

As we note in the “Risk Factors”, there is no guarantee that Amgen or we will be able to successfully develop any FKBP neuroimmunophilin compounds or other product candidates into safe and effective drug(s) for neurological or other uses. Consequently, we may not earn additional milestone payments related to Amgen’s development activities or revenues related to product sales. In particular, the research, development, and commercialization of early-stage technology, like the FKBP neuroimmunophilin ligand technology, are subject to significant risks and uncertainty. These risks involve those relating to, among other things:

- selection of appropriate lead compounds;
- successful completion of pre-clinical and clinical development activities;
- the need to obtain regulatory clearances in the United States and elsewhere to market and sell drug products;
- formulation of final product dosage forms;
- scale-up from laboratory bench quantities to commercial quantities at a reasonable cost;
- successful manufacture of drug products at an acceptable cost;
- successful commercialization of such products at an acceptable price; and

- the successful prosecution, enforcement, and defense of patent and other intellectual property rights.

For a discussion of these and other risks, you should read the “Risk Factors” section included in this quarterly report, particularly those paragraphs specifically addressing the risks we note above.

Results of Operations

In this section we discuss our revenues, costs and expenses, and other income and expenses, as well as the factors affecting each of them for the three- and nine-month periods ended September 30, 2000 and 1999.

Revenues

Our revenues for the three- and nine-month periods ended September 30, 2000 and 1999 primarily came from the following sources:

- net product sales of GLIADEL® Wafer to our marketing and distribution partners;
- royalty payments from Aventis on its sales of GLIADEL® Wafer to others, primarily hospitals;
- non-refundable milestone payments from Aventis; and
- quarterly research funding from Amgen.

We recognized total revenues of $3.0 million and $6.9 million for the three-month periods ended September 30, 2000 and 1999, respectively, and $8.5 million and $13.4 million for the nine-month periods ended September 30, 2000 and 1999, respectively.

These revenues consisted primarily of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2000	1999	2000	1999
	(in thousands)		(in thousands)	
Revenues from Aventis relating to GLIADEL® Wafer:				
Net product sales	$ 285	$ 565	$1,492	$3,432
License fees and royalties	521	542	1,603	1,785
Non refundable milestones payments	1,000	4,500	2,000	4,500
Revenues from Amgen:				
Research funding under collaborative agreements	1,125	1,125	3,375	3,375

GLIADEL® Wafer Net Product Sales

During the three-month period ended September 30, 2000, we supplied GLIADEL ® Wafer to our marketing and sales partners. We earned $0.3 million and $0.6 million for the three-month periods ended September 30, 2000 and 1999, respectively, and $1.5 million and $3.4 million for the nine-month periods ended September 30, 2000 and 1999, respectively, from the net product sales of GLIADEL ® Wafer to our marketing and distribution partners, Aventis (for the entire world, except Scandinavia and Japan) and Orion Corporation Pharma (for Scandinavia only). The decrease in revenues attributable to net product sales of GLIADEL ® Wafer to Aventis for the three- and nine-month periods ended September 30, 2000 compared to the three- and nine-month periods ended September 30, 1999 is the result of Aventis managing existing inventory requirements to meet their current sales requirement.

Royalties on GLIADEL® Wafer Sales to Third Parties

During the three-month and nine-moth periods ended September 30, 2000, Aventis paid us a royalty on its sales of GLIADEL® Wafer. These royalty payments are a function of the demand for the product in the market. Net royalty revenues on Aventis’ sales of

GLIADEL® Wafer to third parties were $0.5 million and $0.5 million for the three month periods ended September 30, 2000 and 1999, respectively, and $1.6 million and $1.8 million for the nine-month periods ended September 30, 2000 and 1999, respectively. As we discuss in greater detail in the “Risk Factors” section of this quarterly report, a number of factors subject our future sales of GLIADEL® Wafer to significant risk and uncertainty. Additional factors such as, our ability to sell, market and distribute the GLIADEL® Wafer through CORD and Cardinal may also affect GLIADEL® Wafer sales. We cannot be sure that GLIADEL® Wafer sales will increase from, or even remain at, current levels or will ever generate significant revenues for us in the future.

Cost of Sales

Our cost of net product sales excluding unabsorbed manufacturing overhead, as a percentage of net product sales revenue were 49% and 54% for the three-month periods ended September 30, 2000 and 1999, respectively, and 53% and 51% for the nine-month periods ended September 30, 2000 and 1999, respectively. The cost to manufacture GLIADEL® Wafer at current market levels can vary materially with production volume. Production volume in turn is dependent upon purchase orders. As a result of the reacquisition of GLIADEL® Wafer, we did not manufacture GLIADEL® Wafer during the three-month period ended September 30, 2000. Therefore, the fixed costs associated with our manufacturing capabilities were shown on our Consolidated Statement of Operations as "Cost of Sales — unabsorbed manufacturing overhead". To the extent that GLIADEL® Wafer production levels increase in the future, we anticipate that the unit cost to manufacture GLIADEL® Wafer may decrease, although we cannot be sure that GLIADEL® Wafer product sales will ever reach levels necessary for us to realize such a reduction in the per unit cost of manufacturing GLIADEL® Wafer. To the extent that GLIADEL® Wafer production levels decrease, we anticipate that the unit cost to manufacture GLIADEL® Wafer will increase. Based on our experience to date, we would expect the cost of net product sales of GLIADEL® Wafer to fluctuate from quarter to quarter, based on production volumes.

Research and Development Expenses

Our research and development expenses were $12.2 million and $11.0 million for the three-month periods ended September 30, 2000 and 1999, respectively, and $34.1 million and $30.7 million for the nine-month periods ended September 30, 2000 and 1999, respectively. The increase in our research and development expenses for the three- and nine-month periods ended September 30, 2000 when compared to the corresponding periods of 1999, can be attributed largely to our propofol, pro-drug development program which did not exist in 1999.

In order to continue to advance our research and development programs, we anticipate that our research and development expenses will increase in future periods.

At September 30, 2000, we employed 206 individuals on a full-time basis in the areas of research, development and manufacturing compared to 193 and 192 at December 31, 1999 and September 30, 1999, respectively.

General and Administrative Expenses

Our general and administrative expenses increased to $3.1 million from $2.2 million when comparing the three-month periods ended September 30, 2000 and 1999, respectively, and increased to $8.6 million from $8.4 million when comparing the nine-month periods ended September 30, 2000 and 1999, respectively. The increase when comparing the three-month periods is attributable to recruiting costs as we replace and expand certain senior management positions. The increase during the nine-month period ended September 30, 2000, when compared to the corresponding period in 1999 is attributable to higher personnel costs as we increased staff in certain administrative departments.

At September 30, 2000, we employed 39 individuals on a full-time basis in general and administrative areas compared to 35 and 33 at December 31, 1999 and September 30, 1999, respectively.

Termination of Proposed Merger with Gliatech Inc.

On August 28, 2000, we terminated an Agreement and Plan of Merger entered into on May 29, 2000 with Gliatech. The parties mutually agreed that, in light of Gliatech’s need to focus on certain of its ongoing regulatory and product development matters, the parties elected not to proceed with the proposed merger. We incurred costs related to the proposed merger with Gliatech of $0.3 million and $1.4 million for the three and nine-month periods ended September 30, 2000, respectively.

Other Income and Expense

Other income and expense consists primarily of investment income on our monetary investments and interest expense on our debt and other financial obligations. Our investment income was $1.9 million and $1.6 million for the three-month periods ended

September 30, 2000 and 1999, respectively, and $6.0 million and $5.6 million for the nine-month periods ended September 30, 2000 and 1999, respectively. The increase experienced during the three-month and nine-month periods is a result of higher average invested balances.

We incurred interest expense of $ 0.1 and $0.2 for the three-month periods ended September 30, 2000 and 1999, respectively, and $0.4 and $0.5 for the nine-month periods ended September 30, 2000 and 1999, respectively. These expenses resulted from loans from a commercial bank that helped fund the construction of certain of our manufacturing, administrative, and research and development facilities and the purchase of certain furniture and equipment. Because we continued to repay these loans, resulting in a lower average principal balance, interest expense decreased in the three- and nine-month periods ended September 30, 2000 as compared to the corresponding periods of 1999.

