#### TRIANGLE PHARMACEUTICALS INC

Form 10-Q November 09, 2001

SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2001

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 |X| No |\_|

As of October 15, 2001, there were 76,816,387 shares of Triangle Pharmaceuticals, Inc. Common Stock outstanding.

TRIANGLE PHARMACEUTICALS, INC.

TABLE OF CONTENTS

Part I. Financial Information

Page No.

Item 1. Financial Statements

Condensed Consolidated Balance Sheets - September 30, 2001 (unaudited) and December 31, 2000.... 3

Condensed Consolidated Statements of Operations

		(unaudited) - Three and Nine Months Ended September 30, 2001 and September 30, 2000 and Period From Inception (July 12, 1995) Through September 30, 2001
		Condensed Consolidated Statements of Cash Flows (unaudited) - Nine Months Ended September 30, 2001 and September 30, 2000 and Period From Inception (July 12, 1995) Through September 30, 2001
		Condensed Consolidated Statements of Stockholders'  Equity - Period From Inception (July 12, 1995)  Through September 30, 2001 (unaudited)6-7
		Notes to Condensed Consolidated Financial Statements (unaudited) 8-10
	Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations
	Item 3.	Quantitative and Qualitative Disclosures About Market Risk
Part II.	Other In	formation
	Item 2.	Changes in Securities and Use of Proceeds 31
	Item 6.	Exhibits and Reports on Form 8-K
	Signatur	es

2

# 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)

ASSETS	SEPT	TEMBER 30, 2001	DEC	20 20
	 (UI)	NAUDITED)		
Current assets:				
Cash and cash equivalents	\$	48,544	\$	14
Investments		15,692		39
Interest receivable		579		1
Receivable from collaborative partner		123		
Prepaid expenses		667		
Total current assets		65 <b>,</b> 605		55

Property, plant and equipment, net	4,815 13,466	6 9 
Total assets	\$ 83,886 ======	\$ 71 ====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities: Accounts payable	\$ 9 <b>,</b> 858	\$ 9
Payable to collaborative partner	2,274 	6
Accrued expenses  Deferred revenue	20,918 4,139	17 6
Total current liabilities	37 <b>,</b> 189	39 
Deferred revenue	15,521	17
Total liabilities	52,710	57
Commitments and contingencies (See notes 4, 6 and 7)		
Convertible Preferred Stock, \$0.001 par value; 5,000 shares authorized; 0 shares issued and outstanding		
58,143 and 38,529 shares, issued and outstanding, respectively	58	
Additional paid-in capital	423,936	344
Accumulated deficit during development stage	(393,187) 369	(330
Total stockholders' equity	31 <b>,</b> 176	13 
Total liabilities and stockholders' equity	\$ 83,886 ======	\$ 71 ====

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

3

TRIANGLE PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

2001	2000	2001	
2001	2000	2001	
THREE MONTHS E	NDED SEPTEMBER 30,	NINE MONTHS ENDER	S

Revenue:			
Collaborative revenue	\$ 1 <b>,</b> 271	\$ 1,744	\$ 4,760
Operating expenses:			
License fees	500	2 <b>,</b> 978	2,453
Development	15 <b>,</b> 477	22 <b>,</b> 925	58 <b>,</b> 115
Purchased research and development .	320		320
Selling, general and administrative	1,602	3,621	6,561
Restructuring	2,342		2,342
Total operating expenses	20,241	29 <b>,</b> 524	69 <b>,</b> 791
Loss from operations	(18,970)	(27,780)	(65,031)
Interest income, net	773	1,723	2,813
Net loss	\$(18 <b>,</b> 197)	\$(26 <b>,</b> 057)	\$(62,218)
	======	======	======
Basic and diluted net loss per common			
share	\$ (0.35)	\$ (0.68)	\$ (1.32)
Shares used in computing basic and	======	======	======
diluted net loss per common share	52,366	38,301	47,036
-	=======	======	=======

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

4

# TRIANGLE PHARMACEUTICALS, INC. (A DEVELOPMENT STAGE COMPANY) CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED) (IN THOUSANDS)

	NINE MONTHS END	ED SEPTEMBER 30,
	2001	2000
Cash flows from operating activities: Net loss	\$(62,218)	\$ (84,200)
Adjustments to reconcile net loss to net cash used by operating activities:  Depreciation and amortization	1,349	1,282
Loss from disposal of property, plant and equipment .  Purchased research and development	260 320	 5,350
Stock-based compensation	183	322
Receivables  Prepaid expenses	792 (124)	1,459 (178)
Accounts payable	(3,453)	3,633

Accrued expenses	3,650 (4,760)	4,140 1,164
Net cash used by operating activities	(64,001)	
Cash flows from investing activities:  Sale of restricted deposits  Purchase of investments  Proceeds from sale and maturity of investments  Purchase of property, plant and equipment  Acquisition of Avid Corporation, net of cash acquired	(19,184) 39,110 (331)	27 (90,223) 119,616 (1,516)
Net cash provided (used) by investing activities	19 <b>,</b> 595	27 <b>,</b> 904
Cash flows from financing activities:  Sale of stock, net of related issuance costs  Sale of options under salary investment option	78 <b>,</b> 557	801
grant program  Proceeds from stock options/warrants exercised  Proceeds from notes payable  Equipment financing  Principal payments on capital lease obligations  and notes payable	57 288   (7)	40 378   (111)
Net cash provided by financing activities	78 <b>,</b> 895	1,108
Net increase (decrease) in cash and cash equivalents Cash and cash equivalents at beginning of period	34,489 14,055	(38,016) 58,486
Cash and cash equivalents at end of period	\$ 48,544 ======	\$ 20,470 ======

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

5

# TRIANGLE PHARMACEUTICALS, INC. (A DEVELOPMENT STAGE COMPANY) CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (IN THOUSANDS)

	CONVER PREFERR	TIBLE ED STOCK		COMMON	ADDI PA	
	SHARES	AMOUNT	WARRANTS	SHARES	AMOUNT	CA
Initial sale of stock Additional sale of stock Stock-based compensation Comprehensive loss: Net loss	933 4,249 	·	\$  	1,175 1,495 	·	\$
Balance, December 31, 1995 Sale of stock Stock-based compensation	5,182 3,756	5 4 	  152	2,670 4,943 700	3 5 1	

