SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended September 30, 1999

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 X No ____

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

Class	Outstanding at November 15, 1999
Common Stock, $.01 par value	**23,049,670**

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GUILFORD PHARMACEUTICALS INC.
AND SUBSIDIARIES

Consolidated Balance Sheets
(in thousands, except share data)

	September 30, 1999 (Unaudited)	December 31, 1998
Assets		
Current assets:		
Cash and cash equivalents	$ 43,119	$ 8,480
Investments	75,175	103,281
Accounts receivable	1,415	1,241
Inventories	1,368	1,291
Other current assets	896	709
Total current assets	121,973	115,002
Investments — restricted	26,356	16,500
Property and equipment, net	17,978	18,790
Other assets	627	736
	$166,934	$151,028
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,107	$ 3,265
Current portion of long-term debt	2,159	2,159
Accrued payroll related costs	1,841	2,279
Accrued outside services	2,782	2,095
Accrued expenses and other current liabilities	1,653	960
Deferred income	1,125	1,125
Total current liabilities	10,667	11,883
Long-term liabilities:		
Long-term debt, net of current portion	7,146	8,766
Total liabilities	17,813	20,649
Stockholders' equity:		
Preferred stock, par value $.01 per share		
Authorized 4,700,000 shares, none issued	—	—
Series A junior participating preferred stock, par value $.01 per share. Authorized 300,000 shares, none issued	—	—
Common stock, par value $.01 per share		
Authorized 75,000,000 shares 23,328,313 and 19,594,316 issued at September 30, 1999 and December 31, 1998, respectively	233	196
Additional paid-in capital	232,441	187,139
Accumulated deficit	(78,329)	(56,009)
Accumulated other comprehensive income (loss)	(1,656)	876
Notes receivable on common stock	(60)	(60)
Treasury stock, at cost: 278,643 and 77,224 shares at September 30, 1999 and December 31, 1998, respectively	(3,352)	(1,399)
Deferred compensation	(156)	(364)
Total stockholders' equity	149,121	130,379
	$166,934	$151,028

See accompanying notes to consolidated financial statements.

GUILFORD PHARMACEUTICALS INC.
AND SUBSIDIARIES

Consolidated Statement of Operations
(Unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	1999	1998	1999	1998
Revenues:				
Contract Revenues	$ 4,500	$ 1,000	$ 4,500	$ 1,000
Product sales	565	920	3,432	2,575
License fees and royalties	542	717	1,785	2,027
Revenues under collaborative agreements	1,269	1,194	3,682	3,521
Total revenues	6,876	3,831	13,399	9,123
Costs and Expenses:				
Cost of sales	303	423	1,746	1,267
Research and development	10,396	9,479	29,535	27,444
General and administrative	2,862	2,675	9,508	7,724
Total costs and expenses	13,561	12,577	40,789	36,435
Operating loss	(6,685)	(8,746)	(27,390)	(27,312)
Other income (expense):				
Investment and other income	1,642	2,028	5,584	6,832
Interest expense	(166)	(189)	(514)	(588)
Net loss	$(5,209)	$(6,907)	$(22,320)	$(21,068)
Basic and diluted loss per common share	$ (0.26)	$ (0.35)	$ (1.14)	$ (1.08)
Weighted average common shares outstanding	19,937	19,481	19,608	19,453

See accompanying notes to consolidated financial statements.

GUILFORD PHARMACEUTICALS INC.
AND SUBSIDIARIES

Consolidated Statement of Changes in Stockholders' Equity
Nine Months Ended September 30, 1999
(Unaudited)
(in thousands, except share data)

	Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Note receivable on common stock	Treasury stock, at cost	Deferred compensation	Total stockholders' equity
	Number of shares issued	Dollar Amount							
Balance, December 31, 1998	19,594,316	$196	$187,139	$(56,009)	$ 876	$(60)	$(1,399)	$(364)	$ 130,379
Comprehensive loss:									
Net loss for the period				(22,320)					(22,320)
Unrealized loss on available-for-sale securities					(2,532)				(2,532)
Total comprehensive loss									$ (24,852)
Issuance of common stock in private placement @ $13.50 per share, net of offering costs	3,360,000	34	42,486						42,520
Issuances of common stock	373,997	3	2,616						2,619
Purchase of 222,275 shares of common stock							(2,209)		(2,209)
Distribution of 20,856 shares of treasury stock to 401(k) plan			5				256		261
Stock option compensation			337						337
Amortization of deferred compensation								66	66
Forfeiture of unvested restricted stock			(142)					142	—
Balance, September 30, 1999	23,328,313	$233	$232,441	$(78,329)	$(1,656)	$(60)	$(3,352)	$(156)	$ 149,121

See accompanying notes to consolidated financial statements.

