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 June 30, 2000

Commission File Number 000-23736

GUILFORD PHARMACEUTICALS INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

6611 Tributary Street Baltimore, Maryland

(Address of principal executive offices)

52-1841960

(IRS Employer Identification No.)

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 ⊠ 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 August 11, 2000

Common Stock, \$.01 par value

23,481,175

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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)

Assets Current assets: \$ 14,078 \$ 14,336 Cash and cash equivalents 95,337 108,997 Accounts receivable 952 1,020 Inventories 1,883 1,348 Other current assets 607 752 Total current assets 607 752 Investments — restricted 19,962 21,385 Property and equipment, net 14,562 15,793 Other assets 1,248 611 \$ 148,629 \$164,242
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Other assets 1,248 611
\$ 148,629 \$164,242
Liabilities and Stockholders' Equity
Current liabilities:
Accounts payable
Current portion of long-term debt
Accrued payroll related costs
Accrued contracted services
Accrued expenses and other current liabilities
Deferred income 1,125 1,125 1,125
Total current liabilities
Long-term debt, net of current portion
Total liabilities
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, 23,713,234 and 23,328,313 issued at June 30,
2000 and December 31, 1999, respectively
Additional paid-in capital
Accumulated deficit
Accumulated other comprehensive loss
Note receivable from officer
Treasury stock, at cost: 267,564 and 274,880 shares at June 30,
2000 and December 31, 1999, respectively
Deferred compensation
Total stockholders' equity
<u>\$ 148,629</u> <u>\$164,242</u>

See accompanying notes to consolidated financial statements.

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

	Three Mon June		Six Mont June	
	2000	1999	2000	1999
Revenues:				
Contract revenues	\$ —	\$ —	\$ 1,000	\$ —
Net product sales	643	1,674	1,207	2,866
License fees and royalties	523	697	1,101	1,244
Revenues under collaborative agreements	1,125	1,276	2,250	2,413
Total revenues	2,291	3,647	5,558	6,523
Costs and expenses:				
Cost of sales	333	813	657	1,443
Research and development	12,085	10,012	21,876	19,139
General and administrative	2,889	3,125	5,488	6,646
Merger costs	774		1,071	
Total costs and expenses	16,081	13,950	29,092	27,228
Operating loss	(13,790)	(10,303)	(23,534)	(20,705)
Other income (expense):				
Investment and other income	2,168	1,873	4,128	3,942
Interest expense	(139)	(184)	(274)	(348)
Net loss	<u>\$(11,761</u>)	\$ (8,614)	<u>\$(19,680</u>)	<u>\$(17,111</u>)
Basic and diluted loss per common share	<u>\$ (0.50</u>)	\$ (0.44)	\$ (0.84)	\$ (0.88)
Weighted-average common shares outstanding	23,435	19,392	23,354	19,441

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

	Common Stock				Accumulated	Note			
	Numbers of Shares Issued	Dollar Amount	Additional Paid-In Capital	Accumulated Deficit	Other Comprehensive Loss	Receivable From Officer	Treasury Stock, at Cost	Deferred Compensation	Total Stockholders' Equity
Balance, January 1, 2000	23,328,313	\$233	\$232,913	\$ (82,877)	\$(1,838)	\$(60)	\$(3,284)	\$(107)	\$144,980
Comprehensive loss:									
Net loss for the period				(19,680)					(19,680)
Other comprehensive income:									
Unrealized gain on available-for-sale									
securities					29				29
Total comprehensive loss									<u>\$(19,651)</u>
Other issuances of common stock	384,921	4	4,593						4,597
Purchase of 2,427 shares of common stock							(91)		(91)
Distribution of 9,743 shares of treasury							, ,		, ,
stock to 401(k) plan			79				117		196
Stock option compensation			167						167
Amortization of deferred compensation								26	26
Balance, June 30, 2000	23,713,234	\$237	\$237,752	<u>\$(102,557</u>)	<u>\$(1,809</u>)	<u>\$(60</u>)	<u>\$(3,258</u>)	<u>\$ (81</u>)	\$130,224

