

TRIANGLE PHARMACEUTICALS INC
Form 10-Q
May 10, 2002

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, 2002

OR

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

For the transition period from _____ to _____.

Commission File Number: 000-21589

TRIANGLE PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation or organization)

56-1930728
(I.R.S. Employer
Identification No.)

4 University Place
4611 University Drive
Durham, North Carolina
(Address of principal executive offices)

27707
(zip code)

Registrant's telephone number, including area code: (919) 493-5980

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 ☐

As of March 31, 2002, there were 76,850,837 shares of Triangle Pharmaceuticals, Inc. Common Stock outstanding.

TRIANGLE PHARMACEUTICALS, INC.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

TRIANGLE PHARMACEUTICALS, INC.
(A Development Stage Company)CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share amounts)

	March 31, 2002	December 31, 2001
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 54,562	\$ 64,994
Investments	27,411	21,280
Interest receivable	603	798
Receivable from collaborative partner	472	480
Prepaid expenses	577	641
	<u> </u>	<u> </u>
Total current assets	83,625	88,193
Property, plant and equipment, net	3,649	4,091
Investments	14,768	21,881
	<u> </u>	<u> </u>
Total assets	\$ 102,042	\$ 114,165
	<u> </u>	<u> </u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 7,089	\$ 11,884
Payable to collaborative partner	822	2,645
Debt-current	1,359	1,454
Accrued expenses	11,677	13,923
Deferred revenue	4,139	4,139
	<u> </u>	<u> </u>
Total current liabilities	25,086	34,045
Debt-noncurrent	1,382	1,680
Deferred revenue	13,452	14,487
	<u> </u>	<u> </u>
Total liabilities	39,920	50,212
	<u> </u>	<u> </u>
Commitments and contingencies (See note 4 and note 6)		
Stockholders' equity:		
Convertible Preferred Stock, \$0.001 par value; 10,000 shares authorized; 0 shares issued and outstanding		
Common Stock, \$0.001 par value; 175,000 shares authorized; 76,851 and 76,829 shares issued and outstanding, respectively	77	77
Additional paid-in capital	470,585	470,478
Accumulated deficit during development stage	(408,682)	(406,895)
Accumulated other comprehensive income	142	293
	<u> </u>	<u> </u>
Total stockholders' equity	62,122	63,953
	<u> </u>	<u> </u>
Total liabilities and stockholders' equity	\$ 102,042	\$ 114,165
	<u> </u>	<u> </u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

TRIANGLE PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended March 31, 2002	Three Months Ended March 31, 2001	Period from Inception (July 12, 1995) Through March 31, 2002
Revenue:			
Collaborative revenue	\$ 1,035	\$ 1,744	\$ 14,124
Operating expenses:			
License fees	109	1,095	26,672
Development	11,963	21,839	352,587
Purchased research and development			18,178
Selling, general and administrative	1,403	2,708	58,806
Restructuring			2,342
	<u>13,475</u>	<u>25,642</u>	<u>458,585</u>
Total operating expenses			
	<u>13,475</u>	<u>25,642</u>	<u>458,585</u>
Loss from operations	(12,440)	(23,898)	(444,461)
Gain (loss) on investments, net	3	80	(1,357)
Interest income, net	650	960	27,136
Other income	10,000		10,000
	<u>10,653</u>	<u>1,040</u>	<u>16,779</u>
Net loss	\$ (1,787)	\$ (22,858)	\$ (408,682)
	<u>(1,787)</u>	<u>(22,858)</u>	<u>(408,682)</u>
Basic and diluted net loss per common share	\$ (0.02)	\$ (0.55)	
	<u>(0.02)</u>	<u>(0.55)</u>	
Shares used in computing basic and diluted net loss per common share	76,837	41,288	
	<u>76,837</u>	<u>41,288</u>	

The accompanying notes are an integral part of these condensed consolidated financial statements.

TRIANGLE PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Three Months Ended March 31, 2002	Three Months Ended March 31, 2001	Period from Inception (July 12, 1995) Through March 31, 2002
Cash flows from operating activities:			
Net loss	\$ (1,787)	\$ (22,858)	\$ (408,682)
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation and amortization	389	500	6,716
(Gain) loss from disposal of property, plant and equipment	(6)		156
(Gain) loss on investments	(3)	(80)	1,357
Purchased research and development			18,178
Stock-based compensation	22		2,092
Change in assets and liabilities:			
Receivables	203	449	(1,075)
Prepaid expenses	64	(742)	(577)
Accounts payable	(6,618)	(8,231)	7,911
Accrued expenses	(2,246)	3,563	11,677
Deferred revenue	(1,035)	(1,744)	17,591
Net cash used by operating activities	(11,017)	(29,143)	(344,656)
Cash flows from investing activities:			
Purchase of investments	(5,577)	(1,385)	(351,848)
Proceeds from sale and maturity of investments	6,411	25,571	308,454
Proceeds from sale of property, plant and equipment	59		733
Purchase of property, plant and equipment		(323)	(11,079)
Acquisition of Avid Corporation, net of cash acquired			(3,053)
Net cash provided (used) by investing activities	893	23,863	(56,793)
Cash flows from financing activities:			
Sale of stock, net of related issuance costs	60	54,493	452,220
Sale of options under salary investment option grant program	25	36	407
Proceeds from stock options/warrants exercised		286	909
Proceeds from notes payable			3,793
Equipment financing			354
Principal payments on capital lease obligations and notes payable	(393)	(4)	(1,672)
Net cash (used) provided by financing activities	(308)	54,811	456,011
Net (decrease) increase in cash and cash equivalents	(10,432)	49,531	54,562
Cash and cash equivalents at beginning of period	64,994	14,055	
Cash and cash equivalents at end of period	\$ 54,562	\$ 63,586	\$ 54,562

The accompanying notes are an integral part of these condensed consolidated financial statements.

TRIANGLE PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Convertible Preferred Stock			Common Stock		Additional Paid-In Capital	Accumulated Deficit	Comprehensive Income (Loss)	Accumulated Other Comprehensive Income/ (Loss)	Deferred Compensation	Total
	Shares	Amount	Warrants	Shares	Amount						
Initial sale of stock	933	\$ 1	\$	1,175	\$ 1	\$ 710	\$	\$	\$	\$	\$ 712
Additional sale of stock	4,249	4		1,495	2	3,137					3,143
Stock-based compensation						12				(12)	
Comprehensive loss:											
Net loss							(967)	(967)			(967)
Balance, December 31, 1995	5,182	5		2,670	3	3,859	(967)	(967)		(12)	2,888
Sale of stock	3,756	4		4,943	5	59,506					59,515
Stock-based compensation			152	700	1	1,127				(141)	1,139
Stock options exercised				317		57				(26)	31
Conversion of Preferred to Common Stock	(8,938)	(9)		8,938	9						
Comprehensive loss:											
Net loss							(10,917)	(10,917)			(10,917)
Balance, December 31, 1996			152	17,568	18	64,549	(11,884)	(10,917)		(179)	52,656
Sale of stock				2,014	2	29,521					29,523
Acquisition of Avid Corp.				400		8,117					8,117
Sale of stock options						70					70
Stock-based compensation			(38)							48	10
Stock options exercised				13		3				6	9
Comprehensive loss:											
Net loss							(37,668)	(37,668)			(37,668)
Balance, December 31, 1997			114	19,995	20	102,260	(49,552)	(37,668)		(125)	52,717
Sale of stock	170			8,868	9	116,325					116,334
Sale of stock options						97					97
Stock-based compensation										48	48
Stock options exercised				8		1				7	8
Comprehensive loss:											
Change in unrealized gains/(losses) on investments								18	18		18
Net loss							(67,271)	(67,271)			(67,271)
Balance, December 31, 1998	170		114	28,871	29	218,683	(116,823)	(67,253)	18	(70)	101,951
Sale of stock				6,605	7	116,211					116,218
Sale of stock options						95					95
Stock-based compensation				6		101				58	159
Stock options/warrants exercised			(114)	296		479				12	377
Conversion of Preferred to Common Stock	(170)			1,700	2	(2)					
Purchased in-process research and development costs				100		1,247					1,247
Comprehensive loss:											
Reclassification adjustment for gains/(losses) in net loss								(21)	(21)		(21)
Change in unrealized gains/(losses) on investments								(132)	(132)		(132)
Net loss							(104,621)	(104,621)			(104,621)

