SECURITIES AND EXCHANGE COMMISSION

# **FORM 10-Q**

Quarterly report pursuant to sections 13 or 15(d)

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# **FILER**

# **NEOPATH INC**

CIK:851729| IRS No.: 911436093 | State of Incorp.:WA | Fiscal Year End: 1231 Type: 10-Q | Act: 34 | File No.: 000-25210 | Film No.: 98749980 SIC: 3845 Electromedical & electrotherapeutic apparatus Mailing Address 8271 154TH AVE NE REDMOND WA 98052

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# 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, 1998 or

Commission file number: 0-25210

NEOPATH, INC. (Exact name of registrant as specified in its charter)

Washington	91-1436093		
(State or Other Jurisdiction of	(I.R.S. Employer		
Incorporation or Organization)	Identification No.)		

8271 - 154th Avenue NE, Redmond, Washington98052(Address of Principal Executive Offices)(Zip Code)

Registrant's Telephone Number, Including Area Code: (425) 869-7284

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days Yes [X] No [ ]

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

Class Outstanding at November 2, 1998 (Common stock, \$.01 par value) 14,499,552

#### NEOPATH, INC.

#### QUARTERLY REPORT ON FORM 10-Q

TABLE OF CONTENTS

Page

1

#### Part I FINANCIAL INFORMATION

Item 1. Financial Statements

Balance Sheets -- September 30, 1998 (unaudited) and December 31, 1997

Statements of Operations (unaudited) -for the three months and nine months ended September 30, 1998 and 1997

Statements of Cash Flows (unaudited) -for the nine months ended September 30, 1998 and 1997

Notes to Financial Statements

- Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 7
- Item 3. Quantitative and Qualitative Disclosures About Market Risk 13

Part II OTHER INFORMATION

Item 1.	Legal Proceedings	14
Item 6.	Exhibits and Reports on Form 8-K	14

Signatures 15

Part I FINANCIAL INFORMATION

Item 1. Financial Statements

NEOPATH, INC.

# BALANCE SHEETS

		September 30, 1998	December 31, 1997
		(Unaudited)	
Assets			
Current assets:			
Cash and cash equivalents	\$		\$ 
Securities available-for-sale		10,529,485	25,409,633
Accounts receivable, net		3,690,846	3,863,818
Inventories		9,683,961	7,514,001
Other current assets		406,563	187,147
Total current assets		28,406,422	 40,283,569
Fee-per-use systems, net		8,127,596	8,564,189
Property and equipment, net		4,519,375	5,979,849
Intangible assets, net		3,304,595	3,383,925
Deposits and other assets		1,302,608	729,280
Total assets	\$ ==	45,660,596	\$ 58,940,812
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable	\$	2,156,651	\$ 2,173,179
Salaries and wages payable		1,769,738	2,357,045
Customer deposits		341,768	431,877
Other accrued liabilities		841,913	567 <b>,</b> 759
Current portion of long-term			
obligations		2,547,290	80,966

Total current liabilities	7,657,360	5,610,826
Long-term obligations, less current portion	1,895,028	101 <b>,</b> 872
Shareholders' equity: Common stock Accumulated deficit	141,834,782 (105,750,743)	141,057,881 (87,633,118)
Accumulated other comprehensive income (loss)	24,169	(196,649)
Total shareholders' equity	36,108,208	53,228,114
Total liabilities and shareholders' equity	\$ 45,660,596	\$ 58,940,812

See accompanying notes.

Page 1

NEOPATH, INC.

# STATEMENTS OF OPERATIONS (Unaudited)

	Three months ended September 30,			onths ended ember 30,
_	1998	1997	1998	1997
Revenues \$ Cost of revenues	1,873,850 1,154,404	\$ 3,109,044 1,230,849	\$ 9,745,006 5,567,004	\$ 7,584,101 3,276,289
- Gross margin	719,446	1,878,195	4,178,002	4,307,812
Operating expenses: Research and development	2,800,913	3,109,225	8,758,156	11,418,727
Selling, general and administrative	4,391,252	5,231,003	14,227,084	13,635,188
-	7,192,165	8,340,228	22,985,240	25,053,915
Loss from operations	(6,472,719)	(6,462,033)	(18,807,238)	(20,746,103)
Interest income Interest expense	202,107 (121,003)	537,724 (14,540)	835,183 (145,570)	1,956,999 (29,150)

Net Loss	\$ (6,391,615)	\$ (5,938,849)	\$(18,117,625)	\$(18,818,254)
Basic and diluted net loss per share	\$ (0.44)	\$ (0.41)	\$ (1.25)	\$ (1.33)
Weighted average common shares outstanding	14,486,627	14,358,144	14,457,055 	14,135,615 ======

See accompanying notes.