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

	Three Months Ended June 30,		Six Month June	
	2000	1999	2000	1999
Cash Flows from Operating Activities:				
Net loss	\$(11,761)	\$(8,614)	\$ (19,680)	\$(17,111)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	1,039	1,596	1,997	2,649
Noncash compensation expense	160	219	480	357
Changes in assets and liabilities:				
Accounts receivable and other assets	993	(300)	(434)	(395)
Inventories	(242)	173	(535)	148
Accounts payable	1,400	394	1,096	(736)
Accrued expenses and other current liabilities	1,408	(1,454)	(937)	(78)
Net cash used in operating activities	(7,003)	(7,986)	(18,013)	(15,166)
Cash Flows from Investing Activities:				
Purchases of property and equipment	(580)	(1,654)	(756)	(2,214)
Maturities of marketable securities	62,133	6,065	125,334	85,771
Purchases of marketable securities	(48,957)	(2,901)	(110,222)	(73,422)
Net cash provided by investing activities	12,596	1,510	14,356	10,135
Cash Flows from Financing Activities:				
Net proceeds from issuances of common stock	225	2,373	4,597	2,390
Purchase of treasury stock	_	(932)	(91)	(2,209)
Principal payments on debt	(548)	(540)	(1,107)	(1,080)
Net cash provided by (used in) financing activities	(323)	901	3,399	(899)
Net increase (decrease) in cash and cash equivalents	5,270	(5,575)	(258)	(5,930)
Cash and Cash Equivalents at the Beginning of Period	8,808	8,125	14,336	8,480
Cash and Cash Equivalents at the End of Period	\$ 14,078	\$ 2,550	\$ 14,078	\$ 2,550
Supplemental disclosures of cash flow information: Net interest paid	\$ 139	\$ 170	\$ 274	\$ 342

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

1. Organization and Basis of Presentation

Guilford Pharmaceuticals Inc. (together with its subsidiaries, "Guilford" or the "Company") is a biopharmaceutical company located in Baltimore, Maryland, engaged in the development and commercialization of novel products in two principal areas: (i) targeted and controlled drug delivery systems using proprietary biodegradable polymers for the treatment of cancer and other diseases or conditions and (ii) 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 ("SEC"). 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 notes thereto included in the Company's 1999 annual report on Form 10-K for the year ended December 31, 1999.

In the opinion of the Company's management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, necessary to present fairly its financial position, results of operations, changes in stockholders' equity and cash flows for the three-month and six-month periods ended June 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") is 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 of the Company's basic and diluted EPS (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2000	1999	2000	1999
Net loss	\$(11,761)	\$(8,614)	\$(19,680)	\$(17,111)
Weighted-average common shares outstanding	23,435	19,392	23,354	19,441
Basic and diluted loss per common share	\$ (0.50)	\$ (0.44)	\$ (0.84)	\$ (0.88)

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

Notes to Consolidated Financial Statements — (Continued)

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 fiscal years 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.

3. Inventories (in thousands)

	June 30, 2000	December 31, 1999
Raw materials	\$ 313	\$ 280
Work in process	681	416
Finished goods	889	652
	\$1,883	\$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 the Company's development activities. Inventories identified for development activities are expensed in the period in which such inventories are designated for such use.

4. Merger with Gliatech Inc.

On May 29, 2000, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") under which a wholly-owned subsidiary of the Company would acquire all of the outstanding shares of Gliatech Inc. ("Gliatech") in a tax-free transaction intended to be accounted for as a pooling of interests. Gliatech is a biopharmaceutical company engaged in the discovery and development of biosurgical and therapeutic products to improve surgical outcomes and to treat neurological disorders. Under the terms of the Merger Agreement, each shareholder of Gliatech will receive 1.38 shares of Guilford common stock at the time of closing. The transaction, which is subject to shareholder and regulatory approval, is expected to close in the third quarter of 2000. Assuming a closing in September 2000, there would be approximately 10,946,000 shares of Gliatech common stock outstanding (which assumes the exercise of all outstanding Gliatech stock options (1,364,000)). Accordingly, based on the above exchange ratio, Guilford will issue approximately 15,106,000 shares of its common stock in exchange for these shares.