GUILFORD PHARMACEUTICALS INC.
AND SUBSIDIARIES

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	1999	1998	1999	1998
Cash Flows From Operating Activities:				
Net loss	$(5,209)	$ (6,907)	$(22,320)	$(21,068)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	1,152	830	3,801	2,578
Noncash compensation expense	638	160	995	433
Changes in assets and liabilities:				
Accounts receivable, other current assets and other assets	(300)	155	(695)	(928)
Inventories	(225)	(148)	(77)	(264)
Accounts payable	(1,422)	(2,428)	(2,158)	(1,544)
Accrued expenses and other current liabilities	(192)	1,036	855	3,375
Deferred income	1,125	—	—	—
Net cash used in operating activities	(4,433)	(7,302)	(19,599)	(17,418)
Cash Flows From Investing Activities:				
Purchases of property and equipment, net	(576)	(633)	(2,790)	(6,358)
Sale and maturities of investments	4,505	31,455	90,276	75,573
Purchases of investments	(1,136)	(20,793)	(74,558)	(66,033)
Net cash provided by investing activities	2,793	10,029	12,928	3,182
Cash Flows From Financing Activities:				
Net proceeds from issuances of common stock	42,749	393	45,139	887
Purchase of treasury stock	—	—	(2,209)	(46)
Principal payments on bond and term loan payable	(540)	(540)	(1,620)	(1,620)
Net cash (used in) provided by financing activities	42,209	(147)	41,310	(779)
Net increase (decrease) in cash and cash equivalents	40,569	2,580	34,639	(15,015)
Cash and cash equivalents at the beginning of period	2,550	7,385	8,480	24,980
Cash and cash equivalents at the end of period	$43,119	$ 9,965	$ 43,119	$ 9,965
Supplemental disclosures of cash flow information:				
Interest paid	$ 161	$ 181	$ 497	$ 594
Distribution of treasury stock to 401(k) plan	$ 92	$ —	$ 261	$ —

See accompanying notes to consolidated financial statements.

Guilford Pharmaceuticals Inc.

Notes to Consolidated Financial Statements
September 30, 1999
(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 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, 1998.

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 and nine month periods ended September 30, 1999 as set forth in the Index. Interim results are not necessarily indicative of results for the full fiscal year.

2. 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) available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted EPS is computed by increasing the weighted-average number of shares outstanding for the period by the number of additional common shares that would have been outstanding if the dilutive potential common shares had been issued. Potential common shares are excluded if the effect on any loss per share is antidilutive.

The following table sets forth the computation of the Company's basic and diluted net earnings (loss) per share:

	Three Months ended September 30,	
	1999	1998
	(in thousands, except per share amounts)	
Net loss	$(5,209)	$(6,907)
Weighted-average common shares outstanding	19,937	19,481
Basic and diluted earnings (loss) per common share	$ (0.26)	$ (0.35)

	Nine Months ended September 30,	
	1999	1998
	(in thousands, except per share amounts)	
Net loss	$(22,320)	$(21,068)
Weighted-average common shares outstanding	19,608	19,453
Basic and diluted earnings (loss) per common share	$ (1.14)	$ (1.08)

3. Inventories

Inventories at September 30, 1999 and December 31, 1998 consist of the following:

	September 30, 1999	December 31, 1998
	(in thousands)	
Raw materials	$ 238	$ 283
Work in process	546	371
Finished goods	584	637
	$1,368	$1,291

Inventories are net of applicable reserves and allowances. Inventories include finished goods and raw materials that may be either 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. Lease — Research and Development Facility

In February 1998, the Company entered into a Real Estate Development Agreement and an operating lease agreement in connection with the construction of a new research and development facility. The facility is located adjacent to the Company's corporate headquarters in Baltimore, Maryland and was substantially completed in June 1999. Construction costs are expected to total slightly less than the initial budget of $20 million. During the construction period, the Company must maintain cash collateral equal to 100% of the cost of construction, not to exceed $20 million. As of September 30, 1999, the Company had established cash collateral of approximately $19.0 million related to this transaction. The cash collateral is included in the accompanying consolidated balance sheets as "Investments-restricted". Close-out of the construction is expected to occur in the fourth quarter, at which time the Company expects up to approximately $5 million of such cash collateral to be released. In addition to its cash collateral requirements, the Company is subject to certain financial covenants, the most restrictive of which requires that the Company maintain unrestricted cash, cash equivalents and investments in the aggregate equal to $40 million. The lease term is for a maximum of 84 months (including the construction period). 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. The Company anticipates the annual lease payments to be approximately $1.4 million during the initial lease term.

5. Equity Transaction

In September 1999, the Company completed a private placement of 3.36 million shares of its common stock to certain institutional and other accredited investors, resulting in net proceeds to the Company of approximately $42.5 million.

GUILFORD PHARMACEUTICALS INC.

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 which 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 Rhone-Poulenc Rorer Pharmaceuticals Inc. (or "RPR") to obtain international regulatory clearances to market and sell GLIADEL® Wafer ("GLIADEL") and to increase end-user sales of GLIADEL,
- our efforts in conjunction with RPR to expand the labeled uses for GLIADEL,
- 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, 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) 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 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,
- anticipated expenditures and the potential need for additional funds, and
- plans to assess and implement solutions, if necessary, to the Year 2000 issue.

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 Securities and Exchange Commission. Our SEC filings include our Annual Report on Form 10-K for the year ended December 31, 1998 and our registration statement on Form S-3 (SEC file no. 333-87091) we initially filed on September 14, 1999. For convenience we refer to these documents as the "1998 Form 10-K" and the "September 1999 Form S-3" in the discussion set forth below. In addition, any forward-looking statement we make in this document speaks only as of the date of this document, and we do not intend to update any such forward-looking statement to reflect events or circumstances that occur after that date.