Page 2

# NEOPATH, INC.

# STATEMENTS OF CASH FLOWS (Unaudited)

Nine months ended September 30,

1998	1997	
S (18,117,625)	\$ (18,818,254)	
4,255,232	2,901,103	
	74,246	
421,312	917,863	
172,972	(2,703,273)	
(3,321,579)	(7,151,457)	
(289,140)	1,361,189	
(779,029)	(523,703)	
(17,657,857)	(23,942,286)	
(792,721)	(5,349,511)	
15,472,375	23,624,921	
	(2,696,114)	
(591,653)	(758,679)	
	(4,163)	
	4,255,232  421,312 172,972 (3,321,579) (289,140) (779,029) (17,657,857) (792,721) 15,472,375 	

Net cash provided by investing activities	14,088,001	14,816,454
Financing activities Proceeds from note payable to bank	4,950,000	
Exercise of stock options and warrants	96 <b>,</b> 973	3,901,601
Principal payments on long-term obligations	(690,520)	(58,091)
Net cash provided by financing activities	4,356,453	3,843,510
Net increase (decrease) in cash and		
cash equivalents Cash and cash equivalents:	786,597	(5,282,322)
Beginning of period	3,308,970	7,871,401
End of period	\$ 4,095,567	\$ 2,589,079
Noncash transactions and supplemental disclosures		
Inventories reclassified to fee-per-use systems, net	\$ 1,156,785	\$ 3,083,867
Inventories reclassified to property and equipment, net	(30,444)	1,579,191

See accompanying notes.

Page 3

# NEOPATH, INC.

# NOTES TO FINANCIAL STATEMENTS (Unaudited)

Note 1 - Basis of Presentation

The accompanying unaudited financial statements have been prepared by NeoPath, Inc. ("NeoPath" or the "Company") in accordance with generally accepted accounting principles for interim financial information and according to the rules and Securities and Exchange regulations of the Commission. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (which include only normal recurring adjustments) considered necessary for a fair presentation have been included. The balance sheet at December 31, 1997 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

The results of operations for the three-month and nine-month periods ended September 30, 1998, are not necessarily indicative of results to be expected for the entire year ending December 31, 1998 or for any other fiscal period. For further information, refer to the financial statements and footnotes thereto incorporated by reference in the Company's Form 10-K for the year ended December 31, 1997.

# Note 2 - Revenue Recognition

The Company recognizes AutoPap(R) System fee-per-use revenues based on the number of customer slides processed, beginning in the month an AutoPap System is initially placed in commercial use at the customer site. Certain fee-per-use contracts are subject to agreed-upon minimum processing levels or minimum rental payments. Sales of AutoPap and Pathfinder Systems are generally recognized at date of shipment.

#### Note 3 - Recently Issued Accounting Standards

As of January 1, 1998, NeoPath adopted Financial Accounting ("FASB") Statement Board No. 130, "Reporting Standards Comprehensive Income." Statement 130 establishes new rules for the reporting and display of comprehensive income or loss and its components; however, the adoption of this Statement had no impact on the Company's operating results or shareholders' equity. Statement 130 requires unrealized gains or losses on the Company's securities available-for-sale, which prior to adoption were reported within shareholders' equity, to be included in other comprehensive income or loss. Statement 130 also requires presentation of accumulated other comprehensive income or loss separately in shareholders' equity; accordingly, prior year financial statements have been reclassified to conform to these requirements.

Components of comprehensive net loss are as follows:

Three a	months	ended	September	30,
---------	--------	-------	-----------	-----

	 1998	 1997
Net loss Unrealized gain	\$ (6,391,615)	\$ (5,938,849)
on securities available-for-sale	117,794	200,849
Comprehensive net loss	\$ (6,273,821)	\$ (5,738,000)

	 1998	 1997
Net loss Unrealized gain on securities	\$ (18,117,625)	\$ (18,818,254)
available-for-sale	220,818	264,923
Comprehensive net loss	\$ (17,896,807)	\$ (18,553,331)

Nine months ended September 30,

Page 4

In 1997, the FASB issued Statement No. 131, "Disclosures about Segments of an Enterprise and Related Information," which is required to be adopted for periods beginning after December 15, 1997. The new Statement supersedes FASB Statement No. 14, "Financial Reporting for Segments of a Business Enterprise." Companies will be required to report each operating segment and related information, as defined in Statement 131, in the notes to financial statements. NeoPath plans to adopt the new Statement in 1998. Statement 131 is not required to be applied to interim financial statements in the initial year of adoption.

Note 4 - Inventories

Inventories consist of the following:

	Sept	cember 30, 1998	Dece	mber 31, 1997
Raw materials Work-in-process Finished goods	\$	2,861,105 1,614,234 5,208,622	\$	3,819,830 1,061,900 2,632,271
	\$ ======	9,683,961	\$	7,514,001

The increase in finished goods inventories as of September 30, 1998 was attibutable to NeoPath's manufacturing AutoPap Systems in anticipation of significant customer contracts. The balance decreased significantly in October 1998 as AutoPap Systems were shipped to fee-per-use customers and inventory costs were reclassified to fee-per-use systems, a long-term asset category.

Note 5 - Purchase of Pathfinder System Product Line

NeoPath acquired the Pathfinder System product line in June 1997 for an initial purchase price of \$4.1 million. The initial purchase price included cash of \$2.7 million (including transaction-related expenses), a \$500,000 short-term note paid in October 1997, and 48,564 shares of NeoPath common stock. In addition, certain shares of NeoPath common stock were issued and were held in escrow contingent upon certain specific technology decisions to be made within one year of closing. In April 1998 the Company released the remaining shares held in escrow, consisting of approximately 42,000 shares of NeoPath common stock, resulting in recognition of an additional \$550,000 in intangible assets that are amortized over the remaining five-year amortization term established in June 1997.

