# 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 March 31, 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** | **21224** |
| *(Address of principal executive offices)* | *(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 May 10, 2000 |
|---|---|
| **Common Stock, $.01 par value** | 23,424,676 |

## INDEX

## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

### GUILFORD PHARMACEUTICALS INC. AND SUBSIDIARIES

### Consolidated Balance Sheets (in thousands, except share data)

| | March 31, 2000 (unaudited) | December 31, 1999 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 8,808 | $ 14,336 |
| Investments | 108,140 | 108,997 |
| Accounts receivable | 1,924 | 1,020 |
| Inventories | 1,641 | 1,348 |
| Other current assets | 679 | 752 |
| Total current assets | 121,192 | 126,453 |
| Investments — restricted | 20,310 | 21,385 |
| Property and equipment, net | 15,016 | 15,793 |
| Other assets | 1,202 | 611 |
| | $157,720 | $164,242 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,781 | $ 3,085 |
| Current portion of long-term debt | 2,214 | 2,214 |
| Accrued payroll and related costs | 1,076 | 2,070 |
| Accrued contracted services | 1,195 | 2,066 |
| Accrued expenses and other current liabilities | 1,183 | 1,550 |
| Deferred income | 1,125 | 1,125 |
| Total current liabilities | 9,574 | 12,110 |
| Long-term debt, net of current portion | 6,593 | 7,152 |
| Total liabilities | 16,167 | 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, 23,682,971 and 23,328,313 issued at March 31, 2000 and December 31, 1999, respectively | 237 | 233 |
| Additional paid-in capital | 237,408 | 232,913 |
| Accumulated deficit | (90,796) | (82,877) |
| Accumulated other comprehensive loss | (1,834) | (1,838) |
| Note receivable from officer | (60) | (60) |
| Treasury stock, at cost: 271,708 and 274,880 shares at March 31, 2000 and December 31, 1999, respectively | (3,308) | (3,284) |
| Deferred compensation | (94) | (107) |
| Total stockholders' equity | 141,553 | 144,980 |
| | $157,720 | $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 March 31, | |
|---|---|---|
| | **2000** | **1999** |
| Revenues: | | |
| Contract revenues | $ 1,000 | $ — |
| Net product sales | 564 | 1,192 |
| License fees and royalties | 578 | 547 |
| Revenues under collaborative agreements | 1,125 | 1,137 |
| Total revenues | 3,267 | 2,876 |
| Costs and expenses: | | |
| Cost of sales | 324 | 630 |
| Research and development | 9,791 | 9,127 |
| General and administrative | 2,896 | 3,521 |
| Total costs and expenses | 13,011 | 13,278 |
| Operating loss | (9,744) | (10,402) |
| Other income (expense): | | |
| Investment and other income | 1,960 | 2,069 |
| Interest expense | (135) | (164) |
| Net loss | $(7,919) | $ (8,497) |
| Basic and diluted loss per common share | $ (0.34) | $ (0.44) |
| Weighted-average common shares outstanding | 23,276 | 19,491 |

*See accompanying notes to consolidated financial statements.*

**GUILFORD PHARMACEUTICALS INC.**
**AND SUBSIDIARIES**

**Consolidated Statement of Changes in Stockholders' Equity**
**Three Months Ended March 31, 2000**
**(unaudited)**
**(in thousands, except share data)**

| | Common Stock | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Numbers of Shares Issued | Dollar Amount | Additional Paid-In Capital | Accumulated Deficit | Accumulated Other Comprehensive Loss | Note Receivable From Officer | Treasury Stock, at Cost | Deferred Compensation | Total Stockholders' Equity |
| **Balance, December 31, 1999** | 23,328,313 | $233 | $232,913 | $(82,877) | $(1,838) | $(60) | $(3,284) | $(107) | $144,980 |
| Comprehensive loss: | | | | | | | | | |
| Net loss for the period | | | | (7,919) | | | | | (7,919) |
| Other comprehensive income: | | | | | | | | | |
| Unrealized gain on available-for-sale securities | | | | | 4 | | | | 4 |
| Total comprehensive loss | | | | | | | | | $ (7,915) |
| Issuances of common stock | 354,658 | 4 | 4,368 | | | | | | 4,372 |
| Purchase of 2,427 shares of common stock | | | | | | | (91) | | (91) |
| Distribution of 5,599 shares of treasury stock to 401(k) plan | | | 17 | | | | 67 | | 84 |
| Stock option compensation | | | 110 | | | | | | 110 |
| Amortization of deferred compensation | | | | | | | | 13 | 13 |
| **Balance, March 31, 2000** | 23,682,971 | $237 | $237,408 | $(90,796) | $(1,834) | $(60) | $(3,308) | $ (94) | $141,553 |