Introduction

In the following section, called "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 third quarter and first nine months of 1999 and 1998, as well as our financial position at September 30, 1999 and December 31, 1998. In Management's Discussion and Analysis, we analyze and explain the changes in the specific line items set forth in the section of our Consolidated Financial Statements entitled "Consolidated Statements of Operations".

You will notice some changes in this year's discussion compared to prior years. In 1998 the SEC adopted new rules requiring public companies like Guilford 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 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, in the United States through RPR. GLIADEL 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. RPR is our exclusive worldwide marketing partner for GLIADEL,

except in Japan and Scandinavia. Orion Corporation Pharma (formerly Orion Corporation Farmos) is our marketing partner for GLIADEL 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, and
- a new class of biodegradable polymers different from the type used in GLIADEL, which we are using for the targeted and controlled delivery of cancer chemotherapeutics.

In addition, in the third quarter of 1999, we continued to increase our investment in research and development activities with respect to certain of these technologies.

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

- sales of those products we manufacture to our marketing partners, which currently consists of sales of GLIADEL to our marketing partners. We may sometimes refer to these amounts as "transfer payments" or "product sales",
- royalties from our marketing partners related to the sale of products to third parties, such as RPR's sales of GLIADEL to hospitals, and any other products we may develop in the future, and/or
- one-time rights, milestone, and other payments from corporate partners under our current collaborative agreements and new ones we may enter into with others in the future.

As we discuss in greater detail below, if we or our corporate collaborators, RPR and Amgen Inc. ("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 1998 Form 10-K, we cannot be sure that our corporate partners 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 in the United States in February 1997 through September 30, 1999, we have recognized an aggregate of $18.9 million in product sales and royalties. Of this amount, $12.9 million represent revenues from sales of GLIADEL to both RPR and Orion Corporation Pharma. The additional $6.0 million are royalties paid to us from RPR on its sales of GLIADEL to third parties, such as hospitals.

Under the terms of our agreements with RPR, if RPR is able to achieve certain specified regulatory objectives, RPR is obligated to pay us up to an additional $30.5 million in milestone payments and payments for the purchase of shares of our stock. These regulatory objectives include obtaining approvals to market GLIADEL in certain foreign countries. In July and August 1999, we received an aggregate of $4.5 million in non-refundable milestone payments from RPR. These milestone payments were paid upon RPR's receipt of specified regulatory approvals to market and sell GLIADEL for the recurrent surgery indication in France and Germany.

As we discuss below and in greater detail in the 1998 Form 10-K and the September 1999 Form S-3, a number of factors subject our future sales of GLIADEL to significant risk and uncertainty. We cannot be sure that our sales of GLIADEL to RPR and RPR's sales of GLIADEL to third parties will increase over time or even continue at the current rate. The milestone payments and other amounts payable by RPR are contingent on:

- making certain international regulatory filings and obtaining clearances to market GLIADEL for the recurrent surgery indication pursuant to such filings,

- obtaining authorization from the FDA and international health regulatory authorities to expand the description of the clinical uses for GLIADEL that we can put on its label to include use of the product in first surgeries, and
- obtaining permission to sell GLIADEL in certain countries at prices that are acceptable to RPR and us.

We cannot control the timing and extent of governmental clearances. We also cannot be sure that we and RPR will attain any of these regulatory objectives. Except for GLIADEL, 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 September 30, 1999, we had recognized an aggregate of approximately $9.4 million in research support from Amgen under this 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., medical uses), 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 results from our collaboration.

As we discuss below and in greater detail in the 1998 Form 10-K and the September 1999 Form S-3, 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 foreign 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 GLIADEL, the only other significant revenues we recognized for the first nine months of 1999 consist of approximately $3.4 million in research payments from Amgen. Under the Amgen agreement, we expect to recognize an additional $1.1 million of revenue in the fourth quarter of 1999 relating to research support for the FKBP neuroimmunophilin ligand technology.

With the sole exception of 1996, we have not earned a net profit in any year since our inception in July 1993. Our net profit in 1996 was $5.1 million. This net profit was primarily due to two, one-time rights payments from RPR which totaled $27.5 million.

For the three and nine months ended September 30, 1999, we incurred a net loss of $5.2 million and $22.3 million, respectively. Since inception through September 30, 1999, we have an accumulated deficit of $78.3 million. Our accumulated deficit is equal to the sum of our cumulative profits and losses since inception in July 1993.

We do not expect 1999 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 to RPR and RPR's sales to others,
- the timing and realization of milestone and other payments from our corporate partners, including RPR 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 September 30, 1999, we had 225 full-time employees. This compares to 222 full-time employees at September 30, 1998.

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

- our ability, either alone or with others, to develop our product candidates successfully, including NIL-A with Amgen, and any other product candidates,
- the level of future sales of GLIADEL,
- 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 new technologies and/or in-license new technologies from others and to obtain, 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 the September 1999 Form S-3, particularly those paragraphs specifically addressing the risks we note above.