Liquidity and Capital Resources

Our cash, cash equivalents, and investments were approximately $117.1 million at September 30, 2000. Of this amount, we pledged $19.6 million as collateral for certain of our loans and other financial lease obligations. In addition to these restricted investments, we are required to maintain, in the aggregate, unrestricted cash, cash equivalents, and investments of $40.0 million at all times under the terms of certain of its financial obligations.

Our total debt decreased to $7.7 million at September 30, 2000 compared to $9.4 million at December 31, 1999. This decrease is a result of our continued repayment of principal under our loans with a commercial bank.

We incurred capital expenditures of $0.5 million and $1.3 million during the three- and nine-month periods ended September 30, 2000, respectively, which resulted primarily from the purchase of equipment to support our ongoing research and development and production activities.

During 1998, we entered into arrangements with certain equipment leasing companies that permit us to lease up to an aggregate of $10.8 million in equipment, including certain computer hardware, and furniture and fixtures. As of September 30, 2000, we had leased approximately $8.7 million in equipment under these arrangements. Depending on the type of equipment covered and certain other factors, the term of any lease we enter under these arrangements can range from two to four years. At September 30, 2000, $2.1 million was available under these arrangements to lease additional equipment. Although these lease arrangements expire on December 31, 2000, we expect to be able to extend any unused portions and will seek to develop additional lines as necessary.

We expect our existing financing arrangements, our internal capital resources, and potential external sources of funds to provide for our current equipment needs at least through the end of 2001. If we decide to expand our research and development programs beyond current expectations or if we engage in acquisitions, our capital equipment requirements could increase, and thus, we may require additional capital funding.

In order to meet our anticipated future facilities needs, in 1997 we initiated a project to design, construct, and lease a new research and development facility. To accomplish this, in February 1998 we entered into an operating lease and other related agreements with a commercial bank and related entities in connection with such a facility. This new facility, which was completed in 1999, was constructed adjacent to our current headquarters in Baltimore, Maryland. This facility is owned by a trust affiliated with a commercial bank (the “Trust”) and provides approximately 73,000 square feet of research and development capacity. The initial lease term expires in February 2005. At the end of the initial lease term, we may re-lease the facility, purchase the building, or arrange for the sale of the building to a third party. In the event the building is sold to a third party, we will be obligated to pay the lessor any shortfall between the sales price and 83% of the lessor’s net investment in the facility. We anticipate that this new research and development facility, along with our current facility, will support our research, development, commercialization, and administrative activities through at least the end of 2001.

During 1998 and 1999, we entered into a series of interest rate swap transactions with a commercial bank covering $20.0 million in financial obligations under our lease with the Trust and $10.0 million with the commercial bank covering our bond and term loans. As a result, we fixed the interest rates on our financial lease obligations and debt at approximately 6% in the aggregate. Certain of the interest rate swap agreements provide the commercial bank with a call provision exercisable during 2003.

During 1998, we established an unsecured, revolving line of credit for $5.0 million with a commercial bank. Borrowings under this line of credit carry an interest rate of LIBOR plus 0.55% and are available on demand. We may draw on this line of credit from time to

time to meet our short-term working capital needs. There were no amounts drawn upon or outstanding during the three- and nine-month periods ended September 30, 2000 and 1999.

We believe that our existing resources are sufficient to fund our current activities though at least December 31, 2001. However, we expect to need significantly greater capital in the near future to:

- cover the costs of setting up a commercial operations function to take over the selling, marketing, and distributing of GLIADEL® Wafer

- increase pre-clinical and clinical development activities for development candidates such as:

    - PACLIMER™ Microspheres (for ovarian and other cancers),
    - GPI-5693 (our lead NAALADase inhibitor initially targeting diabetic neuropathic pain),
    - GPI-1571 (our propofol pro-drug for sedation), and
    - LIDOMER™ Microspheres (our delayed release lidocaine analgesic product candidate targeting post-surgical pain).

As a result, we currently intend to seek funds in the capital markets in the near term by filing a shelf registration statement for up to 3,500,000 shares of our common stock. We cannot predict with certainty the amount or timing of our sale of common stock under this shelf registration statement because this action depends upon market conditions that we cannot control.

Recently Issued Accounting Pronouncements

In December 1999, the staff of the SEC issued Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements ("SAB 101"). SAB 101 summarizes certain of the staff's views in applying generally accepted accounting principles to revenue recognition in the financial statements, including recognition of non-refundable fees received upon entering into arrangements. In June 2000, the SEC issued Staff Accounting Bulletin No. 101B which delays the implementation date of SAB 101 until no later than the fourth fiscal quarter of fiscal year beginning after December 15, 1999. Accordingly, the Company is evaluating SAB 101 and the effect it will have on its consolidated financial statements and current revenue recognition policy.

Outlook

For the fourth quarter of 2000, we expect to only record revenue from royalties related to sales of GLIADEL ® Wafer to third parties. We expect the total amount of royalty revenue to be consistent with royalty revenues reported for each of the first three quarters of 2000. As a result of our reacquisition of GLIADEL ® Wafer, we will no longer be receiving milestone payments, nor will we be recording additional revenue from net product sales of GLIADEL® Wafer to Aventis.

Expenses in the fourth quarter are currently projected to increase over those in the third quarter between $1.5 million to $2.0 million, primarily due to costs of establishing our commercial operations.

As a result of the increase in expenses and decrease in revenues, we expect our operating loss for the fourth quarter to be between $14.0 million and $16.0 million. Although we cannot be certain, we do not expect to continue to incur losses at that rate during 2001.

In 2001, we expect sales of GLIADEL ® Wafer to be between $17.0 million and $22.0 million. Revenue from GLIADEL® Wafer may be greater if we receive a first surgery label in the United States and internationally, especially if GLIADEL® Wafer were to achieve "standard of care" acceptance by the neurosurgical community.

We expect that our total expenses for 2001, other than expenses associated with our commercial operations group, will increase by approximately $10.0 million to $12.0 million over the total expenses for 2000. This increase would result from an increase in clinical development costs as we advance four product candidates (PACLIMER™ Microspheres, GPI-5693, GPI-15715 and LIDOMER™ Microspheres) through clinical development.

We plan to seek additional revenues from partnering activities in 2001. Specifically, we are attempting to license GLIADEL® Wafer in Japan and, possibly conclude a corporate partnership for non-U.S. rights for the NAALADase program. If we are successful in these efforts (and subject to our ability to recognize revenue from these types of transactions under the current accounting literature),

we would hope to achieve $15.0 million to $20.0 million in revenues from these corporate partners.

We currently anticipate that research and development expenses in 2001 will increase by approximately $10.0 million when compared to 2000. As we stated above, most of this increase will be related to increased clinical trial costs. We anticipate that general and administrative costs will increase by approximately $2.0 million compared to 2000. Sales, marketing and distribution costs will be part of the operating statement for the full year in 2001. We would expect such costs to be between $12 million to $14 million for 2001. Cost of sales as a percentage of net sales will range from 14% to 16%, commencing in 2001, as a result of our recording the full value of sales of GLIADEL® Wafer. We expect our capital expenditures in 2001 will be between $2.0 million and $2.5 million.

Over the next few months, if our progress remains on target, we expect to begin clinical development of two new programs, GPI-5693 and GPI-15715. During 2001, we expect to file and hope to obtain a supplemental New Drug Application for GLIADEL® Wafer for first surgery from the FDA, and to re-launch GLIADEL® Wafer directly though our own contract marketing and sales organization. We also expect to report results from our PACLIMER™ Microspheres Phase I clinical trial and neuroimmunophilin Phase II clinical trial.

Item 3. ***Quantitative and Qualitative Disclosures About Market Risk***

A substantial portion of our assets are investment grade debt instruments such as direct obligations of the U.S. Treasury, securities of federal agencies which carry the direct or implied guarantee of the U.S. government, bank certificates of deposit and corporate securities, including commercial paper and corporate debt instruments. The market value of such investments fluctuates with current market interest rates. In general, as rates increase, the market value of a debt instrument would be expected to decrease. The opposite is also true. To minimize such market risk, we have in the past and, to the extent possible, will continue in the future to hold such debt instruments to maturity at which time the debt instrument will be redeemed at its stated or face value. Due to the short duration and conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk related to our investment portfolio. The investment portfolio at September 30, 2000 was $94.1 million and the weighted-average interest rate was approximately six percent (6%).