Related to the 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. Pursuant to the settlement agreement (i) if the proposed merger closes then Guilford will pay Cartech \$4.5 million within seven days after the proposed merger has been closed and (ii) if the merger agreement is terminated prior to closing or if the merger does not close by December 1, 2000, then Gliatech will pay Cartech \$4.5 million. In the event that Gliatech makes the payment to Cartech and upon Gliatech's written request, Gliatech will enter into good faith negotiations for a new build-to-suit lease and Gliatech will receive a credit against the cost of the new lease of up to \$2,187,500. The lawsuit has been dismissed by Cartech without prejudice, and the parties have agreed to a full mutual release of claims and termination of the existing build-to-suit lease effective upon receipt by Cartech of the payment by Guilford or Gliatech. Pending such payment, Cartech has agreed to abstain from further legal action against Guilford and Gliatech.

Notes to Consolidated Financial Statements — (Continued)

The Company incurred merger costs related to the transaction of \$0.8 million and \$1.1 million for the three- and six-month periods ended June 30, 2000, respectively. The Company's policy is to expense such costs in the period incurred. The Company expects to incur additional charges to reflect costs associated with the proposed merger.

5. Investment in ProQuest Pharmaceuticals Inc.

During the six-month period ended June 30, 2000, the Company acquired from ProQuest Pharmaceuticals Inc. ("ProQuest") an exclusive worldwide license to a novel pro-drug of a widely used anesthetic agent, propofol. Pursuant to this transaction, the Company paid approximately \$0.7 million for 133,333 shares of common stock of ProQuest. In addition, the Company 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, the Company will make milestone payments based on clinical development and royalties on any product sales. ProQuest is a privately-held pharmaceutical company based in Lawrence, Kansas. As the Company's investment in ProQuest is less than 20% of the outstanding common stock, the Company accounts for its investment under the cost method.

6. Related Party Transaction

A note receivable on common stock of \$60,000 at June 30, 2000 and December 31, 1999, represents an amount due from an officer of the Company related to such officer's purchase of shares of Guilford common stock. The note bears interest at the rate of 5.34% per annum and is due and payable on February 14, 2002. Such amount is reflected as a reduction of stockholders' equity in the accompanying balance sheets.

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

From time to time in this quarterly report we may 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:

- our efforts in conjunction with Aventis Pharmaceutical Products, Inc. (successor by merger between Rhone-Poulenc Rorer Pharmaceuticals Inc. and Hoechst AG in December 1999) ("Aventis") to obtain additional international regulatory clearances to market and sell GLIADEL® Wafer and to increase end-user sales of GLIADEL® Wafer;
- our efforts in conjunction with Aventis to expand the labeled uses for GLIADEL® Wafer;
- our efforts to develop polymer drug delivery product line extensions and new polymer drug delivery products;
- conducting and completing 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;
- clinical development activities, including commencing and conducting clinical trials, related to our polymer-based drug delivery products and product candidates (including GLIADEL® Wafer and PACLIMERTM Microspheres) and our pharmaceutical product candidates (including lead compounds in our FKBP neuroimmunophilin ligand and NAALADase 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; and
- anticipated expenditures and the potential need for additional funds.

All of these items involve significant risks and uncertainties.

In addition, the proposed merger between Guilford and Gliatech involves additional risks and uncertainties, such as:

- The merger may not succeed.
- The anticipated synergies and benefits of the merger may not be realized.

- Guilford may not be able to successfully integrate Gliatech into its operations, which could decrease the value of the merger to both companies' stockholders.
- The cost of the merger, the costs of integrating the Guilford and Gliatech businesses and other potential adjustments are substantial.
- Guilford has no prior experience in marketing products such as the Gliatech products, in the United States and internationally.
- The FDA could issue a formal warning letter or take enforcement action against Gliatech.
- Gliatech is the subject of legal proceedings.

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 significantly 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 the section titled "Risk Factors" in 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 any such forward-looking statements to reflect events or circumstances that occur after that date.