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

- RPR is not obligated to purchase any minimum amounts of GLIADEL from us, and so our revenues from the sale and distribution of GLIADEL are entirely dependent on the level of RPR's sales to end-users.
- RPR may not be successful in its efforts to market and sell GLIADEL.
- Neurosurgeons and their patients may not accept GLIADEL for a number of reasons, including the fact that GLIADEL 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.
- RPR may not be successful in its attempts to obtain any additional regulatory and marketing approvals to market GLIADEL and sell GLIADEL at acceptable prices.

- BCNU, the chemotherapeutic agent we use in GLIADEL, is currently only available from two suppliers, and thus this material may not be available for GLIADEL manufacture.

- The Company's current manufacturing plant for GLIADEL 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 manufacture.

As we noted in the section captioned "Risk Factors" in the September 1999 Form S-3, 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 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 a price acceptable to us, any partners, and payers, and

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

For discussion of these and other risks, you should see the section captioned "Risk Factors" in the September 1999 Form S-3.

Results of Operations

In this section we discuss our revenues, costs and expenses, and other income and expenses for the three and nine month periods ended September 30, 1999 and 1998 as well as the factors affecting each of them.

Revenues

For the three month periods ended September 30, 1999 and 1998, we recognized revenues of $6.9 million and $3.8 million, respectively. For the nine month periods ended September 30, 1999 and 1998, we recognized revenues of $13.4 million and $9.1 million, respectively. Our revenues for the third quarter and first nine months of 1999 and 1998 consisted primarily of:

- revenues from product sales and royalties relating to GLIADEL,

- $1.1 million in quarterly research funding from Amgen for each of the first three quarters of 1999 and 1998, and

- in the third quarter of 1999 only, two milestone payments from RPR in the aggregate amount of $4.5 million for the receipt of certain regulatory approvals to market and sell GLIADEL for the recurrent surgery indication in France and Germany.

Revenues from the sale and distribution of GLIADEL consist primarily of:

- revenues from our marketing and distribution partners, RPR (for the entire world except Scandinavia and Japan) and Orion Corporation Pharma (for Scandinavia only), from our sales of GLIADEL to them, and
- royalty payments from RPR based on its sales of GLIADEL to others, primarily hospitals.

GLIADEL Product Sales

We earned $565,000 in the third quarter of 1999 from the sale of GLIADEL to our marketing partners compared to $920,000 in the same period in 1998. This represents a 39% decrease in net product sales in the 1999 period as compared to the same period in 1998. We earned $3.4 million in the first nine months of 1999 from the sale of GLIADEL to our marketing partners compared to $2.6 million in 1998. This represents a 33% increase in net product sales in the first nine months of 1999 compared to the same period in 1998.

We believe the decrease in revenues attributable to sales of GLIADEL to RPR in the third quarter of 1999 compared to the third quarter of 1998 is due to fluctuations in the timing of deliveries of product to RPR, and expect GLIADEL product sales in 1999 will exceed last year's level. We believe that the 33% increase in net product sales in the first nine months of 1999 primarily reflects RPR's build-up of inventory of the product to support anticipated launch in France, Germany and other countries in Europe and elsewhere around the world. We cannot guarantee, however, that RPR will obtain all necessary regulatory approvals to launch the product in additional European countries or elsewhere to market and sell GLIADEL. In addition, we cannot be sure that, even if RPR does obtain these approvals in one or more European or other countries, GLIADEL will be launched in these countries in 1999 or thereafter, or that sales in those countries, if any, including France and Germany, will be significant.

Royalties on GLIADEL Sales to Third Parties

Our net royalty revenue on RPR's sales of GLIADEL to third parties was $542,000 in the third quarter of 1999 as compared to $717,000 in the third quarter of 1998. This represents a 24% decrease in net royalty revenue in the 1999 period compared to the same period in 1998. Our net royalty revenue on RPR's sales of GLIADEL to third parties was $1.8 million in the first nine months of 1999 compared to $1.9 million in the first nine months of 1998. This represents a 5% decrease in net royalty revenue in the first nine months of 1999 as compared to the same period in 1998. A decrease in the net number of units sold by RPR to third parties caused the decrease in royalty revenue during the 1999 periods. RPR has informed us that this decrease is due in part to unusually low sales in August.

As we discuss in greater detail in the 1998 Form 10-K and September 1999 Form S-3, a number of factors subject our future sales of GLIADEL to significant risk and uncertainty. We cannot guarantee that GLIADEL 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 for the three months ended September 30, 1999 and 1998 was $303,000 and $423,000, respectively. Our cost of sales for the nine months ended September 30, 1999 and 1998 was $1.8 million and $1.3 million, respectively. In the third quarter and first nine months of 1999, cost of product sales represented 54% and 51%, respectively, of total product sales revenues compared to 46% and 49%, respectively, for the comparable periods in 1998. The cost to manufacture GLIADEL at current production levels can vary materially with the production volume. Production volume in turn is dependent upon purchase orders and sales forecasts as provided by our partner, RPR. To the extent GLIADEL production levels increase in the future, we anticipate that the unit cost to manufacture GLIADEL may decrease, although we cannot be sure that GLIADEL product sales will ever reach levels necessary for us to realize such a reduction in the per unit cost of manufacturing GLIADEL. To the extent GLIADEL

production levels decrease, we anticipate that the unit cost to manufacture GLIADEL will increase. Based on our experience to date, we would expect the cost of product sales of GLIADEL to fluctuate from quarter to quarter, based on production volumes.