Stock options exercised				317		
Conversion of Preferred to						
Common Stock	(8,938)	(9)		8,938	9	
Net loss	 	 	 			
Balance, December 31, 1996			152	17,568	18	
Sale of stock				2,014	2	
Acquisition of Avid Corp				400		
Sale of stock options						
Stock-based compensation			(38)			
Stock options exercised				13		
Comprehensive loss:						
Net loss	 					
Balance, December 31, 1997			114	19,995	20	1
Sale of stock	170			8,868	9	1
Sale of stock options				·		
Stock-based compensation						
Stock options exercised				8		
Comprehensive loss:				_		
Change in unrealized						
gains/(losses) on						
investments						
Net loss						
Balance, December 31, 1998	170		114	28,871	29	2
Sale of stock				6,605	7	1
Sale of stock options						
Stock-based compensation				6		
Stock options/warrants						
exercised			(114)	296		
Conversion of Preferred to						
Common Stock	(170)			1,700	2	
Purchased in-process research						
and development costs				100		
Comprehensive loss:						
Reclassification adjustment						
for gains/(losses) in net						
loss						
Change in unrealized						
gains/(losses) on						
investments						
Net loss						
_						
Balance, December 31, 1999 (CONTINUED)	\$	\$		37 <b>,</b> 578	\$ 38	\$ 3

	OT COMPR	MULATED CHER SEHENSIVE SE/(LOSS)	 ERRED NSATION	TOTAL		
Initial sale of stock Additional sale of stock Stock-based compensation	\$	 	\$   (12)	\$	712 3,143 	
Comprehensive loss: Net loss					(967)	
Balance, December 31, 1995			 (12)		2,888	

Sale of stock		 (1.4.1.)	59,515
Stock-based compensation Stock options exercised		(141) (26)	1,139 31
Conversion of Preferred to			
Common Stock			
Net loss			(10,917)
Balance, December 31, 1996		(179)	52,656
Sale of stock			29,523
Acquisition of Avid Corp			8 <b>,</b> 117
Sale of stock options Stock-based compensation		48	10
Stock options exercised		6	9
Comprehensive loss:			
Net loss			(37,668)
Balance, December 31, 1997		(125)	52,717
Sale of stock			116,334
Sale of stock options			97
Stock-based compensation		48	48
Stock options exercised		7	8
Comprehensive loss:			
Change in unrealized			
gains/(losses) on			
investments	18		18
Net loss			(67,271)
Balance, December 31, 1998	18	(70)	101,951
Sale of stock			116,218
Sale of stock options			95
Stock-based compensation		58	159
Stock options/warrants			
exercised		12	377
Conversion of Preferred to			
Common Stock Purchased in-process research			
and development costs			1,247
Comprehensive loss:			
Reclassification adjustment			
for gains/(losses) in net			
loss	(21)		(21)
Change in unrealized			
gains/(losses) on	(1.20)		(120)
investments	(132)		(132)
Net loss			(104,621)
Balance, December 31, 1999 (CONTINUED)	\$ (135)	\$	\$ 115,273

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

6

TRIANGLE PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(IN THOUSANDS)

	CONVERI PREFERRE	ED ST	OCK			COMMON STOCK		ADDI
	SHARES AMOUNT			WARRANTS		SHARES	AMOUNT	PA CA
(CONTINUED)								
Sale of stock		\$		\$		326	\$ 1	\$
Sale of stock options								
Stock-based compensation								
Stock options/warrants exercised						225		
Purchased in-process research						220		
and development costs						400		
Comprehensive loss:								
Reclassification adjustment								
for gains/(losses) in net loss								
Change in unrealized gains/(losses) on								
investments								
Net loss								
D-1 D						20 520	20	
Balance, December 31, 2000 (UNAUDITED)						38 <b>,</b> 529	39	ے
Sale of stock	200					17,385	17	
Sale of stock options								
Stock-based compensation								
Stock options/warrants						100		
exercised Purchased in-process research						129		
and development costs						100		
Conversion of Preferred to								
Common Stock	(200)					2,000	2	
Comprehensive loss:								
Reclassification adjustment for gains/(losses) in net								
lor gains/(losses) in net								
Change in unrealized								
gains/(losses) on								
investments								
Net loss								
Balance, September 30, 2001.		\$		\$		58,143	\$ 58	 \$ 4
Balance, September 30, 2001.			=====	•		========	=======	====
	ACCUMULATE OTHER COMPREHENSI INCOME/(LOS	IVE	DEFERF COMPENSA		TOT	AL 		
(CONTINUED)								
Sale of stock	\$	-	\$		\$	1,609		
Sale of stock options Stock-based compensation		_				52 348		
Stock options/warrants						J=0		

exercised.....

378

Purchased in-process research and development costs  Comprehensive loss:  Reclassification adjustment			-	-	5,350
for gains/(losses) in net loss		133	-	-	133
investments		163	_	_	163
Net loss		105	_	_	(109,525)
Nec 1033					
Balance, December 31, 2000 (UNAUDITED)		161	_	-	13,781
Sale of stock			_	_	78,557
Sale of stock options			-	_	57
Stock-based compensation			-	_	183
Stock options/warrants					
exercised			-	_	288
Purchased in-process research					
and development costs			-	_	320
Conversion of Preferred to					
Common Stock			-	_	
Comprehensive loss:					
Reclassification adjustment					
for gains/(losses) in net					
loss		(32)	-	_	(32)
Change in unrealized					
gains/(losses) on					
investments		240	-	_	240
Net loss			-	-	(62,218)
Balance, September 30, 2001.	\$	369	т		\$ 31,176
	=====	=====		= =	

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

7

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- and nine-month periods ended September 30, 2001 and 2000, 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 September 30, 2001, the Company has multiple license agreements for its drug candidates as well as collaborative agreements with specific third parties to assist in the identification and development of other novel drug candidates. In the aggregate, these agreements may require future payments of up to \$83,000 contingent upon the achievement of development milestones, up to \$30,000 upon the achievement of sales milestones, and \$2,500 of future research and development payments. One of the Company's licensors has the option to receive \$2,000 of future milestone payments in shares of Common Stock (based on the then current market price) in lieu of a cash payment. 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 based on a percentage of net sales of each licensed product incorporating these drug candidates. Most of the Company's license agreements require minimum royalty payments commencing three years after regulatory approval of the licensed compound. 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 \$51,500 (if all drug candidates are approved for all indications) under the Company's existing license agreements. In addition, the Company has option agreements that allow it to obtain licenses on additional drug candidates in the future.