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Balance, December 31, 1999	\$	\$	37,578	\$ 38	\$ 336,814	\$ (221,444)	\$ (104,774)	\$ (135)	\$	\$ 115,273
(Continued)										

TRIANGLE PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)
(In thousands)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Comprehensive Income (Loss)	Accumulated Other Comprehensive Income/(Loss)	Deferred Compensation	Total
	Shares	Amount	Warrants	Shares	Amount					
(Continued)										
Sale of stock		\$	\$	326	\$ 1	\$ 1,608	\$	\$	\$	\$ 1,609
Sale of stock options						52				52
Stock-based compensation						348				348
Stock options/warrants exercised				225		378				378
Purchased in-process research and development costs				400		5,350				5,350
Comprehensive loss:										
Reclassification adjustment for gains/(losses) in net loss							133	133		133
Change in unrealized gains/(losses) on investments							163	163		163
Net loss							(109,525)	(109,525)		(109,525)
Balance, December 31, 2000				38,529	39	344,550	(330,969)	(109,229)	161	13,781
Sale of stock	200			36,058	36	125,070				125,106
Sale of stock options						68				68
Stock-based compensation						183				183
Stock options/warrants exercised				142		289				289
Purchased in-process research and development costs				100		320				320
Conversion of Preferred to Common Stock	(200)			2,000	2	(2)				
Comprehensive loss:										
Reclassification adjustment for gains/(losses) in net loss							(57)	(57)		(57)
Change in unrealized gains/(losses) on investments							189	189		189
Net loss							(75,926)	(75,926)		(75,926)
Balance, December 31, 2001				76,829	77	470,478	(406,895)	(75,794)	293	63,953
(Unaudited)										
Sale of stock				22		60				60
Sale of stock options						25				25
Stock-based compensation						22				22
Comprehensive loss:										
Reclassification adjustment for gains/(losses) in net loss							(4)	(4)		(4)
Change in unrealized gains/(losses) on investments							(147)	(147)		(147)
Net loss							(1,787)	(1,787)		(1,787)

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Balance, March 31, 2002	\$	\$	76,851	\$ 77	\$ 470,585	\$ (408,682)	\$ (1,938)	\$ 142	\$	\$ 62,122

The accompanying notes are an integral part of these condensed consolidated financial statements.

TRIANGLE PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except per share amounts)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Triangle Pharmaceuticals, Inc. and its wholly-owned subsidiary (the Company or Triangle) have been prepared in accordance with generally accepted accounting principles and applicable Securities and Exchange Commission regulations for interim financial information. These financial statements do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. It is presumed that users of this interim financial information have read or have access to the audited financial statements for the preceding fiscal year contained in the Company's Annual Report on Form 10-K. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for fair presentation have been included. Operating results for the interim periods presented are not necessarily indicative of the results that may be expected for the full year.

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

2. Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

3. Net Loss Per Common Share

Basic net loss per common share is computed using the weighted average number of shares of Common Stock outstanding during the period. Diluted net loss per common share is computed using the weighted average number of shares of common and dilutive potential common shares outstanding during the period. Potential common shares consist of stock options, warrants and convertible preferred stock using the treasury stock method and are excluded if their effect is antidilutive. For the three-month periods ended March 31, 2002 and 2001, the weighted average shares outstanding used in the calculation of net loss per common share do not include potential shares outstanding because they have the effect of reducing net loss per common share.

4. Licensing Agreements

As of March 31, 2002, the Company has multiple license agreements for its drug candidates as well as a collaborative agreement to assist in the identification and development of other novel drug candidates. In the aggregate, these agreements may require future payments of up to \$57,250 contingent upon the achievement of development milestones, up to \$30,000 upon the achievement of sales milestones, and \$1,875 of future research and development payments. The Company is also obligated to issue 250 shares of common stock if development milestones are achieved regarding compounds for the treatment of hepatitis B obtained in the Avid Corporation acquisition. Additionally, the Company will pay royalties ranging from 7.5% to 23.25% of net sales of each licensed product depending on drug candidate and net sales volume. The Company's license agreements also require minimum royalty payments commencing three years after regulatory approval of the licensed compound. Milestone payments are typically contingent on completing phases of clinical trials and receiving registrations for compounds. Depending on the Company's success and timing in obtaining regulatory approval, aggregate annual minimum royalties and annual license preservation fees could range from \$50 (if only a single drug candidate is approved for one indication) to \$47,000 (if all drug candidates are approved for all indications) under the Company's existing license agreements.

TRIANGLE PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)
(In thousands, except per share amounts)

5. Other Income

In January 2002, the Company's Chief Executive Officer and Chairman of the Board, Dr. David W. Barry, died unexpectedly. The Company subsequently filed a claim under its key-man insurance policy and received a \$10,000 payment.

6. Contingencies

The Company is indirectly involved in several opposition and interference proceedings and two lawsuits filed in Australia regarding the patent rights related to its licensed drug candidate, amdoxovir. Although the Company is not a named party in any of these proceedings, it is obligated to reimburse its licensors for certain legal expenses associated with these proceedings. In one of these patent opposition proceedings, on November 8, 2000, the Australian Patent Office held that several patent claims of Emory University ("Emory") directed to amdoxovir are not patentable over an earlier opposing patent. Emory has appealed this decision of the Australian Patent Office to the Australian Federal Court. If Emory and the Company are unsuccessful in the appeal, then the Company will not be able to sell amdoxovir in Australia without a license, which may not be available on reasonable terms or at all. The Company cannot predict the outcome of these proceedings. The Company believes that an adverse judgment would not result in a material financial obligation to the Company, nor would the Company have to recognize an impairment under Statement of Financial Accounting Standards ("SFAS") No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* as no amounts have been capitalized related to this drug candidate. However, any development in these proceedings adverse to the Company's interests could have a material adverse effect on the Company's future operations.

7. Recent Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 141, *Business Combinations* and SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 141 eliminates the pooling-of-interests method of accounting for business combinations except for qualifying business combinations that were initiated prior to July 1, 2001. SFAS No. 142 changes the accounting for goodwill and indefinite lived intangible assets from an amortization method to an impairment-only approach.

In August 2001, the FASB issued SFAS No. 143, *Accounting for Asset Retirement Obligations*. The objectives of SFAS No. 143 are to establish accounting standards for the recognition and measurement of an asset retirement obligation and its associated asset retirement cost. SFAS No. 143 is effective for fiscal years beginning after June 15, 2002.

In October 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. This statement supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of* and Accounting Principles Board Opinion No. 30, *Reporting the Results of Operations Reporting the Effects of Disposal of a Segment of Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*. The provisions of SFAS No. 144 are effective for fiscal years beginning after December 15, 2001.

The Company adopted SFAS No. 142 and 144 as of January 1, 2002, and expects to adopt SFAS No. 143 as of January 1, 2003, as required. Adoption of SFAS Nos. 142 and 144 did not have a significant impact, and the Company does not expect SFAS 143 to have a significant impact, on its consolidated financial position, results of operations and cash flows.

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

This Quarterly Report on Form 10-Q may contain projections, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed below at Risk and Uncertainties. While this outlook represents management's current judgment on the future direction of the business, risks and uncertainties could cause actual results to differ materially from any future performance suggested below.

The following discussion and analysis should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations included in our 2001 Annual Report on Form 10-K as well as with our condensed consolidated financial statements and notes appearing elsewhere in this Quarterly Report on Form 10-Q.

Overview

Triangle is engaged in the development of new drug candidates primarily for serious viral diseases. Since our inception on July 12, 1995, our operating activities have related primarily to developing our drug candidates, raising working capital, negotiating license and option arrangements for our drug candidates and recruiting personnel. We have not received any revenues from the sale of products and do not believe it likely that any of our drug candidates will be commercially available before the year 2003. As of March 31, 2002, our accumulated deficit was approximately \$408.7 million.

We require substantial working capital to fund the development and potential commercialization of our drug candidates. We will require significant expenditures to fund preclinical testing, clinical research studies, drug synthesis and manufacturing, license obligations, development of a sales and marketing infrastructure and ongoing administrative support before receiving regulatory approvals for our drug candidates. These approvals may be delayed or not granted at all. We have been unprofitable since our inception and expect to incur substantial losses for the next several years. Because of the nature of our business, we expect that losses will fluctuate from period to period and that fluctuations may be substantial.