Research and Development Expenses

Our research and development expenses increased to $10.4 million for the third quarter of 1999. This amount was $9.5 million in the third quarter of 1998. Our research and development expenses increased to $29.5 million for the first nine months of 1999. This amount was $27.4 million in the first nine months of 1998. The increase in research and development expenses of $917,000 from the third quarter of 1998 to the third quarter of 1999 and of $2.1 million from the first nine months of 1998 to the first nine months of 1999 were primarily attributable to increased costs related to outside services such as contracted research and consulting services.

The increase in our research and development expenses for the first nine months of 1999 was partially offset by a decrease in certain costs we incurred in the first nine months of 1998 that were not repeated in first nine months of 1999, including amounts paid to a university licensor expensed in the first quarter of 1998 relating to certain neuroimmunophilin ligand technology.

We also anticipate that our research and development expenses will continue to increase in future periods.

At September 30, 1999, we employed 192 individuals on a full-time basis in the areas of research, development and manufacturing. We employed 189 individuals in these areas at September 30, 1998.

In the third quarter of 1999, we continued to increase our research and product development efforts generally, particularly with respect to our PARP inhibitor neuroprotectant and polymer development technologies. We also continued to provide financial support for RPR's Phase III clinical trial program in support of a first surgery indication for GLIADEL.

In the third quarter and first nine months of 1999 and 1998, our research and development expenses included charges relating to certain consulting agreements related to GLIADEL and the polymer drug delivery business which we entered into in April 1996. These charges consisted of:

- non-cash compensation expense of approximately $110,000 for the third quarter of both 1999 and 1998, respectively, and approximately $330,000 for the first nine months of both 1999 and 1998, respectively; and
- cash compensation expense of approximately $72,000 and $68,000 for the third quarter of 1999 and 1998, respectively, and approximately $213,000 and $196,000 for the first nine months of 1999 and 1998, respectively.

We entered into these agreements to assist in the commercialization of GLIADEL, including our efforts to expand the labeling for this product and to generate product line extensions, and to enhance our ability to develop new polymer technologies and products for the delivery of anti-cancer agents for those diseases or conditions where local tumor recurrence is likely and controlled release may be more effective than current therapies. We expect to record up to an additional $421,000 in total of non-cash compensation charges in our research and development expenses quarterly through 2001 because of these agreements.

General and Administrative Expenses

Our general and administrative expenses increased to $2.9 million in third quarter of 1999. This amount was $2.7 million in the third quarter of 1998. Our general and administrative expenses increased to $9.5 million in first nine months of 1999 compared to $7.7 million in the first nine months of 1998. We attribute the increases in general and administrative expenses of $187,000 from the third quarter of 1998 to the third quarter of 1999 and $1.8 million from the first nine months of 1998 to the first nine months of 1999 to higher legal fees, patent and professional contract services costs and costs for professional, advisory

and related services. These costs increased, in part, because of an increase in the activities necessary to support our research, product development and commercialization efforts.

At both September 30, 1999 and 1998, we employed 33 individuals on a full-time basis supporting general and administrative areas. Our general and administrative expenses, particularly those related to establishing, preserving and enforcing our intellectual property rights, may continue to increase in future periods depending upon the level of activity in these areas.

Other Income and Expense

Other income and expense consist primarily of interest income on our monetary investments and interest expense on our debt and other financial obligations. Our investment and other income decreased to $1.6 million in the third quarter of 1999 compared to $2.0 million in the third quarter of 1998. Our investment and other income decreased to $5.6 million in the first nine months of 1999 compared to $6.8 million in the first nine months of 1998. The decrease between these periods was primarily due to a decrease in the average investment balance during the third quarter and first nine months of 1999 as compared to the same periods in 1998.

For the third quarter of 1999 and 1998, we incurred interest expense of $166,000 and $189,000, respectively. For the first nine months of 1999 and 1998, we incurred interest expense of $514,000 and $588,000, respectively. These interest charges resulted from loans we have with First Union National Bank. These loans helped fund the construction of our manufacturing, administrative, and research and development facilities and the purchase of certain furniture and equipment. Because we continue to repay these loans, our average principal balance outstanding under these loans was lower during the third quarter and first nine months of 1999 compared to the same periods in 1998. As a consequence, interest expense decreased during the 1999 periods as compared to the same periods in 1998.

Liquidity and Capital Resources

Our cash, cash equivalents and investments were approximately $144.7 million at September 30, 1999. Of this amount, we pledged $26.4 million as collateral for certain of our loans and financial lease obligations. We have recorded this amount under "Investments — restricted" on our Consolidated Balance Sheets.

The increase in cash and investments was primarily due to the private sale in September 1999 of an aggregate of 3.36 million shares of our common stock to certain institutional and other accredited investors, resulting in net proceeds of approximately $42.5 million. In addition, in June 1999 we issued 312,933 shares of our common stock upon the exercise of certain warrants in exchange for approximately $2.25 million.