Introduction

In the following sections of this Management's Discussion and Analysis of Financial Condition and Results of Operations ("Management's Discussion and Analysis"), 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 such 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 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- and six-month periods ended June 30, 2000 and 1999, as well as our financial position at June 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. Aventis is our exclusive worldwide marketing partner for GLIADEL® Wafer, except in Japan and Scandinavia. Orion Corporation Pharma (formerly Orion Corporation Farmos) is our marketing partner for GLIADEL® Wafer in Scandinavia.

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 PACLIMERTM Microspheres and LIDOMERTM Microspheres, which we are using for the targeted and controlled delivery of cancer chemotherapeutics and other drugs.

In addition, we continued to increase our investment in research and development activities with respect to certain of these technologies.

We anticipate that our revenues in 2000 will come primarily from the following sources:

- sales of our manufactured products to our marketing partners, which sales currently consist of GLIADEL® Wafer;
- · royalties from our marketing partner related to its sales of our product to third parties; and/or
- one-time rights, milestone, and other payments from corporate partners under our current collaborative agreements and new ones that we may enter into with others in the future.

As we discuss in greater detail below, if we or our corporate collaborators, Aventis and Amgen, attain certain regulatory and/or development objectives, we are eligible to receive certain milestone and other payments from these companies. 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 our corporate collaborators 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 or any future collaborations. 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.

Since the commercial launch of GLIADEL® Wafer in the United States in February 1997 through June 30, 2000, we have recognized an aggregate of \$22.9 million in product sales and royalties. Of this amount, \$15.2 million represents revenues from sales of GLIADEL® Wafer to Aventis and to Orion Corporation Pharma. The additional \$7.7 million are royalties paid to us from Aventis on its sales of GLIADEL® Wafer to third parties, such as hospitals.

Product sales to Aventis, however, are subject to the near-term and longer-term sales forecast of GLIADEL® Wafer. To the extent Aventis' forecast of third party sales increases, we may expect to see increased orders for GLIADEL® Wafer. As we fulfill such purchase orders, product sales are recognized at the time GLIADEL® Wafer has received an appropriate "certificate of analysis" (a quality requirement) and shipment of the product has been made to Aventis. Aventis does not have the right of return related to its purchase of GLIADEL® Wafer except for issues related to quality.

While we recognize product sales upon shipment to Aventis, royalty income is recognized at such time as Aventis sells GLIADEL® Wafer to third parties. While we do not provide a right of return to Aventis, Aventis does provide a right of return to its customers as is industry practice in the pharmaceutical business. Royalty income recognized by us based upon Aventis' sales to third parties reflects estimates by Aventis of sales returns, discounts and other allowances.

Under the terms of our agreements with Aventis, if Aventis is able to achieve certain specified regulatory objectives, then Aventis is obligated to pay us up to an additional \$22.0 million in milestone payments and

\$7.5 million for the purchase of shares of our common stock. These regulatory objectives include obtaining additional approvals to market GLIADEL® Wafer in certain foreign countries and expanding the clinical uses of GLIADEL® Wafer. In March 2000, we earned a non-refundable milestone payment of \$1.0 million from Aventis upon receipt of approval to market and sell GLIADEL® Wafer for the recurrent surgery indication in Spain.

As we discuss below and in greater detail 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 that our sales of GLIADEL® Wafer to Aventis and Aventis' sales of GLIADEL® Wafer to third parties will increase over time or even continue at the current rate. The milestone payments and other amounts payable by Aventis are contingent upon:

- making certain international regulatory filings and obtaining clearances to market GLIADEL® Wafer for the recurrent 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 certain countries at prices that are acceptable to Aventis and us.

We cannot control the timing and extent of governmental clearances. We also cannot be sure that we and Aventis will attain any of these regulatory objectives.

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, Amgen paid \$15 million 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 Guilford's 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 due on July 1, 2000. As of June 30, 2000, we had recognized an aggregate of approximately \$12.4 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 \$392 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 greater detail 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 six-month period ended June 30, 2000 consisted of:

- a \$1.0 million non-refundable milestone from Aventis in March 2000, based upon Aventis' receipt of specified regulatory approval to market and sell GLIADEL® Wafer for the recurrent surgery indication in Spain and
- \$2.3 million relating to research support for the FKBP neuroimmunophilin ligand technology from Amgen.