Substantially all of our financial obligations have variable rates of interest. As a hedge against fluctuations in interest rates, we have entered into certain interest rate swap agreements with a commercial bank (“counter party”), to exchange substantially all of our variable rates of interest on certain financial lease obligations and debt for fixed rates. Our borrowings under our bond and term loans and financial obligations under certain lease arrangements are approximately $26.3 million. Pursuant to these borrowing arrangements, we are obligated to pay variable interest rates on substantially all of these obligations of LIBOR plus between 5/8% and 3/4%. The interest rate swap agreements have a total notional principal amount of approximately $27.1 million as of September 30, 2000. Pursuant to these interest rate swap agreements, we pay a fixed rate of interest to the counter party of approximately 6% and receives from the counter party a variable rate of interest of LIBOR plus 5/8%. The differential to be paid or received as interest rates change is charged or credited, as appropriate, to operations. Thereby, we have effectively fixed the interest rates on our financial obligations at an annual rate of approximately 6% in the aggregate. These interest rate swap agreements have approximately the same maturity as the financial obligations and expire on various dates through February 2005. The commercial bank has the right to terminate certain of the agreements having a total notional principal amount of $20.0 million during February 2003. We do not speculate on the future direction of interest rates nor do we use these derivative financial instruments for trading purposes. In the event of non-performance by the counter party, we could be exposed to market risk related to interest rates.

The aggregate fair value of these interest rate swap agreements was approximately $0.6 million at September 30, 2000. Current market pricing models were used to estimate these fair values.

We describe our exposure to interest rate risk in Notes 4 and 7, “Interest Rate Swap Agreements” and “Indebtedness,” respectively, to the footnotes to our consolidated financial statements, which we have included as Exhibit 13.01 to our annual report on Form 10-K for the year ended December 31, 1999, which we filed with the SEC on March 30, 2000.

PART II. OTHER INFORMATION

Item 1. ***Legal Proceedings:***

None

Item 2. ***Changes In Securities:***

On October 23, 2000, we issued 300,000 shares of common stock valued at approximately $8.0 million to Aventis, in consideration for the reacquisition of worldwide sale, marketing and distribution rights of GLIADEL® Wafer (except in Scandinavia, where GLIADEL® Wafer is marketed by Orion Pharma). In connection with this issuance, we relied on the exemption from registration under the Securities Act of 1933 provided in Section 4 (2) of the Act.

Item 3. ***Defaults Upon Senior Securities:***

None

Item 4. ***Submission of Matters to a Vote of Security Holders:***

None

Item 5. ***Other Information:***

RISK FACTORS

An investment in our stock is very speculative and involves a high degree of risk. You should consider the following important factors, as well as the other information in this report and our SEC filings, carefully before purchasing our stock.

We have a history of losses and our future profitability is uncertain.

We may not be able to achieve or sustain significant revenues or earn a profit in the future. We founded Guilford in July 1993, and since that time, with the sole exception of 1996, we have not earned a profit in any year. Our losses result mainly from the large amount of money that we have spent on research and development. As of September 30, 2000, we had an accumulated deficit of approximately $114.1 million. We expect to have significant additional losses over the next several years.

Most of our product candidates are in research or early stages of pre-clinical and clinical development. Except for GLIADEL®Wafer, none of our products or product candidates has been sold to the public. Up to this point in this time, nearly all of our revenues have come from:

- payments from Aventis from the sale and distribution of GLIADEL®Wafer,
- one-time signing fees from our corporate partners under agreements supporting the research, development and commercialization of our product candidates,
- one-time payments from our corporate partners when we achieve regulatory or development milestones, and
- research funding under our agreement with Amgen.

We recently reacquired from Aventis the right to sell, market and distribute GLIADEL®Wafer so we will not receive any future payments from Aventis for GLIADEL®Wafer. We do not expect revenues from GLIADEL®Wafer to be sufficient to support all our anticipated future activities. Whether we will ever be able to generate significant revenues from GLIADEL®Wafer continues to be uncertain, especially in light of our inexperience in the sales, marketing and distribution area. In addition, we do not expect to generate revenues from the sale of our product candidates for the next several years, if ever.

We may never recognize significant additional revenues from Amgen because of the significant risks. These risks are part of each of the following activities:

- new product development,
- the conduct of pre-clinical animal studies and human clinical trials,
- applying for and obtaining regulatory approval to market and sell product candidates,
- expanding the processes for making product candidates from the relatively small quantities and qualities needed for research and development purposes to the commercial scale manufacture needed to support marketing and sales of new products, and
- commercialization of new products.

We discuss these and other risks in greater detail below in this "Risk Factors" section.

Many factors will dictate our ability to achieve sustained profitability in the future, including:

- our ability to successfully sell, market and distribute GLIADEL ®Wafer,
- receipt of regulatory clearance to market and sell GLIADEL ®Wafer for patients undergoing initial surgery for malignant glioma in the United States as well as in Europe and other countries,
- receipt of regulatory clearance to market and sell GLIADEL ®Wafer for the recurrent indication in Europe and other countries,
- the successful development and commercialization of product candidates that result from our collaboration with Amgen, and
- our ability to enter into additional collaborative arrangements and license agreements with other corporate partners for our product candidates and earlier stage technologies as we develop them.

We will need to conduct substantial additional research, development and clinical trials. We will also need to receive necessary regulatory clearances both in the United States and foreign countries. We expect that these research, development and clinical trial activities, and regulatory clearances, together with future general and administrative activities, will result in significant expenses for the foreseeable future.

We depend on a single product, GLIADEL®Wafer, for revenues.

Our short-term prospects depend to a large extent on sales of GLIADEL ®Wafer, our only commercial product. We commercially launched GLIADEL®Wafer in the United States in February 1997. We currently do not know whether the product will ever gain broad market acceptance or the extent of the marketing efforts necessary to achieve broad market acceptance. If GLIADEL ®Wafer fails to gain market acceptance, the revenues we receive from sales of GLIADEL ®Wafer would be unlikely to increase.

On October 23, 2000, we reacquired from Aventis the right to market, sell and distribute GLIADEL ®Wafer. Until then, Aventis held exclusive worldwide (excluding Scandinavia and Japan) marketing, sales and distribution rights for GLIADEL®Wafer. Under that arrangement, Aventis paid us royalties and also made designated one-time milestone payments upon achieving specified domestic and international regulatory approvals. For example, Aventis made a $1.0 million payments to us in each of March and September 2000. After the reacquisition, Aventis is no longer obligated to make any payments to us.

We have clearance from the FDA to market GLIADEL ®Wafer in the United States for only a limited subset of patients who suffer from brain cancer. Our clearance is for those patients for whom surgical tumor removal, commonly referred to as "resection," is called for and who have "recurrent" forms of a type of brain cancer called glioblastoma multiforme. A recurrent form of glioblastoma multiforme is one in which the cancer has returned after initial surgery to remove a brain tumor. The number of patients undergoing recurrent surgery for glioblastoma multiforme is very limited, and we believe the total number of patients on an annual basis who have glioblastoma multiforme in the United States is approximately 10,000.

In order to expand the medical uses, commonly referred to as "indications," for which we may market GLIADEL®Wafer, we must successfully complete additional lengthy clinical trials. Thereafter, we will have to apply to the FDA and international health regulatory authorities for clearance to market GLIADEL ®Wafer for patients undergoing initial surgery for glioblastoma multiforme and potentially other types of brain cancer. We may not be able to successfully complete these clinical trials or receive the desired regulatory clearance. If GLIADEL®Wafer fails to receive regulatory clearance, that failure would limit our ability to market GLIADEL®Wafer for use in patients beyond the current narrow indication and reduces the likelihood of increasing the revenues that we receive from sales of GLIADEL ®Wafer.