*See accompanying notes to consolidated financial statements.*

**GUILFORD PHARMACEUTICALS INC.**
**AND SUBSIDIARIES**

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2000** | **1999** |
| **Cash Flows from Operating Activities:** | | |
| Net loss | $ (7,919) | $ (8,497) |
| Adjustments to reconcile net loss to net cash used in operating Activities: | | |
| Depreciation and amortization | 958 | 1,053 |
| Noncash compensation expense | 320 | 138 |
| Changes in assets and liabilities: | | |
| Accounts receivable and other assets | (1,427) | (95) |
| Inventories | (293) | (25) |
| Accounts payable | (304) | (1,130) |
| Accrued expenses and other current liabilities | (2,345) | 1,376 |
| Net cash used in operating activities | (11,010) | (7,180) |
| **Cash Flows from Investing Activities:** | | |
| Purchases of property and equipment, net | (176) | (560) |
| Sale and maturities of marketable securities | 63,201 | 79,706 |
| Purchases of marketable securities | (61,265) | (70,521) |
| Net cash provided by investing activities | 1,760 | 8,625 |
| **Cash Flows from Financing Activities**: | | |
| Net proceeds from issuances of common stock | 4,372 | 17 |
| Purchase of treasury stock | (91) | (1,277) |
| Principal payments on debt | (559) | (540) |
| Net cash provided by (used in) financing activities | 3,722 | (1,800) |
| Net decrease in cash and cash equivalents | (5,528) | (355) |
| **Cash and Cash Equivalents at the Beginning of Period** | 14,336 | 8,480 |
| **Cash and Cash Equivalents at the End of Period** | $ 8,808 | $ 8,125 |
| Supplemental disclosures of cash flow information: | | |
| Net interest paid | $ 135 | $ 172 |

*See accompanying notes to consolidated financial statements.*

## 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 generally accepted accounting principles 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 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 period ended March 31, 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 net loss per share:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2000 | 1999 |
| | (in thousands, except per share amounts) | |
| Net loss | $(7,919) | $(8,497) |
| Weighted-average common shares outstanding | 23,276 | 19,491 |
| Basic and diluted (loss) per common share | $ (0.34) | $ (0.44) |

*Recently Issued Accounting Pronouncements*

In December 1999, the staff of the Securities and Exchange Commission (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 March 2000, the SEC issued Staff Accounting Bulletin No. 101A which delays the implementation date of SAB 101 until the second quarter of 2000. Accordingly, the Company is evaluating SAB 101 and the effect it will have on the Consolidated Financial Statements and current revenue recognition policy.

**3. Inventories**

Inventories at March 31, 2000 and December 31, 1999 consist of the following:

| | March 31, 2000 | December 31, 1999 |
|---|---|---|
| | (in thousands) | |
| Raw materials | $ 270 | $ 280 |
| Work in process | 579 | 416 |
| Finished goods | 792 | 652 |
| | $1,641 | $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.

## 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 S.A. (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 PACLIMER™ Microspheres) and our pharmaceutical product candidates (including lead compounds in our FKBP neuroimmunophilin ligand program and any future lead compounds in our NAALADase and PARP programs);
- 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 the clinical development and commercialization of our polymer-based and other drug candidates;
- 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.

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 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 first quarter of 2000 and 1999, as well as our financial position at March 31, 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.

In 1998, the SEC adopted new rules requiring public companies like us to write certain documents in plain English. Even though the SEC does not require us to present our Management's Discussion and Analysis in plain English, we have decided voluntarily to apply these rules to the following discussion. Our goal is to describe and analyze our financial condition in language that may be easier for our stockholders to understand.

**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 products 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 PACLIMER™Microspheres and LIDOMER™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 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 March 31, 2000, we have recognized an aggregate of $21.7 million in product sales and royalties. Of this amount, $14.6 million represents revenues from sales of GLIADEL® Wafer to both Aventis and Orion Corporation Pharma. The additional $7.1 million are royalties paid to us from Aventis on its sales of GLIADEL® Wafer to third parties, such as hospitals.

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 in payments 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. Except for GLIADEL® Wafer, we do not expect to sell other products for at least the next several years, if ever.

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 is payable quarterly over three years, with the last quarterly payment due July 1, 2000. As of March 31, 2000, we had recognized an aggregate of approximately $11.3 million in research support from Amgen under our collaboration arrangement. Amgen also has the option to fund a fourth year of research.

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 in the first quarter of 2000 consisted of:

- a $1.0 million non-refundable milestone from Aventis, based upon Aventis' receipt of specified regulatory approval to market and sell GLIADEL® Wafer for the recurrent surgery indication in Spain and
- $1.125 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 months ended March 31, 2000, we incurred a net loss of $7.9 million. Since inception through March 31, 2000, we had an accumulated deficit of $90.8 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, 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 March 31, 2000, we had 236 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, PACLIMER™ 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 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.