You should consider the operating and financial risks associated with drug development activities when evaluating our prospects. To address these risks we must, among other things, successfully develop and commercialize our drug candidates, secure and maintain all necessary proprietary rights, respond to a rapidly changing competitive market, obtain additional financing and continue to attract, retain and motivate qualified personnel. We cannot assure you that we will be successful in addressing these risks.

Our operating expenses are difficult to predict and will depend on several factors. Development expenses, including expenses for drug synthesis and manufacturing, preclinical testing and clinical research activities, will depend on the ongoing requirements of our drug development programs, availability of capital and direction from regulatory agencies, which are difficult to predict. Management may in some cases be able to control the timing of development expenses in part by accelerating or decelerating preclinical testing and clinical trial activities, but many of these expenditures will occur irrespective of whether our drug candidates are approved when anticipated or at all. As a result of these factors, we believe that period to period comparisons are not necessarily meaningful and you should not rely on them as an indication of future performance. Due to all of the foregoing factors, it is possible that our consolidated operating results will be below the expectations of market analysts and investors. In such event, the prevailing market price of our common stock could be materially adversely affected.

Results of Operations

Collaborative Revenue

Revenue totaled \$1.0 million for the three months ended March 31, 2002 as compared to \$1.7 million for the same period in 2001. Revenue is solely related to collaborative revenue associated with our strategic alliance with Abbott Laboratories and arises from \$31.7 million of non-contingent research and development expense reimbursement, which is being amortized over the anticipated research and development arrangement period. The decrease in 2002 collaborative revenue, as compared to 2001, reflects an extension of the anticipated research and development period in which this reimbursement is to be recognized.

License Fees

License fees totaled \$109,000 for the three months ended March 31, 2002 as compared to \$1.1 million for the same period in 2001. License fees in both 2002 and 2001 relate to the recognition of milestone obligations and/or preservation fees under our license agreements for our portfolio of drug candidates. The decrease in 2002 license fees, as compared to 2001, is related to the timing and magnitude of milestone obligations and preservation payments under our license agreements for our portfolio of drug candidates, and has been impacted by the recent termination of our Coactinon and mozenavir dimesylate license agreements. Future license fees may consist of milestone payments or preservation payments under existing licensing agreements, the amount of which could be substantial and the timing of which will depend on a number of factors that we cannot predict. These factors include, among others, the success of our drug development programs and the extent to which we may in-license additional drug candidates.

Development Expenses

Development expenses totaled \$12.0 million for the three months ended March 31, 2002 as compared to \$21.8 million for the same period in 2001. Development expenses in 2002 consisted primarily of expenses for clinical trials, employee compensation, preclinical testing and drug synthesis and manufacturing. Development expenses in 2001 consisted primarily of expenses for clinical trials, drug synthesis and manufacturing, employee compensation, consultation and preclinical testing. The decrease in 2002 development expenses, as compared to 2001, is the result of significantly reduced drug synthesis and manufacturing spending as well as reduced salary and benefit costs and clinical trial costs due to our August 2001 restructuring of operations and focus on more limited clinical programs, including the January 2002 termination of our Coactinon license agreement. Development resources have, and we expect will continue to be through 2002, heavily focused on Coviracil® as we prepare to file a New Drug Application for Coviracil for the treatment of HIV.

Development expenses by major project for the three months ended March 31, 2002 and 2001 are shown below (dollars in thousands).

Compound	Indication	2002 Costs	%	2001 Costs	%	Difference	%
Coviracil	HIV	\$ 4,809	40	\$ 6,206	29	\$ (1,397)	(23)
Amdoxovir	HIV	383	3	3,495	16	(3,112)	(89)
Clevudine	Hepatitis B	417	4	691	3	(274)	(40)
Emtricitabine	Hepatitis B	895	7	1,180	5	(285)	(24)
Immunostimulatory sequences candidate	Hepatitis B	318	3	1,094	5	(776)	(71)
Other drug candidates		304	3	2,590	12	(2,286)	(88)
Indirect (unallocated) development costs		4,837	40	6,583	30	(1,746)	(27)
Total		\$ 11,963	100	\$ 21,839	100	\$ (9,876)	(45)

Our future development expenses will depend on the results and magnitude of our clinical and preclinical activities, our targeted future cash usage, availability of capital to simultaneously fund multiple drug candidate development programs and requirements imposed by regulatory agencies. In addition, we occasionally enter into collaborative arrangements with governmental and other parties to assist in conducting the clinical trials necessary

for the development of our compounds. This practice allows us to benefit from the experience of the collaborative party in conducting such trials and to share some of the financial and administrative burden of these trials. To date, we have entered into collaborative clinical trial arrangements for our Coviracil and amdoxovir drug candidates. Accordingly, our development expenses may fluctuate significantly from period to period. In addition, if we in-license or out-license rights to drug candidates our development expenses may fluctuate significantly from prior periods.

Selling, General and Administrative Expenses

Selling, general and administrative expenses totaled \$1.4 million for the three months ended March 31, 2002 as compared to \$2.7 million for the same period in 2001. Selling, general and administrative expenses in both 2002 and 2001 consisted primarily of employee compensation, amounts paid for outside professional services and rent expense. The decrease in 2002 selling, general and administrative expenses, as compared to 2001, is due to a reduction in sales and marketing expenses and to a reduction in administrative salary and benefit costs due to our August 2001 restructuring. Our selling, general and administrative expenses may fluctuate from period to period and such fluctuations may be significant. Future selling, general and administrative expenses will depend on the level of our future development and commercialization activities. We expect that our selling, general and administrative expenses will increase in future periods that immediately precede and follow our first product launch.

Gains (Losses) on Investments, Net

Gains on investments totaled \$3,000 for the three months ended March 31, 2002 as compared to \$80,000 of gains for the same period in 2001. These gains represent normal realized gains and losses on our general investment portfolio.

Interest Income, Net

Net interest income totaled \$650,000 for the three months ended March 31, 2002 as compared to \$1.0 million for the same period in 2001. The decrease in 2002 interest income is due primarily to much lower low-risk, short-term interest rates in the first quarter of 2002. Future interest income will depend on our future cash and investment balances and the return on these investments.

Other Income

Other income totaled \$10.0 million for the three months ended March 31, 2002, as compared to no income or expense for the same period in 2001. In January 2002, our Chief Executive Officer and Chairman of the Board, Dr. David W. Barry, died unexpectedly. The Company subsequently filed a claim under a key-man insurance policy and received a \$10.0 million payment.

Liquidity and Capital Resources

We have financed our operations since inception (July 12, 1995) through March 31, 2002 primarily with the net proceeds received from private placements of equity securities, which have provided aggregate net proceeds of approximately \$353.1 million, from public offerings of common stock, which have provided aggregate net proceeds of approximately \$97.7 million, as well as \$31.5 million of net non-contingent research and development reimbursement proceeds from our strategic alliance with Abbott, the Abbott Alliance, and receipt of a \$10.0 million key-man insurance policy payment.

At March 31, 2002, we had net working capital of \$58.5 million, an increase of approximately \$4.4 million over December 31, 2001. The increase in working capital is principally the result of decreased short-term liabilities and the receipt of a \$10.0 million key-man insurance policy payment offset by use of funds for our normal operating expenses. Our principal sources of liquidity at March 31, 2002 were \$54.6 million in cash and cash equivalents, \$41.2 million in investments which are considered available-for-sale, and \$1.0 million of strategic corporate investments, reflecting a \$11.4 million decrease of cash, cash equivalent and investment balances over those at December 31, 2001.

Our working capital requirements may fluctuate in future periods depending on many factors, including the efficiency of manufacturing processes developed on our behalf by third parties, the cost of drugs supplied by third party contractors (including Abbott), the magnitude, scope and timing of our drug development programs, the cost, timing and outcome of regulatory reviews and changes in regulatory requirements, costs under the license and/or option agreements relating to our drug candidates, including the costs of obtaining patent protection for our drug candidates, the timing and terms of business development activities related to current and new drug candidates, the rate of technological advances relevant to our operations, the timing, method and cost of the commercialization of our drug candidates, the level of required administrative and legal support, the availability of capital to support multiple drug candidate development programs and the potential expansion of facility space.