In addition, we have filed for marketing clearance for the current indication for GLIADEL ®Wafer in a number of foreign countries, and as of the date of this quarterly report, we have received international regulatory approvals to market and sell GLIADEL®Wafer in only 21 countries, including France, Spain, Germany and the U.K. We may not be able to obtain any other international regulatory approvals for GLIADEL ®Wafer. If we fail to obtain those approvals, the geographic market for GLIADEL ®Wafer would remain limited, which reduces the likelihood of increasing the revenues that we receive from sales of GLIADEL ®Wafer. Regardless of the number of foreign regulatory approvals that we have received, international sales to date comprise a small percentage of total sales of GLIADEL®Wafer.

GLIADEL ®Wafer is also a very fragile product and can easily break into many pieces if it is not handled with great care. Product recalls due to excessive breakage of the GLIADEL ®Wafers or for other reasons could also have a negative effect on our business, financial condition and results of operations.

We have never marketed or sold our products directly before and we may not be successful in our efforts to market, sell and distribute GLIADEL®Wafer. Additionally, we expect to incur significant expense in marketing, selling and distributing GLIADEL®Wafer.

We currently do not have a sales force, and we have no experience in marketing or selling a product. From GLIADEL® Wafer's commercial launch until December 31, 2000, Aventis marketed, sold and distributed GLIADEL®Wafer. Our recent reacquisition of the right to market, sell and distribute GLIADEL ®Wafer marks an important change in our business. We currently do not have, and have never had, direct sales capability. We have also never engaged in significant marketing efforts. Our limited experience in developing, maintaining and expanding a direct specialty sales force may restrict our success in selling GLIADEL®Wafer.

Alternatively, we may contract with third parties for the sale, marketing and distribution of GLIADEL ®Wafer. We recently entered into an agreement with Cardinal to hire and train sales representatives to market and sell GLIADEL®Wafer.

Our operating results are likely to fluctuate from quarter to quarter, which could cause the price of our common stock to decline.

Our revenues and expenses have fluctuated significantly in the past. This fluctuation has in turn caused our operating results to vary significantly from quarter to quarter and year to year. We expect the fluctuations in our revenues and expenses to continue and thus our operating results should also continue to vary significantly. These fluctuations are due to a variety of factors, including:

- the timing and amount of sales of GLIADEL ®Wafer,
- the timing and realization of milestone and other payments from our corporate partners
- the timing and amount of expenses relating to our research and development, product development, and manufacturing activities, and
- the extent and timing of costs related to our activities to obtain patents on our inventions and to extend, enforce and/or defend our patent and other rights to our intellectual property.

Because of these fluctuations, it is possible that our operating results for a particular quarter or quarters will not meet the expectations of public market analysts and investors, causing the market price of our common stock to decline. We believe that

period-to-period comparisons of our operating results are not a good indication of our future performance and you should not rely on those comparisons to predict our future operating or share price performance.

The market price of our stock may be negatively affected by market volatility.

The market price of our stock has been and is likely to continue to be highly volatile. Furthermore, the stock market generally and the market for stocks of companies with lower market capitalizations and small biotechnology companies, like us, have from time to time experienced and likely will again experience significant price and volume fluctuations that are unrelated to the operating performance of a particular company.

From time to time, stock market professionals publish research reports covering our business and our future prospects. For a number of factors, we may be unable to meet the expectations of securities analysts or investors and our stock price may decline. These factors include:

- announcements by us or our competitors of clinical results, technological innovations, product sales, new products or product candidates,
- developments or disputes concerning patent or proprietary rights,
- regulatory developments affecting our products,
- period-to-period fluctuations in the results of our operations, and
- market conditions for emerging growth companies and biopharmaceutical companies.
- revenues received from GLIADEL® Wafer
- expenditures of Guilford

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against those companies. If we face such litigation in the future, it would result in substantial costs and a diversion of management's attention and resources, which would negatively impact our business.

Our collaboration with Amgen may be a significant source of future revenue for us. The success of this collaboration depends on a number of factors, most of which are outside of our control.

The achievement of the milestones that trigger payments by Amgen to us depend on a number of factors. We do not control many of these factors, including:

- the selection of one or more appropriate lead compounds,
- successful design and completion of pre-clinical and clinical development activities,
- application for and obtaining regulatory clearances to market potential products,
- commercialization of products, and
- the successful preservation and extension of the patent and other intellectual property rights licensed to Amgen.

Moreover, under the terms of our collaboration with Amgen, we have no control over the development activities regarding the FKBP neuroimmunophilin ligand technology, which are within the sole discretion of Amgen. Our agreement with Amgen also does not specify a binding timetable for achieving development and commercialization goals with respect to the FKBP neuroimmunophilin ligand technology. Even if Amgen determines to conduct clinical trials on a product candidate resulting from our collaboration, Amgen still may not be able successfully to complete those clinical trials and then receive clearance from the FDA or foreign regulatory authorities to market and sell any such products.

The FKBP neuroimmunophilin ligand technology we have licensed to Amgen represents a new approach to the treatment of certain types of neurological and other diseases and conditions. We and Amgen have very limited experience in taking the kinds of compounds likely to result from our work and formulating them into final drug products appropriate for sale to the public. In addition,

both of us have limited experience with the transition of these compounds from the quantity and quality needed to support research and development efforts to the quantities needed to support commercial scale distribution. Also, both we and Amgen have limited experience with the manufacture of compounds of this type for commercial sale. Amgen may not be successful in scaling-up and manufacturing adequate quantities needed for commercial sale. For a more complete description of the kinds of risks associated with product manufacture, you should read the section entitled “We have limited manufacturing capabilities” below.

Even if Amgen is able to obtain all regulatory approvals necessary to market a product resulting from our collaboration, our agreement does not specify any minimum sales requirements for Amgen. Thus, any royalty amounts that Amgen pays us in the future will depend entirely on the sales and marketing efforts of Amgen, an activity over which we will have no control. In addition, our agreement with Amgen does not prevent Amgen from pursuing technologies for product candidates that compete with the FKBP neuroimmunophilin ligand technology in the future.

Our manufacturing capabilities are limited by the size of our facilities, our inexperience manufacturing large quantities of product and the potential inability to locate a third party manufacturer for our product candidates.

To commercialize GLIADEL ®Wafer, we must be able to manufacture this product in sufficient quantities, in compliance with regulatory requirements, and at acceptable costs. We manufacture GLIADEL ®Wafer at our two manufacturing facilities in Baltimore, Maryland, which consist of production laboratories and redundant cleanrooms. We estimate that the facilities currently have the capacity to manufacture approximately 8,000 GLIADEL®Wafer treatments per year.

We have manufactured only limited quantities of GLIADEL ®Wafer in our facilities. We cannot be sure that we will be able to continue to satisfy applicable regulatory standards, including FDA requirements, and other requirements relating to the manufacture of GLIADEL ®Wafer in the facilities.

We also face risks inherent in the operation of a facility for manufacture of GLIADEL ®Wafer. These risks include:

- unforeseen plant shutdowns due to personnel, equipment or other factors, and
- the possible inability of the facilities to produce GLIADEL ®Wafer in quantities sufficient to meet demand.

Any delay in the manufacture of GLIADEL ®Wafer could result in delays in product shipment. Delays in product shipment would have a negative effect on our business and operating results.

Currently, we have no manufacturing capabilities for any of our product candidates. Consequently, in order to complete the commercialization process of any of our product candidates, we must either acquire, build or expand our internal manufacturing capabilities or rely on third parties to manufacture these product candidates. We cannot be sure that we or our corporate partners, including Amgen, will be able to (1) acquire, build or expand facilities that will meet quality, quantity and timing requirements or (2) enter into manufacturing contracts with others on acceptable terms. If we or our corporate partners are unable, to accomplish these tasks, it would impede our efforts to bring our product candidates to market, which would adversely affect our business. Moreover, if we decide to manufacture one or more of our product candidates ourselves, we would incur substantial start-up expenses and need to expand our facilities and hire additional personnel.

Third-party manufacturers must also comply with FDA, Drug Enforcement Administration, and other regulatory requirements for their facilities. In addition, manufacture of product candidates on a limited basis for investigational use in animal studies or human clinical trials does not guarantee that large-scale, commercial production is viable. Small changes in methods of manufacture can affect the safety, efficacy, controlled release or other characteristics of a product. Changes in methods of manufacture, including commercial scale-up, can, among other things, require the performance of new clinical studies.

Revenues from our products, specifically GLIADEL®Wafer, depend in part on reimbursement from health care payors, which is uncertain.

