UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 1999

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() 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 000-23186

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

DELAWARE

incorporation or organization)

62-1413174 (State or other jurisdiction of (I.R.S. employer identification no.)

> 2190 Parkway Lake Drive; Birmingham, Alabama 35244 (Address and zip code of principal executive offices)

(205) 444-4600 (Registrant's telephone number, including area code)

NONE

(Former name, former address and former fiscal year, if changed since last report)

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: 15,238,672 shares of the Company's Common Stock, \$.01 par value, were outstanding as of October 27, 1999.

BIOCRYST PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BIOCRYST PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS SEPTEMBER 30, 1999 AND DECEMBER 31, 1998 (IN THOUSANDS, EXCEPT PER SHARE)

ASSETS	1999 (UNAUDITED)	1998 (NOTE 1)			
Cash and cash equivalents Securities held-to-maturity Prepaid expenses and other current assets	\$ 6,227 12,891 842	\$12,311 9,961 598			
Total current assets Securities held-to-maturity Furniture and equipment, net Patents	19,960	22,870 4,740 1,408 82			
Total assets		\$ 29,100			
LIABILITIES AND STOCKHOLDERS' EQUITY Accounts payable Accrued expenses Accrued taxes, other than income Accrued vacation Current maturities of capital lease obligations Total current liabilities Capital lease obligations	\$ 145 789 133 127 14 1,208	\$ 243			
Deferred license fee Total liabilities					
Total liabilities 1,519 1,418 Stockholders' equity: Convertible preferred stock, \$.01 par value, shares Authorized - 5,000; shares issued and outstanding - none Common stock, \$.01 par value, shares authorized - 45,000; shares issued and outstanding -					
15,239 in 1999 and 14,960 in 1998 Additional paid-in capital Accumulated deficit	152 82,747 (58,027)	150 80,702 (53,170)			
	24,872				
Total liabilities and stockholders' equity		\$ 29,100			

See accompanying notes to condensed financial statements.

BIOCRYST PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS PERIODS ENDED SEPTEMBER 30, 1999 AND 1998 (IN THOUSANDS, EXCEPT PER SHARE)

	THREE M		NINE MO	
	1999	1998	1999	1998
Collaborative and other research and development Interest and other	\$48 287	\$6,000 249	\$ 2,456 920	\$ 6,000 920
Revenues	335	6,249	3,376	6,920
Research and development General and administrative Interest	1,889 651 1	2,353 1,226 3	5,895 2,334 4	7,706 2,521 13
Expenses	2,541	3,582	8,233	10,240
Income (loss) before taxes Income taxes	(2,206)	2,667	(4,857)	(3,320)
Net income (loss)	\$(2,206)	\$2,667	\$(4,857)	\$(3,320)
Net income (loss) per share (Note 2): Basic Diluted	\$(.15) \$(.15)	\$.19 \$.19	\$(.32) \$(.32)	\$(.24) \$(.24)
Weighted average shares outstanding (Note 2): Basic Diluted	15,119 15,119	13,952 14,303	15,028 15,028	13,932 13,932

See accompanying notes to condensed financial statements.

BIOCRYST PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF CASH FLOWS NINE MONTHS ENDED SEPTEMBER 30, 1999 AND 1998 (IN THOUSANDS)

	1999	1998
OPERATING ACTIVITIES		
Net loss		\$(3,320)
Depreciation and amortization		401
Non-monetary compensation Changes in operating assets and liabilities, net		167 (5 549)
changes in operating assets and inabilities, het	(100)	(5,549)
Net cash used by operating activities	(4,618)	(8,301)
INVESTING ACTIVITIES		
Purchases of furniture and equipment	(527)	(358)
Purchase of marketable securities	(13,248)	(2,840)
Maturities of marketable securities	10,312	12,051
Net cash (used)/provided by investing activities	(3.463)	8,853
Net oush (useu//provided by investing derivities	(0,400)	
FINANCING ACTIVITIES		
Principal payments on debt and capital lease obligations	(10)	(49)
Proceeds from sale of common stock	2,007	605
Net cash provided by financing activities	1,997	
(Decrease)/increase in cash and cash equivalents		1,108
Cash and cash equivalents at beginning of period	12,311	3,757
Cash and cash equivalents at end of period	\$ 6,227	\$ 4,865

See accompanying notes to condensed financial statements.

BIOCRYST PHARMACEUTICALS, INC. NOTES TO CONDENSED FINANCIAL STATEMENTS

Note 1. Basis of Preparation

The condensed balance sheet as of September 30, 1999 and the condensed statements of operations and cash flows for the nine months ended September 30, 1999 and 1998 have been prepared in accordance with generally accepted accounting principles by the Company and have not been audited. Such financial statements reflect all adjustments which are, in management's opinion, necessary to present fairly, in all material respects, the financial position at September 30, 1999 and the results of operations and cash flows for the nine months ended September 30, 1999 and 1998. These condensed financial statements should be read in conjunction with the financial statements for the year ended December 31, 1998 and the notes thereto included in the Company's 1998 Annual Report. Interim operating results are not necessarily indicative of operating results for the full year. The balance sheet as of December 31, 1998 has been prepared from the audited financial statements included in the previously mentioned Annual Report.