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 six-month periods ended June 30, 2000, we incurred a net loss of \$11.8 million and \$19.7 million, respectively. Since inception through June 30, 2000, we had an accumulated deficit of \$102.6 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 to Aventis and Aventis' sales to end-customers;
- the timing and realization of milestone and other payments from our corporate partners, including Aventis and Amgen;
- 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, extend, enforce and/or defend our patent and other rights to our intellectual property.

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 general and administrative activities. In addition, we expect the number of employees working at our company to continue to increase. At June 30, 2000, we had 234 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, either alone or with others, to develop our product candidates successfully, including NIL-A with Amgen, PACLIMERTM 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;
- 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; and
- we may not be able to successfully integrate Gliatech into our operations, which could decrease the value of the merger to both companies' shareholders.

For a discussion of these and other risks, you should read the "Risk Factors" section of our 1999 Form 10-K, particularly those paragraphs specifically addressing the risks we note above.

Future product sales of GLIADEL® Wafer are subject to certain risks and uncertainties. These risks include the following, among others:

- Aventis is not obligated to purchase any minimum amounts of GLIADEL® Wafer from us, and so our
 revenues from the sale and distribution of GLIADEL® Wafer are entirely dependent on the level of
 Aventis' sales to end-users.
- Aventis may not be successful in its efforts to market and sell GLIADEL® Wafer.
- 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.
- Aventis may not be successful in its 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.
- The Company's current manufacturing plant for GLIADEL® Wafer and a recently completed second manufacturing facility are both located in the same building at our headquarters 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.

As we note in the section captioned "Risk Factors" of our 1999 Form 10-K, there is no guarantee that we or Amgen 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 of our 1999 Form 10-K, 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 six-month periods ended June 30, 2000 and 1999.

Revenues

Our revenues for the three- and six-month periods ended June 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;
- a non-refundable milestone payment from Aventis; and
- · quarterly research funding from Amgen.

We recognized total revenues of \$2.3 million and \$3.6 million for the three-month periods ended June 30, 2000 and 1999, respectively, and \$5.6 million and \$6.5 million for the six-month periods ended June 30, 2000 and 1999, respectively.

These revenues consisted primarily of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2000	1999	2000	1999
	(in millions)		(in mi	llions)
Revenues Relating to GLIADEL® Wafer:				
Net product sales	\$0.6	\$1.7	\$1.2	\$2.9
License fees and royalties	0.5	0.7	1.1	1.2
Non-recurring rights and milestones	_	_	1.0	_
Revenues from Amgen:				
Research funding under collaborative				
agreements	1.1	1.1	2.3	2.3

GLIADEL® Wafer Product Sales

We manufacture and supply GLIADEL® Wafer to our marketing and sales partners. We earned \$0.6 million and \$1.7 million for the three-month periods ended June 30, 2000 and 1999, respectively, and \$1.2 million and \$2.9 million for the six-month periods ended June 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 product sales of GLIADEL® Wafer to Aventis is the result of Aventis managing existing inventory requirements to meet current product demand.

Royalties on GLIADEL® Wafer Sales to Third Parties

Aventis pays 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 \$0.7 million for the three-month periods ended June 30, 2000 and 1999, respectively, and \$1.1 million and \$1.2 million for the six-month periods ended June 30, 2000 and 1999, respectively. Sales to third parties for the three- and six-month period ended June 30, 2000 compared to the same periods in 1999 have remained relatively flat coincident with demand for the product in the market. As we discuss in greater detail 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 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 sales as a percentage of net product sales revenue were 52% and 49% for the three-month periods ended June 30, 2000 and 1999, respectively, and 54% and 50% for the six-month periods ended June 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. 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 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 \$12.1 million and \$10.0 million for the three-month periods ended June 30, 2000 and 1999, respectively, and \$21.9 million and \$19.1 million for the six-month periods ended June 30, 2000 and 1999, respectively. The increase in our research and development expenses for the three- and six-month periods ended June 30, 2000 when compared to the corresponding periods of 1999, can be attributed to increased efforts in our existing NAALADase inhibitor and PARP inhibitor and neuroprotectant programs and the initiation, during the three-month period ended June 30, 2000, of our propofol pro-drug program.