# Note 6 - Note Payable to Bank

In April 1998, NeoPath entered into a loan agreement with a bank pursuant to which the Company may borrow up to \$10 million through June 1999. The bank debt is secured by substantially all of NeoPath's assets, excluding intellectual property, and amounts are repaid over 24 months from the date of each drawdown. In addition, NeoPath must comply with certain financial covenants.

Borrowings under this agreement bear interest at the bank's prime rate plus 1 percent per annum (9.5% at September 30, 1998). The balance outstanding at September 30, 1998 was \$4,332,381, of which \$2,475,000 was classified as due within one year.

Page 5

Note 7 - Litigation

July 15, 1996, Neuromedical Systems, On Inc. ("Neuromedical") filed a lawsuit against NeoPath, Inc. in the United States District Court for the Southern District of New complaint alleged patent infringement, York. The unfair competition, false advertising, and related claims. On September 5, 1996, the Company filed its answer and counter claims. In Mav 1998, a judge in the United States District Court for the Southern District of New York denied Neuromedical's motion for a preliminary injunction against NeoPath. The parties have agreed to dismiss their claims and counterclaims on all but the patent issues, and Neuromedical accordingly served an amended complaint on July 27, 1998 asserting only patent infringement claims. This lawsuit is still in the discovery stage and a trial date has not been set. The Company continues to believe it has a strong position in this action and will defend itself vigorously.

On March 31, 1997, the Company filed a patent infringement lawsuit against Neuromedical in the United States District Court for the Western District of Washington. The complaint alleges patent infringement and seeks permanent injunctions against Neuromedical. In March and April 1998 this lawsuit was amended, and NeoPath filed an additional related patent lawsuit against Neuromedical. Neuromedical filed a motion for summary judgment, which was denied by the court in April 1998. In October 1998, Neuromedical filed another motion for summary judgment for which the judge has not yet rendered a decision. The first lawsuit is currently scheduled for trial in 1999, and the second lawsuit is currently in the discovery stage.

#### Page 6

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

#### Overview

NeoPath, Inc. ("NeoPath" or the "Company") develops and markets visual intelligence technology to increase accuracy in medical testing. NeoPath's current products include (i) two automated screening systems that integrate proprietary high-speed morpho-computers, video imaging technology and sophisticated visual intelligence software to capture and analyze thousands of microscopic images from a Papanicolaou ("Pap") smear slide for the early detection of cervical cancer and (ii) the Pathfinder(R) System product line acquired in 1997.

In 1995, the United States Food and Drug Administration (the "FDA") cleared for commercial use the Company's first automated screening product, the AutoPap(R) 300 QC Automatic Pap Screener System (the "AutoPap QC"). In early 1996, the Health Care Financing Administration ("HCFA") officially allowed clinical laboratories to use the AutoPap QC in the quality control review of Pap smear slides that had been initially screened by cytologists and classified as normal. The HCFA decision allowed AutoPap QCs to be used in determining which slides will be rescreened under the federally mandated rescreening requirement.

NeoPath's second automated screening product is the AutoPap Primary Screening System (the "AutoPap Screener" and, in combination with the AutoPap QC, the "AutoPap System"). The AutoPap Screener uses the same hardware components as the AutoPap QC; however, it uses enhanced software, including additional cellclassification algorithms. During 1997, NeoPath completed a prospective intended-use clinical study to evaluate the performance of the AutoPap Screener as a primary screening This study included analysis of more than 25,000 Pap system. smear slides at five clinical laboratories in the United States and Canada. In August 1997, NeoPath submitted the results of the amendment to its pending PreMarket Approval study in an Supplement to the FDA, which requested approval of the AutoPap

Screener as a primary screener of Pap smear slides. In January 1998, the Hematology and Pathology Devices Advisory Panel of the FDA unanimously recommended that the FDA approve the supplement to NeoPath's submission. On May 5, 1998, the FDA followed the panel's recommendation and approved the AutoPap Screener for use a primary Pap smear screener. As approved by the FDA, as the Screener demonstrates a statistically significant AutoPap increase in identifying disease when compared to current manual practice.

In October 1998, HCFA notified NeoPath that the slides designated by the AutoPap Screener as "No Further Review" are not subject to the manual random quality control rescreening of negative cases required by current rules and regulations. This decision eliminates laboratory workflow uncertainty and supports the effectiveness of the AutoPap Screener.

NeoPath's Pathfinder System provides improved productivity and quality assurance in clinical cytology laboratories by computerizing cytotechnologists' microscopes, thereby helping to eliminate manual screening errors and facilitating critical cell identification in applications such as Pap smear screening.