The continuing efforts of government and insurance companies, health maintenance organizations and other payors of health care costs to contain or reduce costs of health care may affect our future revenues and profitability. These efforts may also affect the future revenues and profitability of our potential customers, suppliers and collaborative partners, in turn affecting demand for our products. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government

control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could have a negative effect on our business and operating results.

Our ability to commercialize our products successfully will depend in part on the extent to which private health insurers, organizations such as HMOs and governmental authorities can obtain appropriate reimbursement levels for the cost of our products and related treatment. Third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our products. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially and adversely affect our ability to operate profitably.

Furthermore, even if reimbursement is available, we cannot be sure that it will be available at price levels sufficient to realize an appropriate return on our investment in GLIADEL ®Wafer or our other product candidates.

We face technological uncertainties in connection with the research, development and commercialization of new products.

The research, development and commercialization of pharmaceutical drugs inherently involve significant risk. Before we or our corporate partners can be in a position to market, distribute and sell a new product, each of us will have to:

- expend substantial capital and effort to develop our product candidates further, which includes conducting extensive and expensive pre-clinical animal studies and human clinical trials,
- apply for and obtain regulatory approval to market and sell such product candidates, and
- conduct other costly activities related to preparation for product launch, among many other activities.

In some of our research programs, we are using compounds that we consider to be “prototype” compounds in the research phase of our work. By prototype compounds we mean compounds that we are using primarily to establish that a relevant scientific mechanism of biological or chemical action could have commercial application in diagnosing, treating or preventing disease. We generally do not consider our prototype compounds to be lead compounds acceptable for further development into a product(s) because of factors that render them unsuitable as drug candidates. These factors include the ability for the compound to be metabolized, absorbed, distributed and excreted from the body. In order to develop commercial products, we will need to conduct research using other compounds that share the key aspects of the prototype compounds but do not have the unsuitable characteristics. This may not always be possible.

In addition, our product candidates are subject to the risks of failure inherent in the development of products based on new and unproved technologies. These risks include the possibility that:

- our new approaches will not result in any products that gain market acceptance,
- a product candidate will prove to be unsafe or ineffective, or will otherwise fail to receive and maintain regulatory clearances necessary for marketing,
- a product, even if found to be safe and effective, could still be difficult to manufacture on the large scale necessary for commercialization or otherwise not be economical to market,
- a product will unfavorably interact with other types of commonly used medications, thus restricting the circumstances in which it may be used,
- proprietary rights of third parties will preclude us from manufacturing or marketing a new product, or
- third parties will market superior or more cost-effective products.

As a result, our activities, either directly or through corporate partners, may not result in any commercially viable products.

We depend on collaborations with third parties for the development and commercialization of our products.

Our resources are limited, particularly because we are developing our technologies for a variety of different diseases. Our business strategy requires that we enter into various arrangements with:

- corporate partners, such as Amgen,
- academic investigators at universities, such as Johns Hopkins and others,
- licensors of technologies, such as Johns Hopkins, Massachusetts Institute of Technology and RTI,
- licensees of our technologies, such as Daiichi Radioisotope Laboratories, Ltd. and others.

Our success depends in large part upon the efforts of our third party collaborators.

Our business strategy includes finding larger pharmaceutical companies to collaborate with us to support the research, development and commercialization of our product candidates. In trying to attract corporate partners to collaborate with us in the research, development and commercialization process, we face serious competition from other small biopharmaceutical companies and even the in-house research and development staffs of the larger pharmaceutical companies themselves. If we are unable to enter into such arrangements with corporate partners, our ability to proceed with the research, development, manufacture or sale of product candidates may be severely limited. For example, we are actively seeking corporate partners to assist in the development of DOPASCAN® Injection as well as our NAALADase and PARP inhibitor neuroprotective drug programs, but we may not find suitable corporate partners for these programs. It is common in many corporate partnerships in our industry for the larger partner to have responsibility for conducting pre-clinical studies and human clinical trials and/or preparing and submitting applications for regulatory approval of potential pharmaceutical or other products. That is the case with our collaboration with Amgen. It is possible that this will also be the case with future arrangements into which we may enter. If one of our collaborative partners fails to develop or commercialize successfully any of our product candidates, we would not be able to remedy this failure would and the failure could negatively affect our business.

Furthermore, larger pharmaceutical companies often explore multiple technologies and products for the same medical conditions. Therefore, they are likely to enter into collaborations with our competitors for products addressing the same medical conditions targeted by our technologies. Thus our collaborators, including Amgen, may pursue alternative technologies or product candidates in order to develop treatments for the diseases or disorders targeted by our collaborative arrangements. Our collaborators may pursue these alternatives either on their own or in collaboration with others, including our competitors. Depending on how other product candidates advance, a corporate partner may slow down or abandon its work on our product candidates or terminate its collaborative arrangement with us in order to focus on these other prospects.

We may be unable to obtain the additional capital needed to operate and grow our business.

We will require substantial funds in order to cover the costs of setting up a commercial operations function to take over the commercialization of GLIADEL® Wafer from Aventis, continue our research and development programs and pre-clinical and clinical testing, and to manufacture and market our products. We may be unable to obtain any future funds that we may require on acceptable terms, or at all. Under our operating lease with a trust affiliated with First Union National Bank for our new research and development facility, we are required to hold, in the aggregate, unrestricted cash, cash equivalents and investments of $40 million at all times during the term of the lease. In addition, we are required to maintain specified amounts of cash, $19.1 million restricted at December 31, 1999, as collateral at First Union under this arrangement and other loan agreements with First Union. These requirements may limit our ability to access our capital in the future.

Our capital requirements depend on numerous factors, including:

- the progress of our research and development programs,
- the progress of pre-clinical and clinical testing,

- the time and costs involved in obtaining regulatory approvals,
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights,
- competing technological and market developments,
- changes in our existing research relationships with universities and others,
- our ability to establish collaborative arrangements with large pharmaceutical companies and others,
- the requirements and timing of entering into technology licensing agreements and other similar arrangements, and
- the progress of efforts to scale-up manufacturing processes.

We may use our existing resources before we may otherwise expect because of changes in our research and development and commercialization plans or other factors affecting our operating expenses or capital expenditures, including potential acquisitions of other businesses, assets or technologies.

Our ability to raise future capital on acceptable terms depends on conditions in the public and private equity markets and our performance, as well as the overall performance of other companies in the biopharmaceutical and biotechnology sectors.

We may be unable to protect our proprietary rights, permitting competitors to duplicate our products and services.

Any success that we have will depend in large part on our ability to:

- obtain, maintain and enforce intellectual property protection for our products and processes,
- license rights to patents from third parties,
- maintain trade secret protection, and
- operate without infringing upon the proprietary rights of others.

Intellectual property for our technologies and products will be a crucial factor in our ability to develop and commercialize our products. Large pharmaceutical companies consider a strong patent estate critical when they evaluate whether to enter into a collaborative arrangement to support the research, development and commercialization of a technology. Without the prospect of reasonable intellectual property protection, it would be difficult for a corporate partner to justify the time and money that is necessary to complete the development of a product.

The rules and criteria for receiving and enforcing a patent for pharmaceutical and biotechnological inventions are in flux and are unclear in many respects. The range of protection given these types of patents is uncertain, and a number of our product candidates are subject to this uncertainty.

Many others, including companies, universities and other research organizations, work in the areas of our business, and we cannot be sure that the claims contained in our issued patents will be interpreted as broadly as we would like in light of the inventions of these other parties. In addition, we cannot be sure that the claims set forth in our pending patent applications will issue in the form submitted. These claims may be narrowed or stricken, and the applications may not ever ultimately result in valid and enforceable patents. Thus, we cannot be sure that our patents and patent applications will adequately protect our product candidates.

We are aware of at least one company, which has asserted publicly that it has submitted patent applications claiming the use of certain of its immunosuppressive compounds and multidrug resistance compounds for nerve growth applications. That company has also stated that it has issued U.S. patents and pending U.S. applications that it states claim compounds that are useful in nerve growth applications. We cannot give any assurance as to the ability of our patents and patent applications to adequately protect our neurotrophic product candidates. Also, our neurotrophic product candidates may infringe or be dominated by patents that have issued or may issue in the future to third parties.