During the three-month period ended March 31, 2000, the Company acquired an exclusive worldwide license to a novel pro-drug of a widely used anesthetic, propofol. Pursuant to the transaction, the Company recorded a charge to earnings of approximately \$0.3 million during the three-month period ended March 31, 2000. During the three-month period ended June 30, 2000, the Company initiated development of the compound and incurred additional costs of approximately \$1.0 million.

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 June 30, 2000, we employed 201 individuals on a full-time basis in the areas of research, development and manufacturing compared to 193 at December 31, 1999.

General and Administrative Expenses

Our general and administrative expenses decreased to \$2.9 million from \$3.1 million when comparing the three-month periods ended June 30, 2000 and 1999, respectively, and to \$5.5 million from \$6.6 million when comparing the six-month periods ended June 30, 2000 and 1999, respectively. The decreases were largely attributable to a reduction in external legal costs incurred in connection with the Company's intellectual property portfolio.

At June 30, 2000, we employed 41 individuals on a full-time basis in general and administrative areas compared to 35 at December 31, 1999.

Merger Expenses

The Company incurred merger costs related to the proposed merger with Gliatech of \$0.8 million and \$1.1 million for the three- and six-month periods ended June 30, 2000, respectively. The Company's policy is to expense such costs in the period incurred.

We expect to incur additional charges to reflect costs associated with the proposed merger.

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 \$2.2 million and \$1.9 million for the three-month periods ended June 30, 2000 and 1999, respectively, and \$4.1 million and \$3.9 million for the six-month periods ended June 30, 2000 and 1999, respectively.

We incurred interest expense of \$139,000 and \$184,000 for the three-month periods ended June 30, 2000 and 1999, respectively, and \$274,000 and \$348,000 for the six-month periods ended June 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 six-month periods ended June 30, 2000 as compared to the corresponding periods of 1999.

Liquidity and Capital Resources

Our cash, cash equivalents, and investments were approximately \$129.4 million at June 30, 2000. Of this amount, we pledged \$20.0 million as collateral for certain of our loans and other financial lease obligations. In addition to these restricted investments, the Company is 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 \$8.3 million at June 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 \$580,000 and \$756,000 during the three- and six-month periods ended June 30, 2000, respectively, which resulted primarily from the purchase of equipment to support our ongoing research and development and production activities.

In March 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 June 30, 2000, we had leased approximately \$7.0 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 June 30, 2000, \$3.8 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 2000. 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, the Company 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, the Company 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 2000.

Under a loan agreement we executed with Aventis in 1996, Aventis has extended to us a \$7.5 million line of credit to support expansion of our GLIADEL® Wafer and polymer manufacturing capacity, of which \$4.0 million is currently available to us. The remaining \$3.5 million becomes available no earlier than 12 months nor later than 18 months following funding of the initial portion. Any principal amounts we borrow are due five years from the date borrowed. These amounts will carry an interest rate equal to the lowest rate

Aventis pays from time to time on its most senior debt. We have not borrowed any amounts under this credit facility as of June 30, 2000.

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 on the fifth anniversary of such interest rate swap agreements.

In the fourth quarter of 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 six-month periods ended June 30, 2000.

We expect to need significantly greater capital to continue our research and product development programs and pre-clinical and clinical testing and to manufacture and possibly market our products. We will also need additional funds to meet our future facility expansion needs if necessary. Our capital requirements depend on a number of 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;
- our ability to establish collaborative arrangements;
- our ability to enter into licensing agreements and contractual arrangements with others;
- the progress of efforts to scale-up manufacturing processes; and
- the merger and integration of Gliatech.

We believe that our existing resources will be sufficient to fund our activities through at least December 31, 2001. We may, however, expend these resources before that time for a number of reasons, including, among others:

- changes in our research, product development, and commercialization plans;
- other factors that increase our expenses or capital expenditures, including potential acquisitions of other companies, assets, products, or in-licensing of drug candidates, or technologies; and
- · unanticipated capital expenditures.