Page 7

Results of Operations

(\$ amounts in thousands)	September 30, 1998	Change	September 30, 1997
Revenues:			
Three months ended	\$1,874	\$(1,235) (40%)	\$3,109
Nine months ended	\$9 <b>,</b> 745	\$2,161 28%	\$7,584

The Company recognizes revenue on either a sale or fee-per-(subject to certain license agreements, use basis lease contracts, and minimum payments on fee-per-use contracts). Under its fee-per-use program, the Company retains ownership of AutoPap Systems placed at customer sites and assesses customers a charge for each Pap smear slide analyzed. The reduction in revenues from the third quarter of the prior year was a result of lower AutoPap System sales, particularly in Asian markets. On a vearto-date basis, higher fee-per-use and sale revenues were reported in comparison to the nine months ended September 30, in 1998 1997.

The AutoPap Screener is the only FDA-approved system for automated primary screening of Pap smears. NeoPath has implemented a strategy to take advantage of this competitive opportunity by offering AutoPap Screeners to customers with initial fee-per-use pricing in line with existing laboratory economics. Per-slide pricing is designed to increase during the contract period to reflect expected increases in third-party reimbursement levels. NeoPath will also continue to offer traditional, fixed price fee-per-use contracts.

In October 1998, NeoPath announced an agreement with SmithKline Beecham Clinical Laboratories ("SmithKline") pursuant which SmithKline has agreed to adopt the AutoPap Screener to throughout its domestic laboratory organization. This four-year contract is intended to enable SmithKline to process 100 percent of its Pap smear volume on AutoPap Screeners. At current AutoPap processing rates, NeoPath estimates that SmithKline may require to 125 AutoPap Screeners to process its nationwide volume of up smears under contract. NeoPath has upgraded the AutoPap QCs Pap SmithKline's laboratories in St. Louis and Atlanta, at and in 1998 NeoPath began shipping AutoPap Screeners October to additional SmithKline sites under the national agreement. SmithKline is one of the three largest clinical laboratory companies in the United States.

Also in October 1998, NeoPath announced a national agreement with Kaiser Permanente ("Kaiser"), which is the largest nonprofit group health plan in the United States. The Kaiser national agreement allows Kaiser and affiliated entities to purchase AutoPap Screeners during the two-year term of the agreement, with additional annual service and licensing fees due over four years. At current AutoPap processing rates, NeoPath estimates that Kaiser may potentially order up to 35 AutoPap Screeners to process its nationwide volume of Pap smears. The timing of specific purchase orders -- and related AutoPap Screener shipments -- is subject to the adoption plans of Kaiser laboratories and affiliates.

NeoPath believes that the national agreements with SmithKline and Kaiser represent significant milestones for the Company.

Page 8

The majority of AutoPap Systems in the United States were placed under multi-year fee-per-use contracts, while international placements have been primarily sale transactions. The Company anticipates that, with the exception of the Kaiser agreement, future AutoPap System placements in the United States will consist primarily of multi-year fee-per-use contracts such

the national agreement signed with SmithKline. However, as AutoPap sale results in NeoPath's immediate because an recognition of product revenue (while a fee-per-use contract provides lower initial revenues but generally extends over several years) near-term AutoPap System sale transactions may account for a higher percentage of total revenues than will the fee-per-use International product placements program. are expected to continue to consist primarily of AutoPap sales.

As a result of increased orders, NeoPath has begun increasing its AutoPap production rate. NeoPath's manufacturing process consists primarily of final assembly and test; therefore, initial capacity constraints relate primarily to lead time associated with component parts from suppliers. NeoPath maintains excellent relations with its suppliers and is working closely with them to meet increasing AutoPap demand.

Approximately 45 percent of third quarter 1998 revenues resulted from AutoPap System sales and upgrades of previously installed AutoPap QCs to enable operation as AutoPap Screeners. This compares to approximately 66 percent in the third quarter of 1997. For each of the nine-month periods ended September 30, 1998 and 1997, approximately 67 percent of total revenues were attributable to AutoPap System sales and upgrades. The remaining revenues represented fee-per-use contract billings and Pathfinder System sales. Pathfinder System sales accounted for less than 3 percent of total revenues in each of the nine-month periods.

NeoPath's AutoPap technology is now available at commercial laboratories in Taiwan, Japan, China (Hong Kong), Korea, Australia, and in Europe. Year-to-date 1998 AutoPap revenues included additional AutoPap System placements in Taiwan, Hong Kong and Japan. The Company's international product placements have primarily been denominated in U.S. dollars; however, future product revenues may be subject to foreign exchange rate fluctuations. Approximately 5 percent of NeoPath's revenues in the third quarter of 1998 represented sales to customers outside of the United States, compared to approximately 45 percent in the same period in 1997. For the nine months ended September 30, 1998, international revenues accounted for approximately 23 percent of total revenues, compared to 59 percent for the same period in 1997.

NeoPath believes that increased third-party reimbursement of Pap smears in general, and increased reimbursement for screening utilizing the AutoPap System in particular, will increase the Company's future revenues. In early 1998, NeoPath established a reimbursement team to work with third-party insurers and managed care organizations to establish and/or improve third-party reimbursement levels for the AutoPap System. These reimbursement specialists work closely with NeoPath's field sales personnel

throughout the United States. Effective January 1, 1998, revised Physicians' Current Procedural Terminology ("CPT") codes (established by the American Medical Association) became effective for the AutoPap QC. CPT codes are a standardized system used by physicians and clinical laboratories to identify specific procedures when billing insurers for their services. New CPT codes that address utilization of the new AutoPap Primary Screener will be available on January 1, 1999. In the interim, NeoPath's reimbursement team is working with AutoPap System customers to help them obtain third-party reimbursement bv utilizing "miscellaneous" CPT codes. AutoPap customers should experience decreased administrative burden after the new codes become available on January 1, 1999.