8

TRIANGLE PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

#### 5. RESTRUCTURING CHARGE

In August 2001, the Company recorded a restructuring charge of \$2,342. The restructuring was designed to lower near term monthly cash usage and focus financial and human resources on activities that are expected to have the highest probability of near term regulatory approval and economic return. This focus includes weighting corporate resources towards drug candidates in Phase III development, eliminating most resources dedicated to basic research, and reducing resources dedicated to sales, marketing and general administration. Approximately \$1,650 of the charge resulted from severance and other termination benefits related to an approximate 35% reduction in the Company's total workforce. The remaining \$692 represents a write-down of net assets, the loss associated with underutilized lease obligations and legal and other expenses associated with reducing the Company's workforce. At September 30, 2001, approximately \$1.1 million of all restructuring costs had yet to be paid, as severance benefits extend into the fourth quarter of 2001 for all terminated employees, and two employees had employment agreements which provide for monthly severance benefits beyond 2001.

#### 6. EQUITY FINANCING AND RELATED SUBSEQUENT EVENT

On August 24, 2001, the Company entered into a purchase agreement with Warburg Pincus Private Equity VIII, L.P. ("Warburg Pincus") for the sale of approximately 28,302 shares of Common Stock in a two-stage private placement at a purchase price of \$2.65 per share. On the same day, the first closing of the private placement occurred and the Company issued approximately 9,628 shares of Common Stock for net proceeds totaling \$23,975.

The purchase agreement provided for the sale of approximately an additional 13,757 shares of our Common Stock to Warburg Pincus and an additional 4,917 shares of Common Stock to other investors (including QFinance, Inc., a related party) at a purchase price of \$2.65 per share in a second closing subject to several conditions, including stockholder approval of the sale. Stockholder approval and the second closing occurred on October 10, 2001 and resulted in net proceeds totaling \$46,550 that will be recorded in the Company's financial statements for the quarter ending December 31, 2001. In the purchase agreement with Warburg Pincus, the Company agreed to register the shares of common stock sold in both closings, to cause two individuals nominated by Warburg Pincus to be appointed to the Board of Directors, and granted Warburg Pincus rights to participate in certain future sales of Common Stock by the Company. Accordingly, the Company filed a registration statement with the Securities and Exchange Commission on October 18, 2001 covering the resale of approximately 28,302 shares of Common Stock; two additional directors affiliated with Warburg Pincus were elected to the Board of Directors; and Warburg Pincus has the right to participate proportionally in future equity financings, as long as Warburg Pincus owns approximately 5,846 shares of the Company's outstanding Common Stock.

#### 7. CONTINGENCIES

The Company is indirectly involved in several opposition and interference proceedings and two lawsuits filed in Australia regarding the patent rights related to two of its licensed drug candidates. 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 directed to amdoxovir, (formerly known as DAPD) 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 No. 121 "ACCOUNTING FOR IMPAIRMENT OF LONG-LIVED ASSETS AND LONG-LIVED ASSETS TO BE DISPOSED OF" as no amounts have been capitalized related to these drug candidates. However, any development in these proceedings adverse to the

9

TRIANGLE PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

Company's interests could have a material adverse effect on the Company's future consolidated financial position, results of operations and cash flow.

#### 8. RECENT ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("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 intends to adopt SFAS No. 142 and 144 as of January 1, 2002, and SFAS No. 143 as of January 1, 2003, as required. Adoption of SFAS Nos. 141, 142 and 143 are not expected to have any financial impact, and the Company is currently assessing the impact of SFAS 144 on its consolidated financial position, results of operations and cash flows.

10

OI DIMITONS

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 2000 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 recruiting personnel, negotiating license and option arrangements for our drug candidates, raising working capital and developing our drug candidates. 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 until at least the year 2003. As of September 30, 2001, our accumulated deficit was approximately \$393.2 million.

We require substantial working capital to fund the development and potential commercialization of our drug candidates. We will require significant expenditures to fund pre-clinical 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 at least 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. See "--Risk and Uncertainties--We have incurred losses since inception and may never achieve profitability."

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. See "--Risk and Uncertainties--All of our drug candidates are in development and we may never successfully commercialize them" and "-- If we need additional funds and are unable to raise them, we will have to curtail or cease operations."

Our operating expenses are difficult to predict and will depend on several factors. Development expenses, including expenses for drug synthesis and manufacturing, pre-clinical 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 pre-clinical 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. See "--Risk and Uncertainties--The market price of our stock may fall as a result of market volatility and future developments in our industry."

11

#### RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2001 AND 2000

#### COLLABORATIVE REVENUE

Revenue totaled \$1.3 million for the three months ended September 30, 2001 as compared to \$1.7 million for the same period in 2000. 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 2001 collaborative revenue reflects an extension of the projected development period in 2001 for which collaborative revenue is amortized.

#### LICENSE FEES

License fees totaled \$500,000 for the three months ended September 30, 2001 as compared to \$3.0 million for the same period in 2000. The decrease in 2001 license fees, as compared to 2000, is related to the timing and magnitude of milestone obligations, including license or option preservation payments for our portfolio of drug candidates. Future license fees may consist of milestone payments or preservation payments under our license or option 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, the amount of capital available for allocation to individual drug candidates in our portfolio, and the extent to which we may in-license or out-license drug candidates.

#### DEVELOPMENT EXPENSES

Development expenses totaled \$15.5 million for the three months ended September 30, 2001 as compared to \$22.9 million for the same period in 2000. The substantial decrease in 2001 development expenses as compared to 2000 is due primarily to reduced manufacturing costs for Coviracil(R) and, to a lesser extent, decreased clinical costs associated with Coviracil and Coactinon(R), somewhat offset by increased Coviracil patent costs. We are continuing to focus our development resources on Coviracil, amdoxovir, and Coactinon. Accordingly, approximately 81% of the third quarter 2001's development expenses were incurred for these candidates.

Our future development expenses will depend on the results and magnitude of our clinical and preclinical activities, restrictions on our targeted future cash usage, availability of capital to simultaneously fund multiple drug candidate development programs and requirements imposed by regulatory agencies. 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.

#### PURCHASED RESEARCH AND DEVELOPMENT EXPENSE

Purchased research and development expense totaled \$320,000 for the three months ended September 30, 2001 as compared to no expense for the same period in

2000. In September 2001, we issued 100,000 shares of common stock as consideration to the former Avid Corporation shareholders for their remaining rights relating to mozenavir dimesylate, which is at an early stage of clinical development and has no alternative future use. The 2001 in-process research and development charge is based upon the fair market value of our common stock on the date on which we were obligated to issue additional shares of common stock to the former Avid Corporation shareholders. This issuance satisfies all current and any future obligations in regards to contingent development obligations for mozenavir dimesylate to the former Avid Corporation shareholders. Under our license agreement, we are still responsible to the DuPont Pharmaceuticals Company for milestone, license preservation, and royalty payments, as well as reimbursing DuPont for patent prosecution costs for mozenavir dimesylate. In addition, there remains a contingency for the issuance of 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. Issuance of any additional contingent shares will be recorded as additional purchase price and will be allocated upon resolution of the underlying contingency.