The increase of $9.9 million in the amount of restricted investments at September 30, 1999 as compared to December 31, 1998 resulted from an increase during the first nine months of 1999 in the amount of cash collateral related to our design and construction of a new research and development facility. We describe the financing for this facility below. This increase in cash collateral was partially offset by our continued repayment of our loans from First Union National Bank, which resulted in a decrease in the cash collateral amounts related to these loans. In addition, under the agreements relating to the new research and development facility, upon completion of that facility, which we expect to occur before the end of 1999, we expect our cash collateral requirements will be reduced by up to approximately $5 million.

In 1998, our Board of Directors approved a program to purchase up to 1,000,000 shares of our common stock in the open market from time to time at our discretion. Through September 30, 1999, we had repurchased a total of 252,500 of our shares under this program for an aggregate cash outlay of $2.7 million. In August 1999, we publicly announced that we had terminated this share repurchase program.

Our total debt decreased to $9.3 million at September 30, 1999 compared to $10.9 million at December 31, 1998. This decrease was a result of our continued repayment of principal under our loans with First Union National Bank.

We incurred net capital expenditures of $576,000 million in the third quarter of 1999 compared to net capital expenditures of $633,000 for the third quarter of 1998. We used these capital expenditures in the third quarter of 1999 to purchase equipment to support our ongoing research and development activities. We used the amounts we spent in the third quarter of 1998 to fund the construction of our new GLIADEL and biodegradable polymer manufacturing facilities. We also used these monies to fund the purchase of research and development equipment.

In March 1998, we entered into arrangements with certain equipment leasing companies that permit us to lease up to $10.8 million in equipment, including computer hardware and software, furniture and fixtures. As of September 30, 1999, we had leased a total of $5.7 million in equipment under these arrangements. Depending on the type of equipment covered and certain other factors, the term of any lease we enter under these arrangements may range from two to four years. Substantially all of the remaining portion of these lines have been extended to the December 31, 2000 period.

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, 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 and construct a new research and development facility. To accomplish this task, in February 1998 we entered into an operating lease and other related agreements with First Union National Bank and related entities in connection with such a facility. This new facility, which was substantially completed in June 1999, was constructed on a lot adjacent to our current headquarters in Baltimore, Maryland. The facility is owned by a trust affiliated with First Union National Bank and provides 73,000 square feet of research and development capacity. 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.

We began moving personnel into the facility in June 1999 and consolidated all of our operations into our current headquarters and the new facility during the third quarter. Our lease for the new facility expires in February 2005. We anticipate that the lease payments for the new facility will not exceed $1.4 million annually. The elimination of certain rental expenses associated with two other research and development facilities we recently vacated should substantially offset this cost.

At the expiration of the lease term, we may purchase the property for an amount equal to:

- all unamortized acquisition and construction costs,

  plus

- all accrued but unpaid interest and similar costs that the First Union trust incurs as part of its acquisition and construction of the property.

For convenience we refer to this amount as the "Termination Amount".

In the alternative, we may sell the property on behalf of the First Union trust. The First Union trust is then obligated to credit the proceeds from the sale against our repayment of the Termination Amount. If the sale proceeds are not enough to cover the entire Termination Amount, we then have to repay the shortfall so long as our total payments to the trust are not more than 83% of the Termination Amount. In addition, we may extend the lease term provided that First Union National Bank in its discretion agrees to such an extension.

Under our agreements with First Union National Bank related to this new R&D facility, we are required to hold in the aggregate unrestricted cash, cash equivalents and investments of $40 million at all

times during the term of the lease. This requirement is in addition to the cash collateral requirements we discuss above in this "Liquidity and Capital Resources" section.

Under a loan agreement we executed with RPR in 1996, RPR has extended to us a $7.5 million line of credit to support expansion of our GLIADEL 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. The agreement provides that loan amounts carry an interest rate equal to the lowest rate RPR pays from time to time on its most senior debt. We have not borrowed any amounts under this credit facility as of September 30, 1999.

During 1998, we entered into a series of interest rate swap transactions with First Union National Bank covering $20 million in financial obligations under our lease with the First Union trust. In January 1999, we entered into additional interest rate swap agreements with First Union National Bank covering $10 million in floating rate debt. As a result, we fixed the interest rates on these financial lease obligations and debt at approximately 6% in the aggregate.

In the fourth quarter of 1998, we established an unsecured, revolving line of credit for $5 million with ALLFIRST (formerly First National Bank of Maryland). Borrowings under this line of credit carry an interest rate of LIBOR plus 0.55% and are payable on demand. We may draw on the line of credit from time to time to meet our short-term working capital needs. No amounts were outstanding under this facility at September 30, 1999.

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 may 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 capital resources will be sufficient to fund our activities through at least December 31, 2000. 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, drug candidates or technologies,
- repurchases of our stock under any stock repurchase program, and
- unanticipated capital expenditures.

The Year 2000 Issue

Introduction

The so-called "Year 2000 issue" results from computer programs that rely on two-digit date codes instead of four-digit date codes to indicate the year. For example, these types of computer systems, which include computer software for desktop computers, software used in scientific equipment, and software embedded in computer chips, indicate the year 1966 by the digits "66". As the year 2000 approaches, these systems will have to process information involving the year 2000 and later years. Systems that only use two-date digit codes may confuse the year 2000 with the year 1900. As a result, these computer programs may not be able to perform computations and decision-making functions correctly. This inability could also cause computer systems or other equipment to malfunction or shutdown completely.