#### Page 9

(\$ amounts in thousands)	September 30, 1998	Percentage of Revenues	September 30, 1997	Percentage of Revenues
Cost of revenues:				
Three months ended	\$1 <b>,</b> 154	62%	\$1,231	40%
Nine months ended	\$5 <b>,</b> 567	57%	\$3,276	43%
Gross margin:				
Three months ended	\$719	38%	\$1,878	60%
Nine months ended	\$4,178	43%	\$4,308	57%

The decrease in gross margin percentages in 1998 was due primarily to the mix of fee-per-use and sale revenues between the periods. Fee-per-use revenues in the periods included lowermargin initial AutoPap QC placements. The Company's 1998 year-todate gross margin also reflects discounts and incentives included in AutoPap QC sale pricing in the first half of the year as customers anticipated the FDA's approval of the AutoPap Screener well as pricing incentives offered as initial primary as screening placements were made. The change in gross margin from the prior year was also attributable to 1997 international sales under a distribution agreement with higher initial AutoPap System pricing in comparison to 1998. The gross margin percentage is expected to increase in the future as NeoPath places AutoPap Screeners under contracts with improved average per-slide pricing compared to the prior AutoPap QC installed base. Primarv screening systems are expected to process a greater number of slides, on average, than the prior installed base of AutoPap QC

Systems, which is also expected to improve the gross margin percentage.

Gross margin may fluctuate depending on the mix of fee-peruse revenues, AutoPap System sales, upgrades, and other revenues, as well as initial pricing of fee-per-use contracts and other sales incentive programs that may be offered. The continued development of the manufacturing, service and support functions, as well as overall production levels, are also expected to contribute to fluctuations in gross margin. Therefore, the Company's historic gross margins are not necessarily indicative of future gross margins.

(\$ amounts in thousands)	September 30, 1998	Change	September 30, 1997
Research and development:			
Three months ended	\$2,801	\$(308) (10%)	\$3,109
Nine months ended	\$8,758	\$(2,661) (23%)	\$11,419

The Company incurred higher research and development costs in 1997 due primarily to NeoPath's AutoPap Screener clinical study, which was completed in 1997.

Page 10

(\$ amounts in thousands)	September 30, 1998	Change	September 30, 1997
Selling, general and administrative:			
Three months ended	\$4,391	\$(840) (16%)	\$5,231
Nine months ended	\$14,227	\$592 4%	\$13,635

For the quarter, selling, general and administrative expenses decreased from the prior year primarily as a result of lower overall adminstrative expenses as well as increased allocation of certain costs to inventories due to higher AutoPap production rates. As a result of specific cost control initiatives, NeoPath reduced various sales, marketing, and other expenses during the third quarter of 1998, compared to the first two quarters of 1998.

For the nine months ended September 30, 1998, selling, general and administrative expenses increased from the prior year due primarily to significant new sales and marketing initiatives in the first half of 1998, including the market launch of the AutoPap Screener, and expansion of the sales and reimbursement team early in 1998. Costs in the first nine months of 1998 also included the amortization of the allocated purchase price and integration of the Pathfinder System product line acquired in June 1997.

(\$ amounts in thousands)	September 30, 1998	Change	September 30, 1997
Interest income:			
Three months ended	\$202	\$(336) (62%)	\$538
Nine months ended	\$835	\$(1,122) (57%)	\$1 <b>,</b> 957

The decrease in interest income in 1998 was due to decreased cash equivalents and securities available-for-sale resulting from NeoPath's negative operating cash flow.

#### Liquidity and Capital Resources

As of September 30, 1998, the Company had \$14.6 million in equivalents, and securities available-for-sale, cash, cash compared to \$28.7 million as of December 31, 1997. The decrease a result of cash used in the Company's operations for the was nine months ended September 30, 1998, offset by \$5 million in cash obtained from drawing down the first tranche of the Company's \$10 million debt facility (of which NeoPath has repaid \$618,000 as of September 30, 1998). The Company's cash used in operating activities was \$17.7 million in the nine months ended September 30, 1998 and \$23.9 million in the comparable period in The Company expended cash for property and equipment, 1997. excluding AutoPap Systems reclassified to either fee-per-use systems or reclassified to property and equipment, of \$592,000 \$759,000 in the nine months ended September 30, 1998 and and 1997, respectively.

Page 11

NeoPath's fee-per-use business strategy requires a

significant investment in the production of AutoPap Systems as well as sufficient resources to meet operating expenses while this recurring revenue stream grows. As a result of NeoPath's reemphasis on the fee-per-use program as its core U.S. product placement strategy, the Company expects negative cash flow from operations to continue into 2000. The Company's current \$10 million bank financing facility is based on the manufacturing cost of fee-per-use AutoPap Systems placed at customer sites. NeoPath plans to pursue additional financing options during the next several months and expects that such financing will be based primarily on the contract value of multi-year fee-per-use contracts such as the national agreement with SmithKline. Such contracts represent a series of future cash flows due NeoPath over the term of the contracts. There can be no assurance that the Company will obtain additional cash resources.