Amounts payable by us in the future under our existing license and research agreements are uncertain due to a number of factors, including the progress of our drug development programs, our ability to obtain regulatory approval to commercialize drug candidates and the commercial success of approved drugs. As of March 31, 2002, our existing license and research agreements may require future cash payments of up to \$57.3 million contingent on the achievement of development milestones, up to \$30.0 million on the achievement of sales milestones, and \$1.9 million of future research and development payments. As of March 31, 2002, we are also obligated to issue 250,000 shares of common stock if development milestones are achieved regarding compounds for the treatment of hepatitis B obtained in the Avid Corporation acquisition, although we are not currently developing these compounds. Additionally, we are obligated to pay royalties ranging from 7.5% to 23.25% of net sales of each licensed product incorporating drug candidates currently in our portfolio. Most of our license agreements require minimum royalty payments commencing three years after regulatory approval of the licensed compound. Depending on our success and timing in obtaining regulatory approval, aggregate annual minimum royalties and license preservation fees under our existing license agreements could range from \$50,000 if only a single drug candidate is approved for one indication, to \$47.0 million if all drug candidates are approved for all indications. In addition, we have license and collaboration agreements that allow us to obtain licenses on additional drug candidates in the future. If these collaborative arrangements identify additional drug candidates, our license obligations would increase.

We believe that our existing cash, cash equivalents and investments will be adequate to satisfy our anticipated working capital requirements through the second quarter of 2003. We are targeting a 2002 cash usage, excluding the effect of any additional financings, of approximately \$61 million. However, we expect that we will be required to raise additional capital to fund our future operations through equity or debt financings or from other sources. Our future financing needs will depend on the results of clinical trials, size of drug candidate portfolio, timing of regulatory filings and approvals, commercial potential of our drug candidates and our ability to successfully commercialize our drug candidates. We may also consider modifying the timing or scope of our clinical programs or out-licensing one or more of our compounds which may impact our anticipated capital requirements. Additional funding may not be available on favorable terms from any of these sources or at all. Our ability to achieve our cash usage target is subject to several risks including unanticipated cost overruns, the need to expand the magnitude or scope of existing development programs, the need to change the number or timing of clinical trials, unanticipated regulatory requirements, the timing and costs related to the Food and Drug Administration's review and preparation for the commercial launch of Coviracil and other factors described under the caption "Risk and Uncertainties" elsewhere in this Form 10-Q.

Critical Accounting Policies and Estimates

Our condensed consolidated financial require us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities. We evaluate our estimates, judgments and the policies underlying these estimates on a periodic basis as the situation changes, and regularly discuss financial events, policies, and issues with members of our audit committee and our independent accountants. We routinely evaluate our estimates and policies regarding clinical trial, preclinical and manufacturing liabilities; patent related liabilities; license milestone obligations; revenue recognition; inventory; intangible assets and deferred tax assets.

We generally enter into contractual agreements with third-party vendors to provide clinical, preclinical and manufacturing services in the ordinary course of business. Many of these contracts are subject to milestone based invoicing and the contract could extend over several years. We record liabilities under these contractual commitments when we determine an obligation has been incurred, regardless of the timing of the invoice. Patent

related and license milestone liabilities are recorded based upon various assumptions or events that we believe are the most reasonable to each individual circumstance, as well as based upon historical experience. License milestone liabilities and the related expense are recorded when the milestone criterion achievement or license preservation payment is probable. We have not recognized any assets for inventory, intangible items or deferred taxes as we have yet to receive regulatory approval for any of our drug candidates. Any potential asset that could be recorded in regards to any of these items is fully reserved. We currently recognize revenue based upon the amortization of non-contingent reimbursed research and development payments that have been received in accordance with terms of the Abbott Alliance. The amortization period in which we recognize this revenue is based upon the estimated time period to submit all drug candidates under the Abbott Alliance for regulatory approval. This amortization period is periodically evaluated and adjusted.

In all cases, actual results may differ from our estimates under different assumptions or conditions.

Litigation and Other Contingencies

As discussed below in Risk and Uncertainties, we are indirectly involved in several patent opposition and adversarial proceedings and two lawsuits filed in Australia regarding the patent rights related to our licensed drug candidate, amdoxovir. Although we are not a named party in any of these proceedings, we are obligated to reimburse our licensors for legal expenses associated with these proceedings. In one of these patent opposition proceedings, on November 8, 2000, the Australian Patent Office held that several patent claims of Emory University directed to amdoxovir are not patentable over an earlier Shire Pharmaceuticals plc patent. Emory has appealed this decision of the Australian Patent Office to the Australian Federal Court. If Emory, the University of Georgia Research Foundation, Inc., University of Georgia, or Triangle is unsuccessful in the appeal, then we will not be able to sell amdoxovir in Australia without a license from Shire Pharmaceuticals, which may not be available on reasonable terms or at all. We cannot predict the outcome of this or any of the other proceedings. We believe that an adverse judgment rendered against us would not result in a material financial obligation, nor would we have to recognize an impairment under Statement of Financial Accounting Standards, SFAS, No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* as no amounts have been capitalized related to this drug candidate. However, any development in these proceedings adverse to our interests, including any adverse development related to the patent rights licensed to us for this drug candidate or our related rights or obligations could have a material adverse effect on our future operations.

Risk and Uncertainties

In addition to the other information contained herein, the following risks and uncertainties should be carefully considered in evaluating Triangle and its business.

All of our drug candidates are in development and we may never successfully commercialize them.

Some of our drug candidates are at an early stage of development and all of our drug candidates will require expensive and lengthy testing and regulatory clearances before we may commercialize them. We do not expect any of our drug candidates to be commercially available before the year 2003. There are many reasons that we may fail in our efforts to develop or commercialize our drug candidates, including that:

our drug candidates may be ineffective, toxic or may not receive regulatory clearances,

our drug candidates may be too expensive to manufacture or market or may not achieve broad market acceptance,

third parties may hold proprietary rights that preclude us from developing or marketing our drug candidates, or

third parties may market equivalent or superior products.

The success of our business depends on our ability to successfully develop and market our drug candidates.

We have incurred losses since inception and may never achieve profitability.

We formed Triangle in July 1995 and have incurred losses since our inception. At March 31, 2002, our accumulated deficit was \$408.7 million. Our historical costs relate primarily to the acquisition and development of our drug candidates and selling, general and administrative costs. We have not generated any revenue from the sale of our drug candidates to date, and do not expect to do so before the year 2003. In addition, we expect annual losses to continue over the next several years as a result of our drug development and commercialization efforts. To become profitable, we must successfully develop and obtain regulatory approval for our drug candidates and effectively manufacture, market and sell any products we develop. We may never generate significant revenue or achieve profitability.

If we need additional funds and are unable to raise them, we will have to curtail or cease operations.

Our drug development programs and our efforts to commercialize our drug candidates require substantial working capital, including expenses for:

- preclinical testing,

- chemical synthetic scale-up,

- manufacture of drug substance for clinical trials,

- toxicology studies,

- clinical trials of drug candidates,

- sales and marketing,

- payments to our licensors, and

- potential commercial launch of our drug candidates.

Our future working capital needs will depend on many factors, including:

- the progress, magnitude and success of our drug development programs,

- the scope and results of preclinical testing and clinical trials,

- the cost, timing and outcome of regulatory filings and reviews,

- the costs under current and future license and option agreements for our drug candidates, including the costs of obtaining and enforcing patent protection for our drug candidates,

- the costs of acquiring any additional drug candidates,

- the out-licensing of existing drug candidates,

- the rate of technological advances by us and other companies,

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the commercial potential of our drug candidates,

the magnitude of our administrative and legal expenses,

the costs of establishing sales and marketing functions, and

the costs of establishing third party arrangements for manufacturing.