In order to protect our intellectual property position with respect to our neuroimmunophilin ligands, we filed an opposition in 1998 in an effort to prevent the final issuance of a European patent to the company we discuss in the above paragraph. While we do not believe the claims of this European patent are valid, any final issuance could result in future litigation if this company were to allege that we infringed the claims of this patent in Europe.

Furthermore, any or all of the patent applications assigned or licensed to us from third parties may not be granted. We may not develop additional products or processes that are patentable. Any patents issued to us, or licensed by us, may not provide us with any competitive advantages or adequate protection for our products. Others may successfully challenge, circumvent or invalidate any of our existing or future patents or intellectual property.

Our policy is to control the disclosure and use of our know-how and trade secrets by entering into confidentiality agreements with our employees, consultants and third parties. There is a risk, however, that:

- these parties will not honor our confidentiality agreements,
- others will independently develop equivalent or competing technology,
- disputes will arise concerning the ownership of intellectual property or the applicability of confidentiality obligations, or
- disclosure of our trade secrets will occur regardless of these contractual protections.

In our business, we often work with consultants and research collaborators at universities and other research organizations. To the extent that any of these consultants or research collaborators uses intellectual property owned by others as part of their work with us, disputes may arise between us and these other parties as to which one of us has the rights to intellectual property related to or resulting from the work done.

We support and collaborate in research conducted in universities, such as Johns Hopkins, and in governmental research organizations, such as the National Institutes of Health. We may not be able to acquire exclusive rights to the inventions or technical information that result from work performed by university personnel or at these organizations. Also, disputes may arise as to which party should have rights in research programs that we conduct on our own or in collaboration with others that are derived from or related to the work performed at the university or governmental research organization. In addition, in the event of a contractual breach by us, some of our collaborative research contracts provide that we must return the technology rights, including any patents or patent applications, to the contracting university or governmental research organization.

Questions of infringement of intellectual property rights, including patent rights, may involve highly technical and subjective analyses. Some or all of our existing or future products or technologies may now or in the future infringe the rights of other parties. These other parties might initiate legal action against us to enforce their claims, and our defense of the claims might not be successful.

We may incur substantial costs if we must defend against charges of infringement of patent or proprietary rights of third parties. We may also incur substantial costs if we find it necessary to protect our own patent or proprietary rights by bringing suit against third parties, including suits involving our neurotrophic product candidates. We could also lose rights to develop or market products or be required to pay monetary damages or royalties to license proprietary rights from third parties. In response to actual or threatened litigation, we may seek licenses from third parties or attempt to redesign our products or processes to avoid infringement. We may not be able to obtain licenses on acceptable terms, or at all, or successfully redesign our products or processes.

In addition to the risk that we could be a party to patent infringement litigation, the U.S. Patent and Trademark Office, or its foreign counterparts, could require us to participate in patent interference proceedings that it declares. These proceedings are often expensive and time-consuming, even if we were to prevail in such a proceeding. We may also be forced to initiate legal proceedings to protect our patent position or other proprietary rights. These proceedings typically are costly, protracted, and offer no assurance of success.

Under our collaboration, Amgen is responsible for preparing, filing, prosecuting, maintaining and defending patent applications and patents relating to the FKBP neuroimmunophilin ligand technology. We cannot be sure that Amgen will pursue these activities in the same manner or as vigorously as we would if we had that responsibility. Furthermore, Amgen has the option to take the lead in bringing actions to enforce patent rights relating to the FKBP neuroimmunophilin ligand technology and to defend against third party

infringement suits regarding that technology. While Amgen and Guilford have agreed to consult with each other on such matters, in the event of disagreement, Amgen's decisions will control.

We rely on licensed intellectual property for GLIADEL®Wafer and our other product candidates.

We have licensed intellectual property, including patents, patent applications and know-how, from universities and others, including intellectual property underlying GLIADEL®Wafer, DOPASCAN®Injection and the neuroimmunophilin ligand technology. Some of our product development programs depend on our ability to maintain rights under these licenses. Under the terms of our license agreements, we are generally obligated to:

- exercise diligence in the research and development of these technologies,
- achieve specified development and regulatory milestones,
- expend minimum amounts of resources in bringing potential products to market,
- make specified royalty and milestone payments to the party from which we have licensed the technology, and
- reimburse patent costs to these parties.

In addition, these license agreements require us to abide by record-keeping and periodic reporting obligations. Each licensor has the power to terminate its agreement if we fail to meet our obligations under that license. We may not be able to meet our obligations under these license agreements, which could deprive us of access to key technology. Furthermore, these obligations may conflict with our obligations under other agreements that we have.

If we default under any of these license agreements, we may lose our right to market and sell any products based on the licensed technology. Losing our marketing and sales rights would have a significant negative effect on our business, financial condition and results of operations. Our license agreements require that we pay a royalty on sales of GLIADEL®Wafer to the university that licensed us the technology underlying that product. In addition, we will have to pay milestone and/or royalty payments in connection with the successful development and commercialization of DOPASCAN®Injection and any products that result from the NIL and PARP technologies.

In the future, to support our product development efforts, we may need research materials or scientific information that researchers at universities or other organizations generate. We may not be able to obtain this scientific information or research materials in a timely manner or at all.

We depend on a single source of supply for several of our key product components.

Currently, we can only purchase some of the key components for GLIADEL®Wafer and our product candidates from single source suppliers. These vendors are subject to many strict regulatory requirements regarding the supply of these components. We cannot be sure that these suppliers will comply, or have complied, with applicable regulatory requirements or that they will otherwise continue to supply us with the key components we require. If suppliers are unable or refuse to supply us, or will supply us only at a prohibitive cost, we may not be able to access additional sources at acceptable prices, on a timely basis, if ever.

The current formulation of GLIADEL®Wafer utilizes the chemotherapeutic agent BCNU, which is also known as "carmustine." Currently we have the option to procure BCNU from only two sources in the United States, and we are not aware of any supplier outside of the United States. We currently obtain BCNU from one of these two U.S. suppliers on a purchase order basis and not through any long-term supply agreement. If we fail to receive key supplies necessary for the manufacture of GLIADEL on a timely basis at a reasonable cost, delays in product shipment could result. Delays of this type would have a negative effect on our business.

The manufacture of DOPASCAN®Injection requires that a precursor compound be labeled with a radioactive isotope of iodine, known as Iodine-123, to form the final product. Only a limited number of companies worldwide are capable of performing the necessary "radioiodination" of the precursor and distribution of the final product. Currently, we do not have any arrangement for the manufacture and supply of DOPASCAN®Injection nor do we have the internal capability to manufacture DOPASCAN®Injection

ourselves. Consequently, we will not be in a position to commence Phase III or other clinical trials for DOPASCAN®Injection until we locate a qualified supplier.

We have assessed the companies that we believe are currently capable of manufacturing a product like DOPASCAN®Injection. Based on this assessment, we believe a significant risk exists that we may not be able to find a manufacturer who can meet the quality and cost requirements required to conduct the Phase III clinical trials that will be necessary to support application to the FDA for regulatory approval. Our inability to contract with a suitable manufacturer for the clinical and commercial supply of DOPASCAN®Injection on acceptable terms would prevent us from developing this product candidate further.

The U.S. Government holds rights which may permit it to license to third parties technology we currently hold the exclusive right to use.

The U.S. government holds rights that govern aspects of specific technologies licensed to us by third party licensors. These government rights in inventions conceived or reduced to practice under a government-funded program may include a non-exclusive, royalty-free, worldwide license for the government to practice or have practiced resulting inventions for any governmental purpose. In addition, the U.S. government has the right to grant to others licenses that may be exclusive under any of these inventions if the government determines that:

- adequate steps have not been taken to commercialize such inventions,
- the grant is necessary to meet public health or safety needs, or
- the grant is necessary to meet requirements for public use under federal regulations.

The U.S. government also has the right to take title to a subject invention if we fail to disclose the invention, and may elect to take title within specified time limits. The U.S. government may acquire title in any country in which we do not file a patent application within specified time limits.