The Company currently estimates that its existing cash resources and established financing facility will enable it to sustain operations for at least the next three quarters. The Company's future capital requirements will depend on manv factors, including the extent and rate of adoption of the AutoPap Screener; the increased market acceptance of the Company's feeper-use programs; the mix of fee-per-use and sale placements; the extent and rate of development of the Company's marketing, sales, and customer service and support capabilities; and the status of competing products. The Company may, from time to time, seek additional funding through public or private financing, including There can be no assurance that adequate equity financing. funding will be available as needed or on terms acceptable to the Company. If additional funds are raised by issuing equity securities, existing shareholders will experience dilution. Insufficient funds may require the Company to delay, scale back or eliminate some or all of its manufacturing, research and development or clinical programs.

### Year 2000 Issue

#### General Description

The Year 2000 Issue is the result of computer programs being written using two digits rather than four to define the applicable year. Any of the Company's internal or product computer programs or hardware that have date-sensitive software or embedded chips may recognize a date using "00" as the year 1900 rather than the year 2000. This could result in system errors or failures, and could significantly disrupt normal business activities.

Based on recent assessments, the Company determined that it will be required to modify or replace certain portions of its internal systems and product software and certain hardware so

that those systems will properly recognize dates beyond December 31, 1999. To date, the Company has completed its assessment of all internal and product systems that could be significantly affected by the Year 2000. The assessment indicated that certain of the Company's internal and product systems could be affected. However, no significant Year 2000 issues have been identified that cannot be resolved through software or hardware upgrades that are currently available or expected to be available soon. The Company presently believes that with modifications or replacements of existing software and certain hardware, the Year 2000 Issue as it relates to the Company's internal systems and products can be effectively mitigated. However, if such modifications and replacements are not made, or are not completed in a timely manner, the Year 2000 Issue could have a material impact on NeoPath's and its customers' operations.

In addition, the Company has gathered information about the Year 2000 compliance status of its significant suppliers and subcontractors and continues to monitor their compliance.

# Timetable and Cost

The Company will utilize existing internal resources to reprogram or replace, test, and implement the internal systems and product software and certain hardware modifications necessary for Year 2000 compliance. The total cost of the Year 2000 project is not expected to be material. The project is estimated to be completed by mid-1999.

Page 12

#### Third Parties

The Company has queried its significant suppliers and subcontractors as to their Year 2000 compliance status. To date, the Company is not aware of any external agent with Year 2000 problems that would materially impact the Company's results of operations, liquidity, or capital resources. However, the Company has no means of ensuring that external agents will be Year 2000 ready. The inability of external agents to complete their Year 2000 resolution process in a timely fashion could materially impact the Company. The Company cannot determine the effect of non-compliance by external agents.

# Contingency Plans and Risk

The Company currently has no contingency plans in place in the event it does not complete all phases of the Year 2000 program or in the event that its external agents are not Year 2000 ready. The Company plans to evaluate the status of its own Year 2000 program in the first quarter of 1999 and determine whether such a plan is necessary.

NeoPath management believes it has an effective program in place to resolve the Year 2000 issues within its control in a timely manner. The Company believes that with modifications to NeoPath's products, existing internal software and conversions to new software, the Year 2000 Issue will not pose significant operational problems for its computer systems. However, if the Company or external agents do not make necessary modifications and conversions, or do not complete them on time, the Year 2000 Issue could disrupt NeoPath's operations and materially affect its business, financial condition, and results of operations.

#### Forward-Looking Statements

The preceding Management's Discussion and Analysis of Financial Condition and Results of Operations contains "forwardlooking statements" which reflect the Company's current views with respect to future events and financial performance. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from historical results or those anticipated. The words "plan," "expect," "anticipate," and similar expressions identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of their dates. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise. Factors that could cause actual results to differ materially from historical results or those anticipated include, without limitation, the following: specific timing of customer orders under national agreements, including the agreements with SmithKline and Kaiser; market acceptance of the Company's products, marketing and sales programs; availability of adequate reimbursement for customers; product and manufacturing regulatory approvals; the Company's limited marketing, sales, customer service and support capabilities; uncertainties relating international transactions; availability of additional to capital; the Company's sole or limited source of supply of certain components; the Company's ability to manufacture AutoPap Screeners at required levels; the status of competing products; dependence on single product line; product liability; dependence on patents and property rights; and the risk of third-party claims of infringement. For a more detailed discussion of these and other factors, see "Factors Affecting Future Results and Forward-Looking Statements" of the Company's Form 10-K for the fiscal year ended December 31, 1997.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Page 13

Part II OTHER INFORMATION

Item 1. Legal Proceedings

15, 1996, Neuromedical On July Systems, Inc. ("Neuromedical") filed a lawsuit against NeoPath, Inc. in the United States District Court for the Southern District of New York. The complaint alleged patent infringement, unfair competition, false advertising, and related claims. On September 5, 1996, the Company filed its answer and counter claims. In May 1998, a judge in the United States District Court for the Southern District of New York denied Neuromedical's motion for a preliminary injunction against NeoPath. The parties have agreed to dismiss their claims and counterclaims on all but the patent issues, and Neuromedical accordingly served an amended complaint on July 27, 1998 asserting only patent infringement claims. This lawsuit is still in the discovery stage and a trial date has not been set. The Company continues to believe it has a strong position in this action and will defend itself vigorously.