We have incurred negative cash flow from operations since we incorporated Triangle and do not expect to generate positive cash flow from our operations for at least the next several years. We believe that our existing cash, cash equivalents and investments, considering our recent steps to reduce cash usage and completed financings, will be adequate through the second quarter of 2003. We expect that we will need additional future financings to fund our operations. We may not be able to obtain adequate financing to fund our operations, and any additional financing we obtain may be on terms that are not favorable to us. In addition, we may not receive the contingent development milestone payments under the Abbott Alliance. In addition, any future financings could substantially dilute our stockholders. If adequate funds are not available, we will be required to delay, reduce or eliminate one or more of our drug development programs, to enter into new collaborative arrangements or to modify the Abbott Alliance on terms that may not be favorable to us. These collaborative arrangements or modifications could result in the transfer of valuable rights to third parties. In addition, we may acquire technologies and drug candidates that would increase our working capital requirements.

Projected development costs are difficult to estimate and may change frequently prior to regulatory approval.

While all new compounds require standard regulated phases of testing, the actual type and scope of testing can vary significantly among different drug candidates which may result in significant disparities in the total costs required to complete the respective development programs.

The number and type of studies that may be required by the Food and Drug Administration, FDA, for a particular compound are based on the compound's clinical profile compared to existing therapies for the targeted patient population. Factors that affect the costs of a clinical trial include:

- the number of patients required to participate in clinical trials to demonstrate statistical significance for a drug's safety and efficacy,

- the time required to enroll the targeted number of patients in clinical trials, which may vary depending on the size and availability of the targeted patient population and the perceived benefit to study participants, and

- the number and type of required laboratory tests supporting clinical trials.

Other activities required before filing a New Drug Application include regulatory preparation for submission, biostatistical analyses, scale-up synthesis, and the production of a required amount of commercial grade drug product inventory which meets current Good Manufacturing Practice standards.

In addition, ongoing development programs and associated costs are subject to frequent, significant and unpredictable changes due to a number of factors, including:

- data collected in preclinical or clinical studies may prompt significant changes or enhancements to an ongoing development program,

- the FDA may direct the sponsor to change or enhance its ongoing development program based on developments in the testing of similar compounds or related compounds,

- unexpected regulatory requirements or interim reviews by regulatory agencies may cause delays or changes to development programs, and

- anticipated manufacturing costs may change significantly due to required changes in manufacturing processes or variances from anticipated manufacturing process yields.

Because we may not successfully complete clinical trials required for regulatory approval of our drug candidates, our business may never achieve profitability.

No regulatory authority has approved any of our drug candidates. To obtain regulatory approvals needed for the sale of our drug candidates, we must demonstrate through preclinical testing and clinical trials that each drug candidate is safe and effective. The clinical trial process is complex and uncertain and the regulatory environment varies widely from country to country. Positive results from preclinical testing and early clinical trials do not ensure positive results in pivotal clinical trials. Many companies in our industry have suffered significant setbacks in pivotal clinical trials, even after promising results in earlier trials. Any of our drug candidates may produce undesirable side effects in humans. These side effects, or side effects from other drugs in a trial, could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a drug candidate, as occurred with our study FTC-302 in South Africa, or could result in regulatory authorities refusing to approve the drug candidate for any and all targeted indications. We, the FDA, or foreign regulatory authorities may suspend or terminate clinical trials at any time if we or they believe the trial participants face unacceptable health risks.

Clinical trials may take longer to complete and cost more than we expect, which would adversely affect our ability to commercialize drug candidates and achieve profitability.

Clinical trials are lengthy and expensive. They require adequate supplies of drug substance and sufficient patient enrollment. Patient enrollment is a function of many factors, including:

the size of the patient population,

the nature of the protocol,

the proximity of patients to clinical sites,

the eligibility criteria for the clinical trial, and

the perceived benefit of participating in a clinical trial.

Delays in patient enrollment can result in increased costs and longer development times. Even if we successfully complete clinical trials, we may not be able to file any required regulatory submissions in a timely manner and we may not receive regulatory approval for the drug candidate. In addition, if the FDA or foreign regulatory authorities require additional clinical trials we could face increased costs and significant development delays.

We conduct clinical trials in many countries around the world and are subject to the risks and uncertainties of doing business internationally. Disruptions in communication and transportation, changes in governmental policies, civil unrest and currency exchange rates may affect the time and costs required to complete clinical trials in other countries.

Changes in regulatory policy or new regulations could also result in delays or rejections of our applications for approval of our drug candidates. Drug candidates designated as fast track products may not, however, continue to qualify for expedited review and our other drug candidates may fail to qualify for fast track development or expedited review. Even though some of our drug candidates have qualified for expedited review, the FDA may not approve them at all or any sooner than other drug candidates that do not qualify for expedited review.

If we or our licensors are not able to obtain and maintain adequate patent protection for our drug candidates, we may be unable to commercialize our drug candidates or prevent other companies from using our technology in competitive products.

Our success will depend on our ability and the ability of our licensors to obtain and maintain patents and proprietary rights for our drug candidates and to avoid infringing the proprietary rights of others, both in the United States and in foreign countries. We have no patents solely in our own name and we have a small number of patent applications of our own pending. We have two patent filings which are jointly owned with other entities. We have licensed, or have an option to license, patents, patent applications and other proprietary rights from third parties for each of our drug candidates. If we breach our licenses we may lose rights to important technology and drug candidates.

Our patent position on some of our drug candidates, like that of many pharmaceutical companies, is uncertain and involves complex legal and factual questions for which important legal principles are unresolved. We may not develop or obtain rights to products or processes that are patentable. Even if we do obtain patents, they may not adequately protect the technology we own or have licensed. In addition, others may challenge, seek to invalidate, infringe or circumvent any patents we own or license. If they do so successfully, rights we receive under those patents may not provide competitive advantages to us. Further, the manufacture, use or sale of our products or processes may infringe the patent rights of others.

Several pharmaceutical and biotechnology companies, universities and research institutions have filed patent applications or received patents that cover our technologies or technologies similar to ours. Others have filed patent applications and received patents that conflict with patents or patent applications we own or have licensed, either by claiming the same methods or compounds or by claiming methods or compounds that could dominate those owned by or licensed to us. In addition, we may not be aware of all patents or patent applications that may impact our ability to make, use or sell any of our drug candidates. For example, United States patent applications are confidential while pending in the Patent and Trademark Office, and patent applications filed in foreign countries are often first published six months or more after filing. Any conflicts resulting from third party patent applications and patents could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection. If other companies obtain patents with conflicting claims, we may be required to obtain licenses to these patents or to develop or obtain alternative technology. We may not be able to obtain any license on acceptable terms or at all. Any failure to obtain licenses could delay or prevent us from pursuing the development or commercialization of our drug candidates, which would adversely affect our ability to achieve profitability.

There are significant risks regarding the patent rights of one of our licensed drug candidates. We may not be able to commercialize amdoxovir due to patent rights held by third parties other than our licensors. Third parties have filed numerous patent applications and have received numerous issued patents in the United States and many foreign countries that relate to this drug candidate and its use alone or in combination to treat HIV and hepatitis B. As a result, our patent position regarding the use of amdoxovir to treat HIV and/or hepatitis B is highly uncertain and involves numerous complex legal and factual questions that are unknown or unresolved. If any of these questions is resolved in a manner that is not favorable to us, we would not have the right to commercialize amdoxovir in the absence of a license from one or more third parties, which may not be available on acceptable terms or at all. Even if any of these questions is resolved in our favor, we may still attempt to obtain licenses from one or more third parties to reduce the risks of challenges to our patent positions. These licenses may not be available on acceptable terms or at all.

There are also risks regarding our rights to Coviracil. We license our rights to Coviracil from Emory. Emory and Shire Pharmaceuticals have been disputing several issues related to the rights to Coviracil. Shire Pharmaceuticals recently announced an agreement as to material terms of a settlement with GlaxoSmithKline, plc and Emory regarding these disputes. This settlement has not been finalized and the definitive settlement may differ from the material terms disclosed.

Amdoxovir (formerly known as DAPD)

We obtained our rights to amdoxovir under a license from Emory and the University of Georgia. Our rights to amdoxovir include a number of issued United States patents that cover:

composition of
matter,

a method for the synthesis of
amdoxovir,

methods for the use of amdoxovir alone or in combination with several other agents for the treatment of hepatitis B,
and

a method to treat HIV with
amdoxovir.