12

#### SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses totaled \$1.6 million for the three months ended September 30, 2001 as compared to \$3.6 million for the same period in 2000. The decrease in 2001 selling, general and administrative expenses, as compared to 2000, is primarily related to decreased 2001 sales and marketing spending for the period. 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 and the commercial availability of our products. We expect that our selling, general and administrative expenses will increase in future periods that immediately precede and follow our first product launch.

#### RESTRUCTURING EXPENSE

Restructuring expense totaled \$2.3 million for the three months ended September 30, 2001 as compared to no expense for the same period in 2000. In August 2001, we announced and began a restructuring of our development activities and overall operations designed to lower our near term monthly cash usage and to focus our financial and human resources on activities that are expected to have the highest probability of near term regulatory approval and economic return. This focus includes weighting our resources towards our drug candidates in Phase III development, eliminating most resources dedicated to basic research, and reducing resources dedicated to sales, marketing and general administration. Approximately \$1.7 million of the total restructuring charge resulted from severance and other termination benefits related to an approximate 35% reduction in our total workforce. The remainder of the charge represents a write-down of net assets, the loss associated with underutilized lease obligations and legal and other expenses associated with reducing our workforce. In September 2001, we terminated our licensing and collaborative agreement with Arrow Therapeutics Limited. This collaboration was to identify and develop novel anti-viral agents for the treatment of hepatitis C and required us to fund the screening program and to pay development milestones and royalty payments on sales of products which resulted from the collaboration.

#### INTEREST INCOME, NET

Net interest income totaled \$773,000 for the three months ended September 30, 2001 as compared to \$1.7 million for the same period in 2000. The

significant decrease in 2001 interest income, as compared to 2000, is due to smaller average investment balances and a much lower low-risk, short-term interest rates in the third quarter of 2001. Future interest income will depend on our future cash and investment balances and the return on these investments. See "--Liquidity and Capital Resources."

NINE MONTHS ENDED SEPTEMBER 30, 2001 AND 2000

#### COLLABORATIVE REVENUE

Revenue totaled \$4.8 million for the nine months ended September 30, 2001 as compared to \$5.6 million for the same period in 2000. 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 2001 collaborative revenue reflects an extension of the projected development period in 2001 for which collaborative revenue is amortized.

#### LICENSE FEES

License fees totaled \$2.5 million for the nine months ended September 30, 2001 as compared to \$3.8 million for the same period in 2000. License fees for 2001 and 2000 relate to the recognition of milestone obligations and/or preservation fees under our license and option agreements for our portfolio of drug candidates. The decrease in 2001 license fee expense, as compared to 2000, is related to the timing and magnitude of milestone obligations and preservation payments under our license and option agreements for our portfolio of drug candidates. Future license fees may consist of milestone payments or preservation payments under our license or option agreements, the amount of which could be substantial and the timing of which will depend on a number of factors,

13

that we cannot predict. These factors include, among others, the success of our drug development programs, the amount of capital available for allocation to individual drug candidates in our portfolio, and the extent to which we may in-license or out-license drug candidates.

#### DEVELOPMENT EXPENSES

Development expenses totaled \$58.1 million for the nine months ended September 30, 2001 as compared to \$76.7 million for the same period in 2000. Development expenses for 2001 consisted primarily of expenses for drug synthesis, clinical trials, employee compensation, amounts paid for professional services, patent costs and preclinical testing. Development expenses for 2000 consisted primarily of expenses for drug synthesis, clinical trials, employee compensation, and preclinical testing. The substantial decrease in 2001 development expenses, as compared to 2000, is due primarily to reduced manufacturing costs for Coviracil and, to a lesser extent, decreased clinical costs for Coviracil and Coactinon, somewhat offset by increased Coviracil patent costs. Development expenses for 2001 have been incurred primarily for Coviracil, amdoxovir and Coactinon.

Our future development expenses will depend on the results and magnitude of our clinical and preclinical activities, restrictions on our targeted future cash usage, availability of capital to simultaneously fund multiple drug candidate development programs and requirements imposed by regulatory agencies.

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.

#### PURCHASED RESEARCH AND DEVELOPMENT EXPENSE

Purchased research and development expense totaled \$320,000 for the nine months ended September 30, 2001 as compared to \$5.4 million for the same period in 2000. The decrease in 2001 purchased research and development expense, as compared to 2000, is related to the magnitude and fair market value of the common stock that was issued as consideration to satisfy milestone obligations for mozenavir dimesylate. In September 2001, we issued 100,000 shares of common stock as consideration to the former Avid Corporation shareholders for their remaining rights relating to mozenavir dimesylate, which is at an early stage of clinical development and has no alternative future use. In March 2000, we issued 400,000 shares of common stock as consideration for the extension of a milestone payment date for mozenavir dimesylate. The in-process research and development charges are based upon the fair market value of our common stock on the date on which we were obligated to issue additional shares of common stock to the former Avid Corporation shareholders. The 2001 issuance satisfies all current and any future obligations in regards to contingent development obligations for mozenavir dimesylate to the former Avid Corporation shareholders. There, however, remains a contingency for the issuance of 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. Issuance of any additional contingent shares will be recorded as additional purchase price and will be allocated upon resolution of the underlying contingency.

#### SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses totaled \$6.6 million for the nine months ended September 30, 2001 as compared to \$9.8 million for the same period in 2000. Selling, general and administrative expenses for 2001 and 2000 consisted primarily of employee compensation, amounts paid for outside professional services, and rent expense. The decrease in 2001 selling, general and administrative expenses, as compared to 2000, is primarily related to decreased 2001 sales and marketing spending for the period. 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 and the commercial availability of our products. We expect that our selling, general and administrative expenses will increase in future periods that immediately precede and follow our first product launch.

#### RESTRUCTURING EXPENSE

Restructuring expense totaled \$2.3 million for the nine months ended September 30, 2001 as compared to no expense for the same period in 2000. In August 2001, we announced and began a restructuring of our development activities and overall operations designed to lower our near term monthly cash usage and to focus our

14

financial and human resources on activities that are expected to have the highest probability of near term regulatory approval and economic return. This focus includes weighting our resources towards our drug candidates in Phase III development, eliminating most resources dedicated to basic research, and reducing resources dedicated to sales, marketing and general administration.