March 31, 1997, the Company filed a patent infringement On lawsuit against Neuromedical in the United States District Court for the Western District of Washington. The complaint alleges patent infringement and seeks permanent injunctions against Neuromedical. In March and April 1998 this lawsuit was amended, NeoPath filed an additional related patent lawsuit and against Neuromedical. Neuromedical filed a motion for summary judgment, which was denied by the court in April 1998. In October 1998, Neuromedical filed another motion for summary judment for which the judge has not yet rendered a decision. The first lawsuit is currently scheduled for trial in 1999, and the second lawsuit is currently in the discovery stage.

Item 6. Exhibits and Reports on Form 8-K

(a) The following exhibits are filed as part of this report.

Exhibit No.	Description
27	Financial Data Schedule
10.29*	Equipment User Agreement with SmithKline Beecham Clinical Laboratories dated as of

September 29, 1998

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(b) Reports on Form 8-K

No reports on Form 8-K were filed during the quarter ended September 30, 1998.

Page 14

#### SIGNATURES

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

NeoPath, Inc.

Date: November 13, 1998

By: /s/ ALAN C. NELSON

Alan C. Nelson President, CEO and Chairman

By: /s/ ROBERT C. BATEMAN

Robert C. Bateman Vice President and Chief Financial Officer

Page 15

NEOPATH, INC.

INDEX TO EXHIBITS

Exhibit No. Description

27 Financial Data Schedule

10.29\* Equipment User Agreement with SmithKline Beecham Clinical Laboratories dated as of September 29, 1998 \* Confidential treatment requested

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This schedule contains summary	financial information extracted from the Form
10-Q as of September 30, $1998$	and for the nine months then ended, and is
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#### EXHIBIT 10.29

"[\*]" = omitted, confidential material, which material has been separately filed with the Securities and Exchange Commission pursuant to a request for confidential treatment.

[NeoPath, Inc. logo]

EQUIPMENT USER AGREEMENT WITH SMITHKLINE BEECHAM CLINICAL LABORATORIES

> 1201 South Collegeville Road Collegeville, PA 19426

Section 1. Overview of Agreement

This Agreement is made and entered into by and between NeoPath, Inc. ("NeoPath") and SmithKline Beecham Clinical Laboratories ("SBCL"). This Agreement supercedes all prior agreements between NeoPath and SBCL. This Agreement includes, and incorporates by this reference NeoPath's Standard Terms and Conditions, NeoPath's Equipment User Agreement Supplemental Terms and Conditions, and NeoPath's AutoPap System Product Insert.

NeoPath agrees to provide SBCL, and SBCL agrees to order from NeoPath, sufficient AutoPap(R) Primary Screening Systems ("System") to process 100 percent of SBCL's internally processed automated Pap smear volume by the end the Term. The initial upgrade of all AutoPap QC Systems of AutoPap Primary Screening Systems at the SBCL St. Louis to and Atlanta sites will be performed immediately, but no later than September 30, 1998. By [\*], NeoPath and SBCL a delivery schedule for AutoPap will agree to Primary Screening Systems to be shipped in 1998 and 1999. By [\*], NeoPath and SBCL will agree to a delivery schedule for Systems to be shipped during the remaining Term.

Section 2. Definitions

The following terms will have the following meanings when used in this Agreement with initial letters capitalized:

"Anniversary Date" means September 1, 1999, 2000, and 2001.

"Annual Period" means any period of twelve consecutive calendar months during the Term beginning on September 1, 1998 or any Anniversary Date.

"Base Fee-Per-Slide" or "Base FPS" means the minimum amount due NeoPath per Pap smear slide processed on a System during the Term. Unless adjusted, the Base FPS is established as follows:

Period						В	ase FPS
						-	
1: Septemb	er 1,	1998 -	August	31,	1999		[*]
2: Septemb	er 1,	1999 -	August	31,	2000		[*]
3: Septemb	er 1,	2000 -	August	31,	2001		[*]
4: Septemb	er 1,	2001 -	August	31,	2002		[*]

"Current Payment" means the national average payment received by SBCL on a per Pap smear basis for all Pap smear slides processed between [\*].

"Fee-Per-Slide" means the Base FPS or the Adjusted Base FPS, in either case as the same may be adjusted pursuant to Section 4 below.

[\*]Confidential treatment requested

Page 1

"Quarter" means a calendar quarter (i.e., a period of three consecutive months commencing with January, April, July or October).

"Term" means a period of four years commencing September 1, 1998.

"Total Payment" means the national average payment received by SBCL on a per Pap smear basis for Pap smear slides processed utilizing the AutoPap System during the twelve months ending [\*].

The parties acknowledge that Total Payment does not encompass [\*]. The Parties agree that if SBCL incorporates such technology into the Pap smear process, there may be an increase in the cost of Pap smear slides. To the extent these increased costs change total payment, the parties agree to factor such amounts into the Total Payment calculation.