We also have rights to several foreign patents and patent applications that cover methods for the use of amdoxovir alone or in combination with other anti-hepatitis B agents for the treatment of hepatitis B. Additional foreign patent applications are pending which contain claims for the use of amdoxovir to treat HIV. Emory and the University of Georgia filed patent applications claiming these inventions in the United States in 1990 and 1992.

Shire Pharmaceuticals filed a patent application in the United States in 1988 on a group of nucleosides in the same general class as amdoxovir and their use to treat HIV, and has filed corresponding patent applications in foreign countries. The Patent and Trademark Office issued a patent to Shire Pharmaceuticals in 1993 covering a class of nucleosides that includes amdoxovir and its use to treat HIV. Corresponding patents have been issued to Shire Pharmaceuticals in many foreign countries. Emory has filed an opposition to patent claims granted to Shire Pharmaceuticals by the European Patent Office based, in part, on Emory's assertion that Shire Pharmaceuticals' patent does not disclose how to make amdoxovir. In a patent opposition hearing held at the European Patent Office on March 4, 1999, the Opposition Division ruled that the Shire Pharmaceuticals European patent covering amdoxovir is valid. Emory has appealed this decision to the European Patent Office Technical Board of Appeal. If the Technical Board of Appeal affirms the decision of the Opposition Division, or if we or Emory do not pursue the appeal, we would not be able to sell amdoxovir in Europe without a license from Shire Pharmaceuticals, which may not be available on acceptable terms or at all. Shire Pharmaceuticals has opposed patent claims granted to Emory on both amdoxovir and DXG, the parent drug into which amdoxovir is converted in the body, in the Australian Patent Office.

In a decision dated November 8, 2000, the Australian Patent Office held that Emory's patent claims directed to amdoxovir are not patentable over an earlier Shire Pharmaceuticals patent. Emory has appealed this decision of the Australian Patent Office to the Australian Federal Court. If Emory, the University of Georgia or we are unsuccessful in the appeal, then we will not be able to sell amdoxovir in Australia without a license from Shire Pharmaceuticals, which may not be available on acceptable terms or at all. Shire Pharmaceuticals' opposition to Emory's patent claims on DXG in Australia is ongoing. If Emory, the University of Georgia or we do not challenge,

or are not successful in any challenge to, Shire Pharmaceuticals' issued patents, pending patent applications, or patents that may issue from its applications, we will not be able to manufacture, use or sell amdoxovir in the United States and any foreign countries in which Shire Pharmaceuticals receives a patent without a license from Shire Pharmaceuticals. We may not be able to obtain a license from Shire Pharmaceuticals on acceptable terms or at all.

Immunostimulatory Sequence Product Candidates

In March 2000, we entered into a licensing and collaborative agreement with Dynavax Technologies Corporation to develop immunostimulatory polynucleotide sequence product candidates for the prevention and/or treatment of serious viral diseases, which became effective in April 2000. Immunostimulatory sequences, ISS, are polynucleotides which stimulate the immune system, and could potentially be used in combination with our small molecule product candidates to increase the body's ability to defend against viral infection. ISS can be stabilized for use through internal linkages that do not occur in nature, including phosphorothioate linkages.

There are a number of companies which have patent applications and issued patents, both in the United States and in other countries, that cover ISS and their uses. Coley Pharmaceuticals, Inc. has filed several patent applications in this area and has in addition exclusively licensed a number of patent applications on this subject from the University of Iowa and Isis Pharmaceuticals, Inc. A number of these patent applications have been issued. A number of companies have also filed patent applications and have or are expected to receive patents on a number of polynucleotides and methods for their use and manufacture. These patents, if granted, could prevent us from making, using or selling any ISS that is covered by a patent issued to a third party unless we obtain a license from that party which may not be available on acceptable terms or at all.

With respect to any of our drug candidates, litigation, patent opposition and adversarial proceedings, including the currently pending proceedings, could result in substantial costs to us. The costs of the currently pending proceedings are significant and may increase significantly during the next several years. We anticipate that additional litigation and/or proceedings will be initiated to enforce any patents we own or license, or to determine the scope, validity and enforceability of our or other parties' proprietary rights and the priority of an invention. Any of these activities could result in substantial costs and/or delays to us. The outcome of any of these proceedings may significantly affect our rights to develop and commercialize drug candidates and technology.

United States patents carry a presumption of validity and generally can be invalidated only through clear and convincing evidence. A court or administrative body may not hold our licensed patents valid or may not find an alleged infringer to be infringing. Further, the license and option agreements with Emory, the University of Georgia and Dynavax provide that each of these licensors is primarily responsible for any patent prosecution activities, such as litigation, patent conflict proceeding, patent opposition or other actions, for the technology licensed to us. These agreements also provide that we generally must reimburse these licensors for the costs they incur in performing these activities. Similarly, Yale University and the University of Georgia, the licensors of clevudine to Bukwang Pharm. Ind. Co., Ltd., are primarily responsible for patent prosecution activities with respect to clevudine at our expense. As a result, we generally do not have the ability to institute or determine the conduct of any patent proceedings unless our licensors elect not to institute or to abandon the proceedings. If our licensors elect to institute and prosecute patent proceedings, our rights will depend in part on the manner in which these licensors conduct the proceedings. In any proceedings they elect to initiate and maintain, these licensors may not vigorously pursue or defend or may decide to settle on terms that are unfavorable to us. An adverse outcome of these proceedings could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using technology, any of which could adversely affect our business. Moreover, the mere uncertainty resulting from the initiation and continuation of any technology related litigation or adversarial proceeding could adversely affect our business pending resolution of the disputed matters.

Because we may not be able to maintain the confidentiality of our trade secrets and know-how, we may lose a competitive advantage.

We also rely on unpatented trade secrets and know-how to maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with employees, consultants and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for any breach. Our trade secrets may also be independently discovered by competitors. We rely on technologies to which we do not have exclusive

rights or which may not be patentable or proprietary and may be available to competitors. We have filed applications for, but have not obtained, trademark registrations for various marks in the United States and other jurisdictions. We have received U.S. trademark registrations for our corporate name and our corporate name and logo, as well as the mark Coviracil®. We have received a Canadian trademark registration for the mark Coviracil®. We have also received a registration in the European Union for our corporate logo. Our pending application in the European Union for the mark Coviracil™ has been opposed by Orsem, based on registrations for the mark Coversyl in various countries, and Les Laboratoires Serveir, based on a French registration for the mark Coversyl. We do not believe that the marks Coviracil and Coversyl are confusingly similar, but, in the event they are found to be confusingly similar, we may need to adopt a different product name for emtricitabine in the applicable jurisdictions. Several other companies use trade names that are similar to our name for their businesses. If we are unable to obtain any licenses that may be necessary for the use of our corporate name, we may be required to change our name. Our management personnel were previously employed by other pharmaceutical companies. The prior employers of these individuals may allege violations of trade secrets and other similar claims relating to their drug development activities for us.

The costs and time required to comply with extensive government regulations could prevent or delay the commercialization of our drug candidates.

In addition to preclinical testing, clinical trials and other approval procedures for human pharmaceutical products, we are subject to numerous domestic and international regulations covering the development, registration, and commercialization of pharmaceutical products. These regulations affect:

- manufacturing,
- safety,
- labeling,
- storage,
- record keeping,
- reporting,
- and
- marketing and promotion.

We must also comply with regulations governing non-clinical and clinical laboratory practices, safe working conditions, and the use and disposal of hazardous substances, including radioactive compounds and infectious disease agents we use in connection with our development work. The requirements vary widely from country to country and some requirements may vary from state to state in the United States. We expect the process of obtaining these approvals and complying with appropriate government regulations to be time consuming and expensive. Even if our drug candidates receive regulatory approval, we may still face difficulties in marketing and manufacturing those drug candidates. Any approval may be contingent on postmarketing studies or other conditions. The approval of any of our drug candidates may limit the indicated uses of the drug candidate. A marketed product, its manufacturer and the manufacturer's facilities are subject to continual review and periodic inspections. The discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including withdrawal of the product from the market. The failure to comply with applicable regulatory requirements can, among other things, result in:

- fines,
- suspended regulatory approvals,
- refusal to approve pending applications,
- refusal to permit exports from the United States,
- product recalls,

seizure of
products,

injunctions,

operating
restrictions, and

criminal
prosecutions.