INTEREST INCOME, NET

Net interest income totaled \$2.8 million for the nine months ended September 30, 2001 as compared to \$6.0 million for the same period in 2000. The significant decrease in 2001 interest income, as compared to 2000, is due to smaller average investment balances in 2001 and lower short-term interest rates. Future interest income will depend on our future cash and investment balances and the return on these investments. See "--Liquidity and Capital Resources."

#### LIQUIDITY AND CAPITAL RESOURCES

We have financed our operations since inception (July 12, 1995) through September 30, 2001 primarily with the net proceeds received from private placements of equity securities, which have provided aggregate net proceeds of approximately \$190.3 million, and from initial and secondary public offerings, which have provided aggregate net proceeds of approximately \$96.8 million, as well as net proceeds from the completion of our strategic alliance with Abbott Laboratories, including net proceeds from the sale of common stock and non-contingent research and development reimbursement of approximately \$147.7 million. In November 2000, we entered into a \$100.0 million Firm Underwritten Equity Facility, the Facility, that provided us the ability to sell our common stock in the public market through November 2003. We have raised approximately \$807,000 in total net proceeds from the Facility. In October 2001, we terminated the Facility due to the added liquidity provided by the financing led by Warburg Pincus Private Equity VIII, L.P., the Warburg Pincus financing. Our financial position and liquidity have been further enhanced through the second closing of the Warburg Pincus financing which took place on October 10, 2001 and which resulted in approximately \$46.6 million of net proceeds to be recorded in our fourth quarter financial statements. See "--Equity Financings."

At September 30, 2001, we had net working capital of \$28.4 million, an increase of approximately \$12.7 million over December 31, 2000. The increase in working capital is principally the result of three separate private equity financings completed during the nine-month period ending September 30, 2001, partially offset by use of funds for our normal operating expenses. Our principal sources of liquidity at September 30, 2001 were \$48.5 million in cash and cash equivalents, \$27.2 million in investments which are considered "available-for-sale," and \$2.0 million of strategic corporate investments. The balance at September 30, 2001 reflected a \$14.8 million increase of cash, cash equivalent and investment balances over those at December 31, 2000.

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 Laboratories), 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, and the potential expansion of required 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 approval to commercialize drug candidates and the commercial success of approved drugs. Our existing license and research agreements, as of September 30, 2001, may require future cash payments of up to \$83.0 million contingent on the achievement of development milestones, up to \$30.0 million on the achievement of sales

milestones, and \$2.5 million of future research and development payments. One of our licensors has the option to receive \$2.0 million of future milestone payments in shares of common stock, based on the then current market price, in lieu of a cash payment. 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 acquisition of Avid Corporation. Additionally,

15

we will pay royalties based on a percentage of net sales of each licensed product incorporating these drug candidates. 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 \$51.5 million if all drug candidates are approved for all indications. In addition, we have option agreements that allow us to obtain licenses on additional drug candidates in the future. Exercise of these option agreements would increase our license obligations.

In August 2001, we announced and initiated a restructuring of our development activities and overall operations designed to lower our near term monthly cash usage. This reduction is expected to be accomplished by prioritizing the allocation of financial and human resources to the development of compounds in Phase III development which are expected to have the highest probability of near term regulatory approval and economic return. In addition, we are reducing resources dedicated to basic research, sales, marketing and general administration. In September 2001, we terminated our licensing and collaborative agreement with Arrow Therapeutics Limited. This collaboration had been established to identify and develop novel antiviral agents for the treatment of hepatitis C and required us to fund the screening program and to pay development milestones and royalty payments on sales of products which resulted from this collaboration. Our ability to achieve our reduced cash usage targets is subject to several risks including unanticipated cost overruns, delays in streamlining operations, the need to expand the magnitude and/or scope of existing development programs, the need to change the number and/or timing of clinical trials and unanticipated regulatory requirements.

We believe that our existing cash, cash equivalents and investments (including the \$46.6 million of net proceeds raised on October 10, 2001 in the second closing of the Warburg Pincus financing) will be adequate to satisfy our anticipated working capital requirements through the second quarter of 2003. 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. 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. We cannot assure you that additional funding will be available on favorable terms from any of these sources or at all. See "--Risk and Uncertainties-- If we need additional funds and are unable to raise them, we will have to curtail or cease operations."

#### EQUITY FINANCINGS

On August 24, 2001, we entered into a purchase agreement with Warburg Pincus for the sale of 28,301,887 shares of common stock in a two-stage private placement at a purchase price of \$2.65 per share. On the same day, the first closing of the private placement occurred and we issued 9,628,002 shares of common stock for net proceeds totaling approximately \$24.0 million.

The purchase agreement provided for the sale of an additional 13,756,885 shares of our common stock to Warburg Pincus and an additional 4,917,000 shares of common stock to other investors (including QFinance, Inc., a related party) at a purchase price of \$2.65 per share in a second closing subject to several conditions, including stockholder approval of the sale. Stockholder approval and the second closing occurred on October 10, 2001 and resulted in net proceeds totaling approximately \$46.6 million which will be recorded in our fourth quarter financial statements. In the purchase agreement with Warburg Pincus, we agreed to register the shares of common stock sold in both closings, to cause two individuals nominated by Warburg Pincus to be appointed to the Board of Directors, and granted Warburg Pincus rights to participate in certain future sales of common stock. Accordingly, we filed a registration statement with the Securities and Exchange Commission on October 18, 2001 covering the resale of 28,301,887 shares of common stock; two additional directors affiliated with Warburg Pincus were elected to the Board of Directors; and Warburg Pincus has the right to participate proportionally in future equity financings, as long as Warburg Pincus owns approximately 5,846,000 shares of our outstanding common stock.

#### 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 two of our licensed drug candidates, Coviracil and amdoxovir. Although we are not a named party in any of these proceedings, we are

16

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, Inc., formerly BioChem Pharma, Inc., 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. 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 No. 121 "ACCOUNTING FOR IMPAIRMENT OF LONG-LIVED ASSETS AND LONG-LIVED ASSETS TO BE DISPOSED OF" as no amounts have been capitalized related to our drug candidates. However, any development in these proceedings adverse to our interests, including any adverse development related to the patent rights licensed to us for these two drug candidates or our related rights or obligations, could have a material adverse effect on our business and future consolidated financial position, results of operations and cash flow.

In July 2001, the Financial Accounting Standards Board, FASB, issued Statement of Financial Accounting Standards, 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. 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."