We have developed a multi-phase program to address this potential problem. It consists of the following steps:

- assess those corporate systems and operations that the Year 2000 issue could adversely affect,
- fix or replace non-compliant systems and components, if any, and then
- test these systems and components to ensure proper functioning.

We have focused our Year 2000 compliance assessment program on four principal areas:

- our internal information technology system, which includes our internal computer network and phone system,
- our internal, non-information technology facilities systems, which include software embedded in:
  - — environmental controls,
  - — security systems,
  - — fire protection systems,
  - — manufacturing hardware and monitoring controls, and
  - — public utility connections for gas, electric and telephone systems, which for convenience we refer to as "Facilities Systems",
- software we use with our laboratory and other equipment, which may either be located outside of the equipment or embedded within it, and
- Year 2000 compliance of those third parties which we have defined as critical to our mission, including:
  - — our principal vendors of goods and services, including raw materials, laboratory and other equipment,
  - — our financial institutions such as banks and investment managers, and
  - — our corporate partners such as RPR and Amgen.

For convenience, we refer to these institutions as our "Major Third Parties".

Assessment and Remediation of Internal Systems

During the later part of 1998 and the beginning of 1999, we conducted an inventory of the internal information technology systems, Facilities Systems, and equipment (which together make up our internal company systems) that we believe could be adversely affected by the Year 2000 issue. As of September 30, 1999, we had taken the following actions to address the Year 2000 issue:

- repaired or replaced, as necessary, those internal company systems that we found not to be Year 2000 compliant,

- re-tested these internal company systems to verify Year 2000 compliance, and
- engaged an independent outside consultant to review our approach to Year 2000 compliance and its conformity with industry best practices.

Our information technology personnel have discussed whether our enterprise-wide software systems are Year 2000 compliant with the vendors of those systems. We have also tested those systems for Year 2000 compliance. Based on these activities, we believe that such systems are Year 2000 compliant. We will continue to stay in contact with these vendors in order to obtain any additional revisions or upgrades the vendors issue to ensure that such enterprise-wide software remains Year 2000 compliant.

Inquiries of Third Parties

We have also been examining the Year 2000 readiness of our Major Third Parties. We consider these institutions, either together as a group or in certain cases on an individual basis, to pose the greatest Year 2000 risk to our business. Their failure to become Year 2000 compliant could:

- limit our ability to obtain raw materials, equipment and supplies in a timely manner,
- limit or prevent us from getting:
  - — our cash and other financial assets, and
  - — timely and accurate information about our financial assets,
- significantly disrupt our financial transactions, and
- interfere with the efforts of our corporate partners to continue their research, development and/or commercialization activities with respect to GLIADEL and the FKBP neuroimmunophilin compound technology.

We have mailed Year 2000 compliance inquiry letters to, or have otherwise contacted, our Major Third Parties, to ask that they give us information about their Year 2000 compliance status, and are following up as necessary.

Except for asking these third parties about their Year 2000 compliance and assessing their responses, we cannot independently verify whether these institutions are or will be Year 2000 compliant. In most cases we have limited or no ability to influence directly the Year 2000 compliance activities of these Major Third Parties. If any or all of these institutions fail to achieve substantial Year 2000 compliance, this failure could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, most of RPR's sales of GLIADEL are to hospitals. The failure of these hospitals, or of any of RPR's other customers for GLIADEL, to pay for their GLIADEL purchases because of a Year 2000 problem could materially and adversely affect our business. In addition, sales of GLIADEL are dependent, in part, on the availability of reimbursements from third-party healthcare payors, such as government insurance plans like Medicare and Medicaid, and private insurance plans and managed-care plans. Again, the failure of these third-party healthcare payors to reimburse or pay for claims because of Year 2000 problems could materially and adversely affect our business.

Remediation Costs

As of September 30, 1999, the total costs for our Year 2000 compliance program have not been significant. Most of our costs relative to the Year 2000 issue have been internal personnel costs, which we have not tracked. We estimate that our internal and external costs did not exceed $100,000 in 1998. There were no costs incurred for the third quarter of 1999 since the major components of the program have been completed. We incurred approximately $57,400 for nine months ended 1999.

Based on information currently available to us, we do not believe that the future costs associated with developing a Year 2000 compliance plan and bringing our internal computer systems into Year 2000 compliance will be material. We estimated that the total costs for our Year 2000 compliance efforts would

not exceed $200,000 in the aggregate. As of September 30, 1999, we estimate that we have incurred approximately 79% of the total costs we anticipated that we would incur to address Year 2000 issues relating to our internal company systems. Further, as of September 30, 1999, we had not separately set aside funds specifically to address the Year 2000 issue, but rather are using funds allocated to our yearly information technology budget. However, as we note above, we will continue to spot check and test our internal computer systems for Year 2000 compliance problems. Depending on the actual outcome of these continuing Year 2000 compliance-testing activities, our remediation costs may be significantly greater than our current estimates.