In addition, adverse clinical results by others could negatively impact the development and approval of our drug candidates. Some of our drug candidates are intended for use as combination therapy with one or more other

drugs, and adverse safety, effectiveness or regulatory developments in connection with the other drugs will also have an adverse effect on our business.

Intense competition may render our drug candidates noncompetitive or obsolete.

We are engaged in segments of the drug industry that are highly competitive and rapidly changing. Any of our current drug candidates that we successfully develop will compete with numerous existing therapies. In addition, many companies are pursuing novel drugs that target the same diseases we are targeting. We believe that a significant number of drugs are currently under development and will become available in the future for the treatment of HIV and hepatitis B. We anticipate that we will face intense and increasing competition as new products enter the market and advanced technologies become available. Our competitors' products may be more effective, or more effectively marketed and sold, than any of our products. Competitive products may render our products obsolete or noncompetitive before we can recover the expenses of developing and commercializing our drug candidates. Furthermore, the development of a cure or new treatment methods for the diseases we are targeting could render our drug candidates noncompetitive, obsolete or uneconomical. Many of our competitors:

- have significantly greater financial, technical and human resources than we have and may be better equipped to develop, manufacture and market products,

- have extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products, and

- have products that have been approved or are in late stage development and operate large, well-funded research and development programs.

Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Academic institutions, governmental agencies and other public and private research organizations are also becoming increasingly aware of the commercial value of their inventions and are more actively seeking to commercialize the technology they have developed.

If we successfully develop and obtain approval for our drug candidates, we will face competition based on many factors including:

- the safety and effectiveness of our products,

- the timing and scope of regulatory approvals,

- the availability of supply,

- marketing and sales capability,

- reimbursement coverage,

- price, and

- patent position.

Our competitors may develop or commercialize more effective or more affordable products, or obtain more effective patent protection, than we do. Accordingly, our competitors may commercialize products more rapidly or effectively than we do, which could hurt our competitive position.

If our licensors terminate their agreements with us, we could lose our rights to our drug candidates.

We have licensed or obtained an option to license our drug candidates under agreements with our licensors. These agreements permit our licensors to terminate the agreements in circumstances such as our failure to achieve development milestones or the occurrence of an uncured material breach by us. The termination of any of these agreements would result in the loss of our rights to a drug candidate. On the termination of most of our license agreements, we are required to return the licensed technology to our licensors. In addition, most of these agreements provide that we generally must reimburse our licensors for the costs they incur in performing any patent prosecution activities such as litigation, patent conflict, patent opposition or other actions, for the technology licensed to us. We believe that these costs as well as other costs under our

license and option agreements will be substantial and may

increase significantly during the next several years. Our inability or failure to pay any of these costs with respect to any drug candidate could result in the termination of the license or option agreement for the drug candidate.

If we are not able to successfully manufacture our drug candidates, our business may never achieve profitability.

We do not have any internal manufacturing capacity and we rely on third party manufacturers for the manufacture of all of our clinical trial material. We plan to use our existing relationships or to establish relationships with additional third party manufacturers for products that we develop. The terms of the Abbott Alliance provide that Abbott will manufacture all or a portion of our product requirements for those products that are or become covered by the Abbott Alliance. We may be unable to maintain our relationship with Abbott or to establish or maintain relationships with other manufacturers on acceptable terms, and manufacturers may be unable to manufacture products in commercial quantities on a cost effective basis. Our dependence on third parties for the manufacture of our products may adversely affect our profit margins and our ability to develop and commercialize products on a timely and competitive basis. Further, third party manufacturers may encounter manufacturing or quality control problems in manufacturing our products and may be unable to maintain the necessary governmental licenses and approvals to continue manufacturing our products.

Because we depend on third parties, we may be unable to successfully market, sell or distribute products we develop.

In the United States, we currently intend to market the drug candidates covered by the Abbott Alliance in collaboration with Abbott and to market other drug candidates that we successfully develop, that do not become part of the Abbott Alliance, through a small sales force or through arrangements or collaborations with third parties. Outside of the United States, we expect Abbott to market drug candidates covered by the Abbott Alliance and, for any other drug candidates that we successfully develop that do not become part of the Abbott Alliance, we intend to market and sell through arrangements or collaborations with third parties. In addition, we expect Abbott to handle the distribution and sale of drug candidates covered by the Abbott Alliance both inside and outside the United States. With respect to the United States, our ability to market the products that we successfully develop may be contingent on recruitment, training and deployment or outsourcing of a sales and marketing force as well as the performance of Abbott under the Abbott Alliance. We may be unable to establish marketing or sales capabilities or to maintain arrangements or enter into new arrangements with third parties to perform those activities on favorable terms. In addition, third parties may have significant control or influence over important aspects of the commercialization of our drug candidates, including market identification, marketing methods, pricing, composition of sales force and promotional activities. We may have limited control over the amount and timing of resources that a third party devotes to our products. Our business may never achieve profitability if we fail to establish or maintain a sales force and marketing, sales and distribution capabilities.

Because we depend on third parties for the discovery and development of drug candidates, we may not successfully acquire additional drug candidates or develop our current drug candidates.

We do not currently intend to engage in drug discovery. Our strategy for obtaining additional drug candidates is to utilize the relationships of our management team and scientific consultants to identify drug candidates for in-licensing from companies, universities, research institutions and other organizations. We may not succeed in acquiring additional drug candidates on acceptable terms or at all.

Because we have engaged and intend to continue to engage third party contract research organizations and other third parties to help us develop our drug candidates, many important aspects of our drug development programs have been and will continue to be outside of our direct control. In addition, the contract research organizations may not perform all of their obligations under arrangements with us. If the contract research organizations do not perform clinical trials in a satisfactory manner or breach their obligations to us, the development and commercialization of any drug candidate may be delayed or precluded.

Because we may not be able to attract and retain key personnel and advisors, we may not successfully develop our drug candidates or achieve our other business objectives.

We are highly dependent on our senior management and scientific staff. The loss of the services of any member of our senior management or scientific staff may significantly delay or prevent the achievement of product development and other business objectives. In order to pursue our drug development programs and marketing plans, we will need to hire additional qualified scientific and management personnel. We are currently conducting a search to fill the position of chief executive officer and it may prove difficult to find an appropriate person to fill this position. Competition for qualified individuals is intense and we face competition from numerous pharmaceutical and biotechnology companies, universities and other research institutions. If we are not able to attract and retain these individuals we may not be able to successfully commercialize our drug candidates.

Health care reform measures and third party reimbursement practices are uncertain and may delay or prevent the commercialization of our drug candidates.

The efforts of governments and third party payors to contain or reduce the cost of health care will continue to affect the business and financial condition of drug companies. A number of legislative and regulatory proposals to change the health care system have been considered in recent years. In addition, an increasing emphasis on managed care in the United States has and will continue to increase pressure on drug pricing. Legislative or regulatory proposals or changes in managed care systems may be adopted that may have a negative effect on our business. The announcement and/or adoption of proposals could have an adverse effect on our ability to earn profits and financial condition. Sales of prescription drugs depend significantly on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. These third party payors frequently require that drug companies give them predetermined discounts from list prices, and they are increasingly challenging the prices for medical products and services. Present combination treatment regimens for the treatment of HIV are expensive and costs may increase as new combinations are developed. These costs have resulted in limitations in the reimbursement available from third party payors for the treatment of HIV infection, and we expect these limitations will continue in the future. Third party payors may not consider products we may bring to the market cost effective and may not reimburse the consumer sufficiently to allow us to sell our products on a profitable basis.

If our drug candidates do not achieve market acceptance, our business may never achieve profitability.

Our success will depend on the market acceptance of any products we develop. The degree of market acceptance will depend on a number of factors, including:

- the receipt and scope of regulatory approvals,

- the establishment and demonstration in the medical community of the safety and effectiveness of our products and their potential advantages over existing treatment methods, and

- reimbursement policies of government and third party payors.

Physicians, patients, payors or the medical community in general may not accept or utilize any product that we may develop.

We may not have adequate insurance protection against product liability.

Our business exposes us to potential product liability risks that are inherent in the testing of drug candidates and the manufacturing and marketing of drug products and we may face product liability claims in the future. We currently have only limited product liability insurance. We may be unable to maintain our existing insurance and/or obtain additional insurance in the future at a reasonable cost or in sufficient amounts to protect against potential losses. A successful product liability claim or series of claims brought against us could require us to pay substantial amounts that would decrease our profitability, if any.