We intend to adopt SFAS No. 142 and 144 as of January 1, 2002, and SFAS No. 143 as of January 1, 2003, as required. Adoption of SFAS Nos. 141, 142 and 143 are not expected to have any financial impact, and we are currently assessing the impact of SFAS 144 on our consolidated financial position, results of operations and cash flows.

#### RISK AND UNCERTAINTIES

IN ADDITION TO THE OTHER INFORMATION IN THIS DOCUMENT, 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. The regulatory authorities have not approved any of our drug candidates. We do not expect any of our drug candidates to be commercially available until at least the year 2003. There are many reasons that we may fail in our efforts to develop our drug candidates, including that:

- o our drug candidates may be ineffective, toxic or may not receive regulatory clearances,
- o our drug candidates may be too expensive to manufacture or market or may not achieve broad market acceptance,
- o third parties may hold proprietary rights that preclude us from developing or marketing our drug candidates, or
- o 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 September 30, 2001, our accumulated deficit was \$393.2 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 until at least 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

17

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:

- o preclinical testing,
- o chemical synthetic scale-up,
- o manufacture of drug substance for clinical trials,
- o toxicology studies,
- o clinical trials of drug candidates,
- o sales and marketing,
- o payments to our licensors, and
- o 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,
- o the scope and results of preclinical testing and clinical trials,
- o the cost, timing and outcome of regulatory filings and reviews,
- o 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,
- o the costs of acquiring any additional drug candidates,
- o the out-licensing of existing drug candidates,
- o the rate of technological advances by us and other companies,
- o the commercial potential of our drug candidates,
- o the magnitude of our administrative and legal expenses,
- o the costs of establishing sales and marketing functions, and
- o  $\,$  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 (including the sale of shares to Warburg Pincus and other investors on October 10, 2001), will be adequate through the second quarter of 2003. We expect that we will need additional future financings to fund our operations. We cannot assure you that available sources of funds will be sufficient to meet our future needs. In addition, we cannot assure you that we will receive the contingent development milestone payments under our strategic alliance with Abbott Laboratories, the Abbott Alliance. 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, 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.

BECAUSE WE MAY NOT SUCCESSFULLY COMPLETE CLINICAL TRIALS REQUIRED FOR COMMERCIALIZATION OF OUR DRUG CANDIDATES, OUR BUSINESS MAY NEVER ACHIEVE PROFITABILITY.

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  $\ensuremath{\mathsf{E}}$ 

18

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 could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a drug candidate, as occurred with mozenavir dimesylate, or could result in regulatory authorities refusing to approve the drug candidate for any and all targeted indications. In 2000, the South African Medicines Control Council terminated one of our phase III clinical studies, study FTC-302, for our drug candidate Coviracil and the Food and Drug Administration, the FDA, issued a clinical hold on the study. Our planned submission of an U.S. New Drug Application for Coviracil will likely be delayed until data from our ongoing FTC-301 study is available for inclusion in the filing. 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:

- o the size of the patient population,
- o the nature of the protocol,
- o the proximity of patients to clinical sites,
- o the eligibility criteria for the clinical trial, and
- o 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.

Changes in regulatory policy or new regulations could also result in delays or rejections of our applications for approval of our drug candidates. The FDA has notified us that three of our drug candidates for the treatment of HIV, Coviracil, Coactinon and amdoxovir, qualify for designation as "fast track" products under provisions of the Food and Drug Administration Modernization Act of 1997. The fast track provisions are designed to expedite the review of new drugs intended to treat serious or life-threatening conditions and essentially codified the criteria previously established by the FDA for accelerated approval. These drug candidates 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 TO 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 one U.S. patent which is jointly owned with another institution. 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

19

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 two of our licensed drug candidates. We may not be able to commercialize Coviracil or 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 these drug candidates and their use alone or in combination to treat HIV and hepatitis B. As a result, our patent position regarding the use of Coviracil and 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 Coviracil and/or 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. Our inability to commercialize either of these drug candidates would adversely affect our ability to achieve profitability.

#### COVIRACIL (EMTRICITABINE)

Coviracil, a purified form of FTC, belongs to the same general class of nucleosides as lamivudine. In the United States, the FDA has approved lamivudine for the treatment of hepatitis B and for use in combination with zidovudine, also known as AZT, for the treatment of HIV. Regulatory authorities have approved lamivudine for the treatment of hepatitis B and for use in combination with other nucleoside analogues for the treatment of HIV in a number of other countries. GlaxoSmithKline plc, Glaxo, currently sells lamivudine for the treatment of HIV and hepatitis B under a license agreement with Shire Pharmaceuticals Group, plc. Shire Pharmaceuticals obtained its rights under this license agreement through a merger with BioChem Pharma, Inc. We obtained rights to Coviracil under a license from Emory University. In 1990 and 1991, Emory filed in the United States and then in numerous foreign countries patent applications with claims to compositions of matter and methods to treat HIV and hepatitis B with Coviracil. In 1991, Yale University filed in the United States patent applications on FTC, including emtricitabine and its use to treat hepatitis B, and subsequently licensed its rights under those patent applications to Emory. Our license arrangement with Emory includes all rights to Coviracil and its uses claimed in the Yale patent applications.

HIV. Emory received a United States patent in 1993 covering a method to treat HIV with Coviracil. Emory has also received United States and European patents containing composition of matter claims that cover Coviracil. BioChem Pharma, now Shire Pharmaceuticals, filed a patent application in the United States in 1989 and received a patent in 1991 covering a group of nucleosides in the same general class as Coviracil, but which did not include Coviracil. Shire Pharmaceuticals filed foreign patent applications in 1990, which expanded on its 1989 United States patent application to include FTC among a large class of nucleosides. The foreign patent applications are pending in many countries and patents have been issued in a number of countries with claims directed to FTC that may cover Coviracil and its use to treat HIV. In addition, Shire Pharmaceuticals filed a United States patent application in 1991 specifically directed to Coviracil. Shire Pharmaceuticals has received two patents in the United

20

States based on this patent application, one directed to Coviracil and the other directed to a method for treating viral diseases with Coviracil. The Patent and Trademark Office has determined that there are conflicts between both Shire Pharmaceuticals patents and patent applications filed by Emory because they have overlapping claims to the same technology. The Patent and Trademark Office is conducting two adversarial proceedings, interferences, to determine whether Shire Pharmaceuticals or Emory is entitled to the patent claims in dispute regarding Shire Pharmaceuticals' two issued patents. On July 5, 2001, the Patent and Trademark Office issued a decision awarding the patent on the method for treating HIV with Coviracil to Emory and ruled that Shire Pharmaceuticals' patent on that subject matter is invalid. The time to appeal this decision has now expired. The decision is therefore final. Emory may not prevail in the remaining adversarial proceeding, and the proceeding may also delay the decision of the Patent and Trademark Office regarding Emory's patent application. Shire Pharmaceuticals also filed patent applications in many foreign countries based on its 1991 United States patent application and has received patents in some of these countries. Shire Pharmaceuticals may have additional patent applications

pending in the United States.