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 new and unfamiliar approach to the treatment of brain cancer and their 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 each of the three months ended March 31, 2000 and 1999.

**Revenues**

Our revenues for the three months ended March 31, 2000 and 1999 primarily came from the following sources:

- net product sales of GLIADEL® Wafer to our marketing and distribution partners, Aventis (for the entire world, except Scandinavia and Japan);
- 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 net revenues of $3.3 million and $2.9 million for the three months ended March 31, 2000 and 1999, respectively.

These revenues consisted primarily of the following:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2000 | 1999 |
| | (in millions) | |
| Revenues Relating to GLIADEL® Wafer: | | |
| Net product sales | $0.6 | $1.2 |
| License fees and royalties | 0.6 | 0.5 |
| Non-recurring rights and milestones | 1.0 | — |
| Revenues from Amgen: | | |
| Research funding under collaborative agreements | 1.1 | 1.1 |

**GLIADEL® Wafer Product Sales**

We manufacture and supply GLIADEL® Wafer to our marketing and sales partners. We earned $0.6 million and $1.2 million for the three months ended March 31, 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 $0.6 million and $0.5 million for the three months ended March 31, 2000 and 1999, respectively. 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 product sales as a percentage of net product sales revenue were 57% and 53% for the three months ended March 31, 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 increased to $9.8 million from $9.1 million for the three months ended March 31, 2000 and 1999, respectively. This increase in our research and development expenses is due to our continuing efforts with respect to our NAALADase inhibitor and PARP inhibitor neuroprotectant programs, our FKBP neuroimmunophilin compound program, and our polymer development program, including our polymer oncology candidate, PACLIMER™ Microspheres. In addition, we continued to provide financial support for Aventis' Phase III clinical trial program in support of a first surgery indication for GLIADEL® Wafer.

During the quarter ended March 31, 2000, the Company acquired an exclusive worldwide license to a novel pro-drug of a widely used anesthetic, propofol. Pursuant to this transaction, the Company recorded a charge to earnings of approximately $0.3 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 March 31, 2000, we employed 198 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 $3.5 million for the three months ended March 31, 2000 and 1999, respectively. The decrease was largely attributable to a reduction in external legal costs incurred in connection with the Company's intellectual property portfolio.

At March 31, 2000, we employed 38 individuals on a full-time basis in general and administrative areas compared to 35 at December 31, 1999.

**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 $2.0 million and $2.1 million for the three months ended March 31, 2000 and 1999, respectively.

We incurred interest expense of $135,000 and $164,000 for the three months ended March 31, 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 first quarter of 2000 as compared to the same period of 1999.

**Liquidity and Capital Resources**

Our cash, cash equivalents, and investments were approximately $137.3 million at March 31, 2000. Of this amount, we pledged $20.3 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 million at all times under the terms of certain of its financial obligations.

Our total debt decreased to $8.8 million at March 31, 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 net capital expenditures of $176,000 in the first quarter ended March 31, 2000, which resulted 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. During the quarter ended March 31, 2000, no additional items were financed through these lease arrangements. As of March 31, 2000, we had leased approximately $6.4 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 March 31, 2000, $4.4 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 March 31, 2000.

During 1998 and 1999, we entered into a series of interest rate swap transactions with a commercial bank covering $20 million in financial obligations under our lease with the Trust and $10 million with the commercial bank covering our floating rate debt. 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 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. No amounts were drawn under this line of credit during the first quarter of 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; and
- the progress of efforts to scale-up manufacturing processes.

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 March 2000, the SEC issued Staff Accounting Bulletin No. 101A which delays the implementation date of SAB 101 until the second quarter of 2000. Accordingly, the Company is evaluating SAB 101 and the effect it will have on the Consolidated Financial Statements and current revenue recognition policy.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

A substantial portion of our assets are portfolio 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.

Substantially all of our financial obligations have variable rates of interest. By entering into certain interest rate swap agreements with a commercial bank (''counter party''), we have effectively fixed the interest rates for these floating rate financial obligations. In the event of non-performance by the counter party, we could be exposed to market risk related to interest rates. 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:***

None

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

None

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

None

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

None

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

A. Exhibits

| Exhibit No. | Description |
|---|---|
| 3.02(C) | Amendments to Amended and Restated By-Laws of the Company. |
| 10.60* | License, Development and Commercialization Agreement dated March 2, 2000 between the Company and ProQuest Pharmaceuticals Inc. |
| 27.02 | Financial Data Schedule |

* The registrant has requested confidential treatment of certain portions of this agreement from the Securities and Exchange Commission.

B. Reports on Form 8-K:

None

## 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: May 12, 2000

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

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

Date: May 12, 2000

/s/ ANDREW R. JORDAN

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