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.

GUILFORD PHARMACEUTICALS INC.

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, the Company has 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 principal amount at June 30, 2000 and weighted-average interest rate of our investment portfolio for the sixmonth period ended June 30, 2000 was \$115.3 million and approximately six percent (6%), respectively.

Substantially all of our financial obligations have variable rates of interest. As a hedge against fluctuations in interest rates, the Company has entered into certain interest rate swap agreements with a commercial bank ("counter party"), to exchange substantially all of its variable rates of interest on certain financial lease obligations and debt, for fixed rates. The Company's borrowings under its bond and term loans and financial obligations under certain lease arrangements are approximately \$26.9 million. Pursuant to these borrowing arrangements, the Company is 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 \$27.7 million as of June 30, 2000. Pursuant to these interest rate swap agreements, the Company pays 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 1/8%. The differential to be paid or received as interest rates change is charged or credited, as appropriate, to operations. Thereby, the Company has effectively fixed the interest rates on its 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 the agreements on the fifth year anniversary date of each agreement. The Company does not speculate on the future direction of interest rates nor does the Company use these derivative financial instruments for trading purposes. In the event of non-performance by the counter party, the Company could be exposed to market risk related to interest rates.

The aggregate fair value of these interest rate swap agreements was approximately \$1 million at June 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:

On May 30, 2000, the Company announced that it would acquire all of the outstanding shares of Gliatech Inc. The transaction which is subject to shareholder and regulatory approval, is expected to close in the third quarter of 2000. 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. Pursuant to the settlement agreement (i) if the proposed merger closes, then Guilford will pay Cartech \$4.5 million within seven days after the proposed merger has been closed; and (ii) if the merger agreement is terminated prior to closing or if the merger does not close by December 1, 2000, then Gliatech will pay Cartech \$4.5 million. In the event that Gliatech makes the payment to Cartech and upon Gliatech's written request, Gliatech will enter into good faith negotiations for a new build-to-suit lease and Gliatech will receive a credit against the cost of the new lease of up to \$2,187,500. The lawsuit has been dismissed by Cartech without prejudice, and the parties have agreed to a full mutual release of claims and termination of the existing build-to-suit lease effective upon receipt by Cartech of the payment by Guilford or Gliatech. Pending such payment, Cartech has agreed to abstain from further legal action against Guilford and Gliatech.

Item 2. Changes In Securities:

None

Item 3. Defaults Upon Senior Securities:

None

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

We held our Annual Meeting of Stockholders on May 16, 2000. The following individuals were elected to our Board of Directors to hold office for the ensuing year:

Name of Nominee	Votes FOR	ABSTAINED
Craig R. Smith, M.D	16,374,096	19,362
Richard L. Casey	16,373,696	19,762
Solomon H. Snyder, M.D.	16,368,196	25,262
W. Leigh Thompson, M.D., Ph.D	16,373,796	19,662
Elizabeth M. Greetham	16,374,096	19,362
George L. Bunting, Jr	16,374,096	19,362
Joseph "Skip" Klein, III	16,374,096	19,362
Ronald M. Nordmann	16,374,086	19,372

The following proposal was approved as follows:

Proposal	Votes FOR	Votes AGAINST	ABSTAINED
Proposal to ratify the selection of KPMG LLP as our			
independent auditors for 2000	16,367,543	19,320	6,595

Item 5. Other Information:

None

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

A. Exhibits

Exhibit No.	Description			
27.03	Financial Data Schedule			

B. Reports on Form 8-K

On June 14, 2000, we filed a Current Report on Form 8-K, the sole purpose of which was to file the press release announcing 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.

Date: August 14, 2000

| S | Craig R. Smith, M.D. |
| Craig R. Smith, M.D. |
| Chairman of the Board, President and Chief |
| Executive Officer |
| Date: August 14, 2000 | /s | Andrew R. Jordan |
| Senior Vice President and Chief Financial Officer |

(Principal Accounting Officer)