In the United States, the first to invent a technology is entitled to patent protection on that technology. For patent applications filed prior to January 1, 1996, United States patent law provides that a party who invented a technology outside the United States is deemed to have invented the technology on the earlier of the date it introduced the invention in the United States or the date it filed its patent application. In a filing with the Securities and Exchange Commission, Shire Pharmaceuticals stated that prior to January 1, 1996, it conducted substantially all of its research activities outside the United States. Shire Pharmaceuticals also stated that it considered this to be a disadvantage in obtaining United States patents based on patent applications filed before January 1, 1996 as compared to companies that mainly conducted research in the United States. We do not know whether Emory or Shire Pharmaceuticals was the first to invent the technology claimed in their respective United States patent applications or patents. We also do not know whether Shire Pharmaceuticals invented the technology disclosed in its patent applications in the United States or introduced that technology in the United States before the date of its patent applications.

In foreign countries, the first party to file a patent application on a technology, not the first to invent the technology, is entitled to patent protection on that technology. We believe that Emory filed patent applications disclosing Coviracil as a useful anti-HIV agent in many foreign countries before Shire Pharmaceuticals filed its foreign patent applications on that technology. However, Shire Pharmaceuticals has received patents in several foreign countries. In addition, Shire Pharmaceuticals has filed patent applications on Coviracil and its uses in countries in which Emory did not file patent applications. Emory has opposed or otherwise challenged patent claims on Coviracil granted to Shire Pharmaceuticals in Australia, Europe and South Korea. Emory may not initiate patent opposition proceedings in any other countries or be successful in any foreign proceeding attempting to prevent the issuance of, revoke or limit the scope of patents issued to Shire Pharmaceuticals. Shire Pharmaceuticals has opposed patent claims on Coviracil granted to Emory in Europe, Japan, Australia and South Korea. The South Korean patent office issued a decision upholding patent claims to Emory that cover Coviracil. Shire Pharmaceuticals can appeal this decision. Shire Pharmaceuticals may make additional challenges to Emory patents or patent applications, which Emory may not succeed in defending. Our sales, if any, of Coviracil for the treatment of HIV may be held to infringe United States and foreign patent rights of Shire Pharmaceuticals. Under the patent laws of most countries, a product can be found to infringe a third party patent either if the third party patent expressly covers the product or method of treatment using the product, or if the third party patent covers subject matter that is substantially equivalent in nature to the product or method, even if the patent does not expressly cover the product or method. If any governmental authority determined that the sale of Coviracil for the treatment of HIV infringes a Shire Pharmaceuticals patent, we would not have the right to make, use or sell Coviracil for the treatment of HIV in that country in the absence of a license from Shire Pharmaceuticals. We may be unable to obtain a license from Shire Pharmaceuticals on acceptable terms or at all.

HEPATITIS B. Burroughs Wellcome Co. filed patent applications in March 1991 and May 1991 in Great Britain on a method to treat hepatitis B with FTC and purified forms of FTC, that include emtricitabine. Burroughs Wellcome filed similar patent applications in other countries, including the United States. Glaxo subsequently acquired Burroughs Wellcome's rights under those patent applications. Those patent applications were filed in foreign countries prior to the date Emory filed its patent application on the use of emtricitabine to treat hepatitis B. Burroughs Wellcome's foreign patent applications, therefore, have priority over those filed by Emory. In July 1996, Emory instituted litigation against Glaxo in the United States District Court to obtain ownership of the patent

21

applications filed by Burroughs Wellcome, alleging that Burroughs Wellcome converted and misappropriated Emory's invention and property and that an Emory employee is the inventor or a co-inventor of the subject matter covered by the Burroughs Wellcome patent applications. In May 1999, Emory and Glaxo settled the litigation, and we became the exclusive licensee of the United States and all foreign patent applications and patents filed by Burroughs Wellcome on the use of emtricitabine to treat hepatitis B. Under the license and settlement agreements, Emory and we were also given access to development and clinical data and drug substance held by Glaxo relating to emtricitabine.

Shire Pharmaceuticals filed a patent application in May 1991 in Great Britain also directed to a method to treat hepatitis B with FTC. Shire Pharmaceuticals filed similar patent applications in other countries. In January 1996, Shire Pharmaceuticals received a patent in the United States, which included a claim to treat hepatitis B with emtricitabine. The Patent and Trademark Office has determined that there is a conflict between the Shire Pharmaceuticals patent and patent applications filed by Yale and Emory. The Patent and Trademark Office is conducting an adversarial proceeding, an interference, to determine which party is entitled to the patent claims in dispute. Yale licensed all of its rights relating to FTC, including emtricitabine, and its uses claimed in this patent application to Emory, which subsequently licensed these rights to us. Neither Emory nor Yale may prevail in the adversarial proceeding, and the proceeding may delay the decision of the Patent and Trademark Office regarding Yale's and Emory's patent applications. In addition, the Patent and Trademark Office has recently added the U.S. patent application filed by Burroughs Wellcome to this interference. Emory may not pursue or succeed in these proceedings. We will not be able to sell emtricitabine for the treatment of hepatitis B in the United States unless a United States court or administrative body determines that the Shire Pharmaceuticals patent is invalid or unless we obtain a license from Shire Pharmaceuticals. We may be unable to obtain a license on acceptable terms or at all. In July 1991, Shire Pharmaceuticals received a United States patent on the use of lamivudine to treat hepatitis B and has corresponding patent applications pending or issued in foreign countries. If the Patent and Trademark Office determines that the use of emtricitabine to treat hepatitis B is not substantially different from the use of lamivudine to treat hepatitis B, a court could hold that the use of emtricitabine to treat hepatitis B infringes these Shire Pharmaceuticals lamivudine patents.

In addition, Shire Pharmaceuticals has filed patent applications and received patents in the United States and foreign countries on manufacturing methods relating to a class of nucleosides that includes emtricitabine. If we use a manufacturing method that is covered by any of Shire Pharmaceuticals' patents, we will not be able to manufacture emtricitabine without a license from Shire Pharmaceuticals. We may not be able to obtain a license on acceptable terms or at all.