Federal law requires any licensor of an invention partially funded by the federal government to obtain a commitment from any exclusive licensee, such as us, to manufacture products using the invention substantially in the United States. Further, these rights include the right of the government to use and disclose technical data relating to licensed technology that was developed in whole or in part at government expense. Our principal technology license agreements contain provisions recognizing these rights.

We have entered into a contract with the U.S. Army, funded by the Office of National Drug Control Policy, to provide financial support for research being conducted by us on a potential cocaine inhibitor. That contract permits the U.S. government to obtain unlimited rights to data developed in the course of our performance if we do not use the data within five years after termination of the contract to conduct further laboratory investigation and/or clinical trials aimed at developing a commercial product to combat drug abuse.

Pre-clinical and clinical trial results for our products may not be favorable.

In order to obtain regulatory approval for the commercial sale of any of our product candidates, we must conduct both pre-clinical studies and human clinical trials. These studies and trials must demonstrate that the product is safe and effective for the clinical use for which we are seeking approval. Together with Aventis, we commenced a Phase III clinical trial for GLIADEL in December 1997 in patients undergoing initial surgery for the brain cancer malignant glioma. The results of this or other clinical trials we may conduct in the future may not be successful. Adverse results from this or any future trial would have a negative effect on our business.

We also face the risk that we will not be permitted to undertake or continue clinical trials for any of our product candidates in the future. Even if we are able to conduct such trials, we may not be able to demonstrate satisfactorily that the products are safe and effective and thus qualify for the regulatory approvals needed to market and sell them. Results from pre-clinical studies and early clinical trials are often not accurate indicators of results of later-stage clinical trials that involve larger human populations.

We are subject to extensive governmental regulation, which may change and harm our business.

Our research, pre-clinical development and clinical trials, and the manufacturing and marketing of our product candidates, are subject to extensive regulation by numerous governmental authorities in the United States and other countries, including the FDA and the DEA. Controlled drugs such as GLIADEL®Wafer and radiolabeled drugs such as DOPASCAN are subject to additional requirements. Except for GLIADEL®Wafer, none of our product candidates has received marketing clearance from the FDA. In addition, none of our product candidates has received clearance from any foreign regulatory authority for commercial sale, except for GLIADEL®Wafer, which has received marketing clearance in a limited number of foreign countries.

As a condition to approval of our product candidates under development, the FDA could require additional pre-clinical, clinical or other studies. Any requirement that we perform additional pre-clinical, clinical or other studies, or purchase clinical or other data from other companies could delay, or increase the expense of, approval of our product candidates, which could have a negative effect on our business.

In order to obtain FDA approval of a new drug product for a specific clinical use, we must demonstrate to the satisfaction of the FDA that the product is safe and effective for its intended use. We must also demonstrate that the product is capable of being manufactured in accordance with applicable regulatory standards. Significant risks exist that:

- we will not be able to satisfy the FDA's requirements with respect to any of our drug product candidates or with respect to the proposed expanded labeling for GLIADEL®Wafer for patients undergoing initial surgery for malignant glioma, or

- even if the FDA does approve our product candidates or expanded labeling, the FDA will approve less than the full scope of uses or labeling that we seek.

Failure to obtain regulatory drug approvals on a timely basis could have a material adverse effect on our business.

Even if we are able to obtain necessary FDA approval, the FDA may nevertheless require post-marketing testing and surveillance to monitor the approved product and continued compliance with regulatory requirements. The FDA may withdraw product approvals if we or our corporate partners do not maintain compliance with regulatory requirements. The FDA may also withdraw product approvals if problems concerning safety or efficacy of the product occur following approval.

The process of obtaining FDA and other required approvals or licenses and of meeting other regulatory requirements to test and market drugs, including controlled substances and radiolabeled drugs, is rigorous and lengthy. We have expended, and will continue to expend, substantial resources. We will need to conduct clinical trials and other studies on all of our product candidates before we are in a position to file a new drug application for marketing and sales approval. Unsatisfactory clinical trial results and other delays in obtaining regulatory approvals or licenses would prevent the marketing of the products we are developing. Until we receive the necessary approvals or licenses and meet other regulatory requirements, we will not receive revenues or royalties related to product sales.

In addition to the requirements for product approval, before a pharmaceutical product may be marketed and sold in some foreign countries, the proposed pricing for the product must be approved as well. Products may be subject to price controls or limits on reimbursement. The requirements governing product pricing and reimbursement vary widely from country to country and can be implemented disparately at the national level. We cannot guarantee that any country which has price controls or reimbursement limitations for pharmaceuticals will allow favorable reimbursement and pricing arrangements for our products or those of our corporate partners.

Where applicable, we hope to capitalize on current FDA regulations and the new provisions of the FDA Modernization Act of 1997. These regulations or provisions permit "fast track", expedited or accelerated approval or more limited "treatment use" of, and cost recovery for, certain experimental drugs under limited circumstances. The fast track and treatment provisions, and FDA's accelerated, expedited and treatment regulations apply generally only to:

- drug products intended to treat severely debilitating or serious or life-threatening diseases, and

- drug products that provide meaningful therapeutic benefit to patients over existing treatments, that potentially address an unmet medical need, or that are for diseases for which no satisfactory or comparable therapy exists.

The FDA Modernization Act contains provisions patterned after the accelerated approval regulations and other provisions pertaining to expanded access, i.e., treatment uses. Since some of the new statutory provisions and current FDA regulations are different from one another, we are uncertain as to how they will apply, if at all, to our drug candidates. Our drug candidates may not qualify for fast track, accelerated or expedited approvals or for treatment use and cost recovery.

Because controlled drug products and radiolabeled drugs are subject to special regulations in addition to those applicable to other drugs, the DEA and the Nuclear Regulatory Commission may regulate some of our products and product candidates, including DOPASCAN®Injection, as controlled substances and as radiolabeled drugs. The NRC licenses persons who use nuclear materials and establishes standards for radiological health and safety. The DEA is responsible for the manufacture, distribution and dispensing of controlled substances, including the equipment and raw materials used in their manufacture and packaging in order to prevent such articles from being diverted into illicit channels of commerce. Registration is required and other activities involving controlled substances are subject to a variety of record keeping and security requirements, and to permits and authorizations and other requirements. States often have requirements for controlled substances as well. The DEA grants certain exceptions from the requirements for permits and authorizations to export or import materials related to or involving controlled substances. Our potential future inability to obtain exceptions from the DEA for shipment abroad or other activities could have a negative effect on us.

We have obtained registrations for our facilities from the DEA. We have also obtained exceptions from the DEA with respect to various of our activities involving DOPASCAN®Injection, including the shipment of specified quantities of a precursor of this product candidate to an overseas collaborative partner. However, we cannot be sure that these exceptions will be sufficient to cover our future activities or that the DEA will not revoke the exceptions. We also cannot be sure that we will be able to meet the other requirements to test, manufacture and market controlled substances or radiolabeled drugs, or that we will be able to obtain additional necessary approvals, permits, authorizations, registrations or licenses to meet state, federal and international regulatory requirements to manufacture and distribute these products. The FDA Modernization Act required the FDA to issue and finalize within one and one-half years regulations governing the approval of radiolabeled drugs. The FDA issued final regulations in May 1999. These cover general factors relevant to safety and effectiveness, possible indications for radiopharmaceuticals, and the evaluation criteria for safety and effectiveness. We do not know and cannot predict how these and other provisions may affect the potential for approval of DOPASCAN®Injection.

Our competitors are pursuing alternative approaches to the same issues we are working on. Our products use novel alternative technologies and therapeutic approaches which have not been widely studied.

Many of our product development efforts focus on novel alternative therapeutic approaches and new technologies that have not been widely studied. Applications for these approaches and technologies include, among other things, the treatment of brain cancer, the diagnosis and monitoring of Parkinson’s disease, the promotion of nerve growth and the prevention of neuronal damage. These approaches and technologies may not be successful. We are applying these approaches and technologies in our attempt to discover new treatments for conditions that are also the subject of research and development efforts of many other companies. Our competitors may succeed in developing technologies or products that are more effective or economical than those we are developing. Rapid technological change or developments by others may result in our technology or product candidates becoming obsolete or noncompetitive.

Our business is dependent on our ability to keep pace with the latest technological changes.