We may incur substantial costs related to our use of hazardous materials.

We use hazardous materials, chemicals, viruses and various radioactive compounds in our drug development programs. Although we believe that our handling and disposing of these materials comply with state and federal regulations, the risk of accidental contamination or injury still exists. We could be held liable for any damages or fines that result from any accidental contamination or injury and the liability could exceed our resources.

Our controlling stockholders may make decisions you do not consider to be in your best interest.

As of March 31, 2002, our directors, executive officers and their affiliates, excluding Abbott and Warburg Pincus Private Equity VIII, L.P., owned approximately 11.1% of our outstanding common stock. Abbott owned approximately 10.3% of our outstanding common stock and Warburg Pincus owned approximately 30.4% of our outstanding common stock. Under the terms of the Abbott Alliance, Abbott has the right to purchase additional shares of our common stock up to a maximum aggregate percentage of 21% of our outstanding common stock and has rights to purchase shares directly from us in order to maintain its existing level of ownership. For so long as Warburg Pincus continues to own at least 5,846,222 shares of our common stock and at least 10% of our outstanding common stock, Warburg Pincus has the right to participate in any sales of equity securities by Triangle, other than sales in connection with a registered underwritten offering, a merger or similar transaction or a stock option or similar plan, in proportion to the percentage of all outstanding securities of Triangle held by Warburg Pincus at the time of the transaction. Abbott has the right to designate one person to serve as a member of our Board of Directors and Warburg Pincus has the right to designate two people to serve as members of our Board of Directors. As a result, our controlling stockholders are able to significantly influence all matters requiring stockholder approval, including the election of directors and the approval of significant corporate transactions. This concentration of ownership could also delay or prevent a change in control of Triangle that may be favored by other stockholders.

The market price of our stock may fall as a result of market volatility and future developments in our industry.

The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including:

announcements of the results of clinical trials by us or our competitors,

announcements of the timing of regulatory submissions and/or approvals by us or our competitors,

developments with respect to patents or proprietary rights,

announcements of technological innovations by us or our competitors,

announcements of new products or new contracts by us or our competitors,

actual or anticipated variations in our operating results, including targeted cash usage, due to the level of development expenses and other factors,

changes in financial estimates by securities analysts and whether our earnings meet or exceed analysts estimates,

conditions and trends in the pharmaceutical and other industries,

new accounting standards,

general economic, political and market conditions and other factors,

low transaction volume due to high concentrations of ownership, and

the occurrence of any of the risks described in these Risk and Uncertainties.

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

Approximately 33,000,000 shares of our common stock may be sold without restriction and approximately 37,300,000 shares are registered for sale. Sales of a large number of our shares may cause our stock price to fall even if our business is doing well.

If our stockholders sell a substantial number of shares of our common stock in the public market, the market price of our common stock could decline. As of March 31, 2002, there were 76,850,837 shares of common stock outstanding, of which approximately 33,000,000 were immediately eligible for resale in the public market without restriction. Holders of approximately 37,300,000 shares have rights to cause us to register their shares for sale to the public and we have filed registration statements to register the sale of these shares. In addition, Abbott will have the right on or after June 30, 2002 to cause us to register for resale in the public market the 6,571,428 shares of common stock purchased at the closing of the Abbott Alliance.

Declines in our stock price might harm our ability to issue equity or secure other types of financing arrangements. The price at which we issue shares is generally based on the market price of our common stock and a decline in our stock price would result in our needing to issue a greater number of shares to raise a given amount of funds or acquire a given amount of goods or services. For this reason, a decline in our stock price might also result in increased ownership dilution to our stockholders.

Provisions in our charter documents and Delaware law could delay or prevent a change in management or a takeover attempt that you consider to be in your best interest.

We have adopted a number of provisions that could deter an acquisition of Triangle which was not approved by our Board of Directors. We have adopted a preferred stock purchase rights plan, commonly referred to as a poison pill. The rights plan is intended to deter an attempt to acquire Triangle in a manner or on terms not approved by the Board of Directors. The rights plan will not prevent an acquisition of Triangle which is approved by the Board of Directors. Our charter authorizes the Board of Directors to determine the terms of any shares of undesignated preferred stock and issue them without stockholder approval. The issuance of preferred stock may make it more difficult for a third party to acquire, or may discourage a third party from acquiring, voting control of Triangle.

Provisions in our charter and bylaws, as well as some provisions of Delaware law could delay or prevent the removal of incumbent directors and could make more difficult a merger, tender offer or proxy contest involving Triangle, even if the events could be beneficial to our stockholders. For example, our bylaws divide the Board of Directors into three classes of directors with each class serving a three-year term. These provisions could also limit the price that investors might be willing to pay for our common stock.

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

Triangle is exposed to various market risks, including changes in foreign currency exchange rates, investment market value and interest rates. Market risk is the potential loss arising from adverse changes in market rates and prices, such as foreign currency exchange and interest rates. We may enter into forward foreign currency contracts or purchase investments in foreign currencies to hedge foreign currency commitments. We have, however, established policies and procedures for market risk assessment and the approval, reporting and monitoring of derivative financial instrument activities. The following discusses our exposure to risks related to changes in interest rates, foreign currency exchange rates and investment market value.

Interest Rate Sensitivity

Triangle is subject to interest rate risk on its investment portfolio. We maintain an investment portfolio consisting primarily of high quality money market instruments, and government and corporate bonds. Our portfolio has a current average maturity of less than 12 months. We attempt to mitigate default risk by investing in high credit quality securities and by monitoring the credit rating of investment issuers. Our investment portfolio includes only marketable securities with active secondary or resale markets to help ensure portfolio liquidity and we have implemented guidelines limiting the duration of investments. These available-for-sale securities are subject to interest rate risk and will decrease in value if market interest rates increase. If market rates were to increase by 10 percent from levels at March 31, 2002, we expect that the fair value of our investment portfolio would decline by an immaterial aggregate amount primarily due to the relatively short maturity of the portfolio. At March 31, 2002, our portfolio consisted of approximately \$27.4 million of investments maturing within one year and approximately \$13.8 million of investments maturing after one year but within 30 months. Additionally, we generally have the ability to hold our fixed income investments to maturity and therefore do not expect that our consolidated operating results, financial position or cash flows will be affected by a significant amount due to a sudden change in interest rates.

Foreign Currency Exchange Risk

The majority of our transactions occur in U.S. dollars and we do not have subsidiaries or investments in foreign countries. Therefore, we are not subject to significant foreign currency exchange risk. We have, however, established policies and procedures for market risk assessment, including a foreign currency-hedging program. The goal of our hedging program is to establish fixed exchange rates on firm foreign currency cash outflows and to minimize the impact to Triangle of foreign currency fluctuations. These policies specifically provide for the hedging of firm commitments and prohibit the holding of derivative instruments for speculative or trading purposes. At March 31, 2002, we had no forward foreign currency contracts, but had investments in foreign currencies totaling approximately \$215,000 used to hedge foreign currency commitments. The purchase and the holding of foreign currencies are governed by established corporate policies and procedures and are entered into when management determines this methodology to be in our best interests. These investments are subject to both foreign currency risk and interest rate risk. The hypothetical loss associated with a 10 percent devaluation of these foreign currencies would not materially affect our consolidated operating results, financial position or cash flow.

Strategic Investment Risk

In addition to our normal investment portfolio, we have a strategic investment in Dynavax valued at \$1.0 million. This investment represents unregistered preferred stock and is subject to higher investment risk than our normal investment portfolio due to the lack of an active resale market for the investment.

PART II OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

a. *Exhibits*

None

b. *Reports on Form 8-K*

None.

TRIANGLE PHARMACEUTICALS, INC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned, thereunto duly authorized.

TRIANGLE PHARMACEUTICALS, INC.

By: /s/ CHRIS A. RALLIS

**Chris A. Rallis
President and Chief
Operating Officer**

Date: May 10, 2002

TRIANGLE PHARMACEUTICALS, INC.

By: /s/ ROBERT F.
AMUNDSEN, JR.

**Robert F. Amundsen, Jr.
Executive Vice President
and Chief Financial
Officer**

Date: May 10, 2002