#### AMDOXOVIR (FORMERLY KNOWN AS DAPD)

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

- o composition of matter,
- a method for the synthesis of amdoxovir,
- o methods for the use of amdoxovir alone or in combination with several other agents for the treatment of hepatitis B, and

o 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

22

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 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. Immunostimulatory sequences can be stabilized for use through internal linkages that do not occur in nature, including phosphorothicate

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 immunostimulatory sequences 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 immunostimulatory sequence 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 necessary or may be initiated to enforce any patents we own or are significant and license, or to determine the scope, validity and enforceability of 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. As indicated above, the Patent and Trademark Office is conducting three adversarial proceedings in connection with the emtricitabine technology. We cannot assure you that a court or administrative body would hold our licensed patents valid or would find an alleged infringer to be infringing. Further, the license and option agreements with Emory, the University of Georgia, The Regents of the University of California, The DuPont Pharmaceuticals Company, Mitsubishi Pharma Corporation (formerly, Mitsubishi-Tokyo Pharmaceuticals,

23

Inc.) 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 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 marks Coactinon(R) and Coviracil(R). We have received Canadian trademark registrations for the marks Coactinon(R) and Coviracil(R). We have also received registrations in the European Union for the mark Coactinon(R) and our corporate logo. Our pending application in the European Union for the mark Coviracil(TM) has been opposed by Orsem, based on registrations for the mark Coversyl in various countries, and Les Laboratories 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 PRODUCTS.

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 and registration of pharmaceutical products. These regulations affect:

- o manufacturing,
- o safety,
- o labeling,
- o storage,
- o record keeping,
- o reporting, and
- o 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

24

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:

- o fines,
- o suspended regulatory approvals,
- o refusal to approve pending applications,
- o refusal to permit exports from the United States,
- o product recalls,
- o seizure of products,
- o injunctions,
- o operating restrictions, and
- o 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:

- o have significantly greater financial, technical and human resources than we have and may be better equipped to develop, manufacture and market products,
- o have extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products, and
- o 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:

2.5

- o the safety and effectiveness of our products,
- o the timing and scope of regulatory approvals,
- o the availability of supply,
- o marketing and sales capability,
- o reimbursement coverage,
- o price, and
- o 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 Laboratories 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 products covered by the Abbott Alliance in collaboration with Abbott and to market other products

that we successfully develop, that do not become part of the Abbott Alliance, through a direct sales force or through arrangements or collaborations with third parties. Outside of the United States, we expect Abbott to market products 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 products 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 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.

26

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, including Dr. David Barry, our Chairman and Chief Executive Officer. 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. 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. We cannot predict whether legislative or regulatory proposals will be adopted or what effect those proposals or managed care efforts may have 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 PRODUCTS 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:

27

- o 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
- o 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 October 15, 2001, our directors, executive officers and their affiliates, excluding Abbott and Warburg Pincus, owned approximately 12.8% 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,
- o announcements of the timing of regulatory submissions and/or approvals by us or our competitors,
- o developments with respect to patents or proprietary rights,
- o announcements of technological innovations by us or our competitors,
- o announcements of new products or new contracts by us or our competitors,  $% \left( 1\right) =\left( 1\right) \left( 1\right)$

28

- o actual or anticipated variations in our operating results, including targeted cash usage, due to the level of development expenses and other factors,
- o changes in financial estimates by securities analysts and whether our earnings meet or exceed analysts' estimates,
- o conditions and trends in the pharmaceutical and other industries,
- o new accounting standards,
- o general economic, political and market conditions and other factors, and
- o the occurrence of any of the risks described in these "Risk Factors."

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 28,000,000 SHARES OF OUR COMMON STOCK MAY BE SOLD WITHOUT RESTRICTION AND APPROXIMATELY 38,950,000 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 October 15, 2001, there were 76,816,387 shares of common stock outstanding, of which approximately 28,000,000 were immediately eligible for resale in the public market without restriction. Holders of approximately 42,200,000 shares have rights to cause us to register their shares for sale to the public. We have filed registration statements to register the sale of approximately 38,950,000 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.

ANTITAKEOVER PROVISIONS IN OUR CHARTER DOCUMENTS AND DELAWARE LAW COULD DELAY, DEFER OR PREVENT A TENDER OFFER OR TAKEOVER ATTEMPT THAT YOU CONSIDER TO BE IN YOUR BEST INTEREST.

We have adopted a number of provisions that could have antitakeover effects. 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. Our bylaws divide the Board of Directors into three classes of directors with each class serving a three year term. These and other provisions of our charter and our bylaws, as well as provisions of Delaware law, could delay or impede 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. These provisions could also limit the price that investors might be willing to pay for our common stock.

29

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. At September 30, 2001, we had no forward foreign currency contracts, but had approximately \$250,000 of 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, 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 September 30, 2001, 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 September 30, 2001, our portfolio consisted of approximately \$15.7 million of investments maturing within one year and approximately \$11.5million 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 September 30, 2001, Triangle had no forward foreign currency contracts, but had investments in foreign currencies totaling approximately \$250,000 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 also have a strategic investment in Dynavax Technologies Corporation for \$2.0 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.

30

#### PART II - OTHER INFORMATION

# ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

#### c. Issuance of Unregistered Securities

On August 24, 2001, we entered into a purchase agreement with Warburg Pincus for the sale of 28,301,887 shares of common stock in a two-stage private placement at a purchase price of \$2.65 per share. On the same day, the first closing of the private placement occurred and we issued 9,628,002 shares of common stock for net proceeds totaling approximately \$24.0 million. The purchase agreement provided for the additional sale of 18,673,885 shares of our common stock to Warburg Pincus and other investors at a purchase price of \$2.65 per share in a second closing subject to several conditions, including stockholder approval of the sale. Stockholder approval and the second closing occurred on October 10, 2001 and resulted in net proceeds totaling approximately \$46.6 million which will be recorded in our fourth quarter financial statements.

# ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

a. Exhibits

None

#### b. Reports on Form 8-K

On August 7, 2001, we filed a current report on Form 8-K announcing second quarter results, layoffs, the reduction of cash usage and an update on Coviracil regulatory status.

On August 10, 2001, we filed a current report on Form 8-K announcing the election of James Tyree to the Board of Directors.

On August 24, 2001, we filed a current report of Form 8-K announcing our completion of a private placement of 9,628,002 newly issued shares of common stock to Warburg Pincus.

31

# 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.

Date: November 9, 2001 By: /s/ CHRIS A. RALLIS

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Chris A. Rallis

President and Chief Operating Officer

TRIANGLE PHARMACEUTICALS, INC.

Date: November 9, 2001 By: /s/ ROBERT F. AMUNDSEN, JR.

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

32