The technological areas in which we work continue to evolve at a rapid pace. Our future success depends upon maintaining our ability to compete in the research, development and commercialization of products and technologies in our areas of focus. Competition from pharmaceutical, chemical and biotechnology companies, universities and research institutions is intense and expected to increase. Many of these competitors have substantially greater research and development capabilities and experience and manufacturing, marketing, financial and managerial resources than we do.

Acquisitions of competing companies by large pharmaceutical companies or other companies could enhance the financial, marketing and other resources available to these competitors. These competitors may develop products that are superior to those we are developing. We are aware of the development by other companies and research scientists of alternative approaches to:

- the treatment of malignant glioma,
- the diagnosis of Parkinson’s disease,

- the promotion of nerve growth and repair,
- the treatment and prevention of neuronal damage, and
- the treatment of cocaine addiction.

Our competitors may develop products that render our products or technologies noncompetitive or obsolete. In addition, we may not be able to keep pace with technological developments.

Our products must compete with others to gain market acceptance.

Any product candidate that we develop and for which we gain regulatory approval, including GLIADEL®Wafer, must then compete for market acceptance and market share. An important factor will be the timing of market introduction of competitive products. Accordingly, the relative speed with which we and competing companies can develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market will be an important element of market success.

Significant competitive factors include:

- capabilities of our collaborators,
- product efficacy and safety,
- timing and scope of regulatory approval,
- product availability,
- marketing and sale capabilities,
- reimbursement coverage from insurance companies and others,
- the amount of clinical benefit of our product candidates relative to their cost,
- the method of administering a product,
- price, and
- patent protection.

Our competitors may develop more effective or more affordable products or achieve earlier product development completion, patent protection, regulatory approval or product commercialization than we do. Our competitors' achievement of any of these goals could have a material adverse effect on our business.

We have limited clinical and regulatory compliance capabilities. We have limited resources in the areas of product testing and regulatory compliance. Consequently, in order to carry our products through the necessary regulatory approvals and prepare our product candidates for commercialization and marketing, we will have to:

- expend capital to acquire and expand such capabilities,
- reach collaborative arrangements with third parties to provide these capabilities, or
- contract with third parties to provide these capabilities.

We are subject to risks of product liability both because of our product line and our limited insurance coverage.

We may potentially become subject to large liability claims and significant defense costs as a result of the design, manufacture or marketing of our products, including GLIADEL®Wafer, or the conduct of clinical trials involving these products. A product liability-related claim or recall could have a negative effect on us. We currently maintain only $15 million of product liability insurance covering clinical trials and product sales. This existing coverage or any future insurance coverage we obtain may not be adequate. Furthermore, our insurance may not cover a claim made against us.

Product liability insurance varies in cost. It can be difficult to obtain, and we may not be able to purchase it in the future on terms acceptable to us, or at all. We also may not be able to otherwise protect against potential product liability claims. If this occurs, it could prevent or inhibit the clinical development and/or commercialization of any products we are developing.

We depend on qualified personnel and consultants, especially Craig R. Smith, M.D. and Solomon H. Snyder, M.D.

We depend heavily on the principal members of our management and scientific staff, including Craig R. Smith, M.D., our Chief Executive Officer, and Solomon H. Snyder, M.D., who is a member of our Board of Directors and a consultant to our company. Both Dr. Smith and Dr. Snyder have extensive experience in the biotechnology industry and provide us with unique access to their contacts in the scientific community. The loss of the services of either of these individuals or other members of our senior management team could have a negative effect on our business.

We have entered into a consulting agreement with Dr. Snyder and an employment agreement with Dr. Smith, each of which provides protection for our proprietary rights. Nevertheless, either Dr. Snyder or Dr. Smith may terminate his relationship with us at any time. Accordingly, we cannot be sure that either of these individuals or any of our other employees or consultants will remain with us. In the future they may take jobs or consulting positions with our competitors. These employees or consultants may also choose to organize competing companies or ventures.

Our planned activities will require individuals with expertise in many areas including:

- medicinal chemistry and other research specialties,
- pre-clinical testing,
- clinical trial management,
- regulatory affairs,
- manufacturing, and
- business development.

These planned activities will require additional personnel, including management personnel, and will also require existing management personnel to develop added expertise. Recruiting and retaining qualified personnel, collaborators, advisors and consultants will be critical to our activities. We may not be able to attract and retain the personnel necessary for the development of our business. Furthermore, many pharmaceutical, biotechnology and health care companies and academic and other research institutions compete intensely for experienced scientists. If we are not able to hire the necessary experienced scientists or develop the necessary expertise, this inability could have a negative effect on us. In addition, we also depend on the support of our collaborators at research institutions and our consultants.

Our business involves using hazardous and radioactive materials and animal testing, all of which may result in environmental liability.

Our research and development processes involve the controlled use of hazardous and radioactive materials. We and our collaborative partners are subject to extensive laws governing the use, manufacture, storage, handling and disposal of hazardous and radioactive materials. There is a risk of accidental contamination or injury from these materials. Also, we cannot control whether our collaborative partners comply with the governing standards. If we or our collaborative partners do not comply with the governing laws and regulations, we could face significant fines and penalties that could have a negative effect on our business, operations or finances. In addition, we and/or our collaborative partners could be held liable for damages, fines or other liabilities, which could

exceed our resources.

However, we may have to incur significant costs to comply with environmental laws and regulations in the future. In addition, future environmental laws or regulations may have a negative effect on our operations, business or assets.

Many of the research and development efforts we sponsor involve the use of laboratory animals. Changes in laws, regulations or accepted clinical procedures may adversely affect these research and development efforts. Social pressures that would restrict the use of animals in testing or actions against us or our collaborators by groups or individuals opposed to testing using animals could also adversely affect these research and development efforts.

Effecting a change of control of Guilford would be difficult, which may discourage offers for shares of our common stock.

Our certificate of incorporation and the Delaware General Corporation Law contain provisions that may delay or prevent an attempt by a third party to acquire control of us. These provisions include the requirements of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits designated types of business combinations, including mergers, for a period of three years between us and any third party who owns 15% or more of our common stock. This provision does not apply if:

- our Board of Directors approves of the transaction before the third party acquires 15% of our stock,
- the third party acquires at least 85% of our stock at the time its ownership goes past the 15% level, or
- our Board of Directors and two-thirds of the shares of our common stock not held by the third party vote in favor of the transaction.

We have also adopted a stockholder rights plan intended to deter hostile or coercive attempts to acquire us. Under the plan, if any person or group acquires more than 20% of our common stock without approval of the Board of Directors under specified circumstances, our other stockholders have the right to purchase shares of our common stock, or shares of the acquiring company, at a substantial discount to the public market price. The plan thus makes an acquisition much more costly to a potential acquirer.

Our certificate of incorporation also authorizes us to issue up to 4,700,000 shares of preferred stock in one or more different series with terms fixed by the Board of Directors. Stockholder approval is not necessary to issue preferred stock in this manner. Issuance of these shares of preferred stock could have the effect of making it more difficult for a person or group to acquire control of us. No shares of our preferred stock are currently outstanding. While our Board of Directors has no current intentions or plans to issue any preferred stock, issuance of these shares could also be used as an anti-takeover device.

Item 6. ***Exhibits and Reports on Form 8-K:***

A. Exhibits

Exhibit No.	Description
27.01	Financial Data Schedule
10.61	Rights Reversion Agreement dated October 23, 2000, by and between Aventis Pharmaceutical Products Inc., Rhone-Poulenc Rorer Inc., GPI Holdings, Inc. and Guilford Pharmaceuticals Inc.
10.62	Agreement dated October 24, 2000, by and between Cardinal Health Sales and Marketing Services, a division of RedKey Inc. and Guilford Pharmaceuticals Inc.

B. Reports on Form 8-K

On August 29, 2000, we filed a Current Report on Form 8-K, the sole purpose of which was to report the termination of the proposed merger with Gliatech Inc.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Guilford Pharmaceuticals Inc.

Date: November 14, 2000

/s/ CRAIG R. SMITH, M.D.

Craig R. Smith, M.D.
Chairman of the Board, President and Chief Executive Officer

Date: November 14, 2000

/s/ ANDREW R. JORDAN

Andrew R. Jordan
Senior Vice President and Chief Financial Officer
(Principal Accounting Officer)