"System" means any AutoPap System subject to this Agreement.

"No Review" means slides that the AutoPap System designates as needing no human review. The No Review rate is the percent of all eligible slides that are so designated.

#### Section 3. Prior Agreements

The terms of this Agreement also apply to AutoPap Systems currently installed at SBCL sites in St. Louis and Atlanta under terms of earlier contracts signed October 5, 1995 and May 9, 1996 respectively, except that the instrument minimum volumes of [\*] slides processed per year still apply to each of those instruments.

Section 4. Fee-Per-Slide

Section 4.1 General

The Fee-Per-Slide will be equal to the Base FPS, as the same may be adjusted pursuant to Section 4.2 or 4.3.

Section 4.2 Adjusted Base FPS

The Base FPS for any Annual Period may be adjusted if the following formula yields a fee per slide different from the Base FPS specified for the corresponding period (in no event is the Adjusted Base FPS less than the initial Base FPS):

Adjusted Base FPS: [\*]

```
Example for first
Anniversary Date: Current Payment assumption = [*]
Total Payment assumption = [*]
Then Adjusted Base FPS for the second Annual Period: [*]
```

SBCL or NeoPath may exercise such option only by giving written notice of such exercise within 30 days prior to the commencement of the applicable Annual Period.

[\*]Confidential treatment requested

Page 2

Section 4.3. Workload Reduction Adjustment

Upon NeoPath's delivery of an FDA-approved upgraded System capability, the Base FPS (or Adjusted Base FPS, as applicable) will be increased by [\*] per Pap smear slide processed for [\*]. Such increase per slide will be payable with respect to all slides processed after the beginning of the Quarter following delivery, installation, and full implementation of the upgrade.

#### Section 5. Records and Audit

SBCL will keep and maintain accurate records of any and all payments received for the processing of Pap smear slides.

NeoPath may designate an independent certified public accountant to audit SBCL's documentation and records as required to verify any proposed Adjusted Base FPS. Unless otherwise agreed by the parties, any such audit will be conducted upon not less than ten (10) business days' advance written notice to SBCL, during SBCL's normal business hours and in a manner that does not interfere with SBCL's normal business operations. The expense of such audit will be borne by [\*]. NeoPath will not conduct any such audit more than once in any twelve (12)-month period.

### Section 6. Exclusivity

During the Term, SBCL agrees to exclusively utilize AutoPap Systems for all eligible internally processed automated Pap smear reading needs. By the end of the Term, SBCL agrees to process 100 percent of eligible internally processed Pap smear slides at installed sites through the AutoPap System.

# Section 7. Other Terms

NeoPath will deliver the AutoPap Systems FOB carrier at the NeoPath manufacturing facility. [\*] will be responsible for all transportation costs.

# Section 8. Additional Systems

If the average number of slides processed per Quarter with all of the Systems located at any SBCL site during any two consecutive Quarters exceeds [\*] slides per System per Quarter, then SBCL may order additional Systems as needed to bring the projected average requirement at such SBCL site down to approximately [\*] slides per System per Quarter. Unless otherwise agreed upon by the parties, NeoPath will use its best efforts to deliver such additional System(s) within [\*] days after receipt of SBCL's order for the same, and the Term with respect to any such System will commence upon [\*] and will end upon [\*].

#### Section 9. Early Termination

If the average number of slides processed per Quarter with all of the Systems located at any SBCL site during any two (2) consecutive Quarters is significantly less than [\*] slides per System per Quarter, then NeoPath may terminate Term with respect to any Systems located at such SBCL the site; provided that after any such termination, the Systems remaining at such SBCL site are sufficient to process a projected average requirement at such SBCL site not greater than approximately [\*] slides per System per Quarter, and provided that at least one System sufficient to handle the eligible slides at that site remains on-site.

[\*]Confidential treatment requested

Page 3

#### Section 10. Press Releases

Each party to this agreement will give the other party reasonable advance notice of, and the opportunity to review, comment upon and approve, any press release or marketing materials that the other party may desire to publish with regard to either the utilization of Systems at SBCL's sites, or the NeoPath system generally.

Section 11. Accessories

11.1 Each offered AutoPap System includes the following NeoPath accessories:

Quantity	Description
40	 AutoPap Slide Trays
1	Operator Manual
1	Start-Up Kit*

- \* Start-Up Kit will include one package of printer paper and one roll of Bar Code Labels (5,000 sets of 4 labels per role)
- 11.2 The following additional accessories are offered by NeoPath at the current indicated prices (prices subject to change):

Section 12. Contract Signatures

OFFERED BY: NeoPath, Inc.	ACCEPTED BY: SmithKline Beecham Clinical Laboratories
Signature: /s/ Alan C. Nelson	Signature: /s/ John B. Okkerse, Jr.
Printed Name: Alan C. Nelson, Ph.D.	Printed Name: John B. Okkerse, Jr.
Title: President, CEO and Chairman	Title: President
Date Signed: September 29, 1998	Date Signed: September 29, 1998
	/s/ Edward A. Kaufman
	Edward A. Kaufman
	Vice-President/National Medical Director

29 September 98

Page 4