We also do not know whether the costs associated with our efforts to assess and address any Year 2000 compliance concerns regarding our Major Third Parties will be material. As we note above, with most Major Third Parties, we have little or no direct ability to influence the Year 2000 compliance efforts of these institutions.

As of September 30, 1999, we had not decided to switch from any vendor because of a concern over Year 2000 compliance. We will continue to evaluate the Year 2000 readiness of our suppliers and will decide on a case-by-case basis whether to seek out alternatives. If we determine to seek out an alternative supplier in the future, we may not be able to find an adequate substitute. In certain cases, a vendor may represent the sole supplier for a good or service.

Disaster Recovery Plans and Certain Mitigating Factors

In addition to our Year 2000 compliance activities, we have worked with an outside consulting firm to implement a comprehensive disaster recovery plan. This plan will cover a variety of areas, including the Year 2000 issue. We do not anticipate that the external costs for putting such a plan in place will exceed $125,000 in the aggregate.

We currently make complete back-up copies and store off-site all of the data generated on our computer systems on a weekly basis. We also track changes to such data on a daily basis. We believe this practice should limit the amount of computer system data that would be lost if our computer systems were to fail as a result of a Year 2000 issue or other disaster.

Many of our Facilities Systems, including our environmental controls, security systems, and fire protection systems, have manual override functions. These will allow us to operate certain of our Facilities Systems even if their software malfunctions. In addition, while a single banking institution acts as custodian for most of our financial assets, we hold certain other financial assets at, and have established a $5 million line of credit with, another banking institution. This arrangement should allow us to meet our operating expenses in the short term in the event our primary banking relationship were to be interrupted because of a Year 2000 issue. With respect to GLIADEL, we maintain what we believe to be sufficient inventories of raw materials, package components and product to prevent a product supply interruption if a vendor should have a Year 2000 problem.

Due to the nature of our business, even if (1) we were to fail to implement our Year 2000 compliance program successfully for our internal company systems or (2) the Year 2000 compliance provisions of our disaster recovery plan prove inadequate, we believe that these circumstances would not have a material adverse effect on our business, financial condition and results of operations over the long term. They would, however, disrupt our operations in the short-term. The failure of one or more of our Major Third Parties, particularly our banks, investment managers, corporate partners, and suppliers of key raw materials to be Year 2000 compliant could have a material adverse effect on our business, financial condition and results of operations in the short term and potentially over the long term.

Risks

We have based our estimate of the costs of our Year 2000 compliance program and disaster recovery plan on the information currently available to us. We have based these estimates on a number of assumptions regarding future events. These include the continued availability of certain resources and other

factors. We cannot be sure that these costs will not exceed our expectations or that the Year 2000 issue will not substantially and adversely affect our business, financial condition or results of operations.

Specific factors that might cause our estimates to be incorrect include:

- our ability to locate and correct all relevant computer codes, including software embedded in environmental controls and manufacturing and laboratory equipment,
- the ability of the Major Third Parties to identify and resolve their own Year 2000 issues,
- the availability and cost of personnel trained in the area of Year 2000 compliance, and
- unforeseen or unanticipated problems that we are unable to address or can only remedy at great cost.

Furthermore, our current cost estimates do not include costs that we may incur as a result of the failure of Major Third Parties, including Amgen and RPR, to become Year 2000 compliant on a timely basis. Moreover, if a Year 2000 issue causes (1) hospitals and other of RPR's customers for GLIADEL to fail to pay for their GLIADEL purchases or (2) third-party healthcare payors to fail to reimburse claims or pay for GLIADEL, such failures could materially and adversely affect our business.

Finally, our ability to continue to manufacture GLIADEL, conduct our research and product development programs, and function as a viable business enterprise depends on the continued availability of various basic infrastructure systems. These include electric power, telecommunications and transportation systems. We cannot be sure that the Year 2000 issue will not disrupt these infrastructure systems. If such disruptions were to occur in the Baltimore, Maryland metropolitan region where our manufacturing facilities and research and development laboratories are located, or in the areas in which we or our Major Third Parties conduct business, these disruptions could very well have a material adverse effect on our business, financial condition, results of operations, or business prospects.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not Applicable.

PART II. — OTHER INFORMATION

Item 1. Legal Proceedings:

None

Item 2. Changes In Securities:

In September 1999, we issued 3.36 million shares of our common stock in a private placement to certain institutional and other accredited investors. In exchange we received in the aggregate approximately $45.4 million (before deduction of related fees and expenses), which we will use for working capital and general corporate purposes. These shares were issued to these investors without registration under the Securities Act of 1933 pursuant to the exemption from registration set forth in sections 4(2).

Item 3. Defaults in 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
10.58	Form of Severance Agreement
10.59	Form of Change in Control Severance Agreement
27.4	Financial Data Schedule

B. *Report on Form 8-K:*

On September 13, 1999, we filed a Current Report on Form 8-K, the sole purpose of which was to file the press release announcing the private placement described in Item 2 above.

SIGNATURES

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

Guilford Pharmaceuticals Inc.

Date: November 15, 1999

/s/ Craig R. Smith, M.D.

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

Date: November 15, 1999

/s/ Andrew R. Jordan

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