Note 2. Net Income (Loss) Per Share

The Company computes net income (loss) per share in accordance with Statement of Financial Accounting Standards No. 128, Earnings per Share. Basic net income (loss) per share is based upon the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is based upon the weighted average number of common shares outstanding and dilutive common stock equivalents during the period. Common stock equivalents are options under the Company's stock option plan, warrants and common shares expected to be issued under the Company's employee stock purchase plan and are calculated under the treasury stock method.

Common stock equivalents of approximately 1,447,000 shares were used to calculate diluted income per share for the three months ending September 30, 1998. For the three- and nine-month periods ended September 30, 1999 and the nine months ended September 30, 1998, common stock equivalents of approximately 2,393,000, 2,456,000 and 2,454,000 shares, respectively, were not used to calculate diluted income (loss) per share because of their anti-dilutive effect. There were no reconciling items in calculating the numerator for basic and diluted income (loss) per share for any of the periods presented.

Subsequent to the close of the third quarter of 1998, the Company completed a private placement of 918,836 shares of its common stock for \$6.0 million.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

THIS QUARTERLY REPORT ON FORM 10-Q CONTAINS CERTAIN STATEMENTS OF A FORWARD-LOOKING NATURE RELATING TO FUTURE EVENTS OR THE FUTURE FINANCIAL PERFORMANCE OF THE COMPANY. SUCH STATEMENTS ARE ONLY PREDICTIONS AND THE ACTUAL EVENTS OR RESULTS MAY DIFFER MATERIALLY FROM THE RESULTS DISCUSSED IN THE FORWARD-LOOKING STATEMENTS. FACTORS THAT COULD CAUSE OR CONTRIBUTE TO SUCH DIFFERENCES INCLUDE THOSE DISCUSSED BELOW AS WELL AS THOSE DISCUSSED IN OTHER FILINGS MADE BY THE COMPANY WITH THE SECURITIES AND EXCHANGE COMMISSION, INCLUDING THE COMPANY'S ANNUAL REPORT ON FORM 10-K.

OVERVIEW

Since our inception in 1986, we have been engaged in research and development activities and organizational efforts, including:

- identification and licensing of enzyme targets;
- drug discovery;
- structure-based design of drug candidates;

- small-scale synthesis of compounds;
- conducting preclinical studies and clinical trials;
- recruiting our scientific and management personnel;
- establishing laboratory facilities; and
- raising capital.

Our revenues have generally been limited to license fees, milestone payments, interest income, collaboration research, development and option fees. Research and development revenue on cost-reimbursing agreements is recognized as expenses are incurred up to contractual limits. Research and development revenues, license fees, milestone payments and option fees are recognized as revenue when irrevocably due. Payments received that are related to future performance are deferred and taken into income as earned over a specified future performance period. We have not received any revenue from the sale of pharmaceutical products. It will be several years, if ever, before we will recognize significant revenues from royalties received pursuant to our license agreements, and we do not expect to ever generate revenues directly from product sales. Future revenues, if any, are likely to fluctuate substantially from quarter to quarter.

We have incurred operating losses since our inception. Our accumulated deficit at September 30, 1999 was \$58.0 million. We will require substantial expenditures relating to the development of our current and future drug candidates. During the three years ended December 31, 1998, we spent 44.7% of our research and development expenses on contract research and development, including:

- payments to consultants;
- funding of research at academic institutions;
- large scale synthesis of compounds;
- preclinical studies;
- engaging investigators to conduct clinical trials;
- hiring contract research organizations to monitor and gather data on clinical trials; and
- using statisticians to evaluate the results of clinical trials.

The above expenditures for contract research and development for our current and future drug candidates will vary from quarter to quarter depending on the status of our research and development projects. Changes in our existing and future research and development and collaborative relationships will also impact the status of our research and development projects. While we may, in some cases, be able to control the timing of development expenses, in part by accelerating or decelerating certain of these costs, many of these costs will be incurred irrespective of whether or not we are able to discover drug candidates or obtain collaborative partners for commercialization. As a result, we believe that quarter-to-quarter comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of future performance. If we fail to meet the clinical and financial expectations of securities analysts and investors, it could have a material adverse effect on the price of our common stock.

RESULTS OF OPERATIONS (THREE MONTHS ENDING SEPTEMBER 30, 1999 COMPARED TO THE THREE MONTHS ENDING SEPTEMBER 30, 1998)

Collaborative and other research and development revenue decreased to \$48,000 in the three months ended September 30, 1999. In September 1998, we entered into an exclusive worldwide license agreement with

The R.W. Johnson Pharmaceutical Research Institute and Ortho-McNeil Pharmaceutical, Inc., both Johnson & Johnson companies, for our influenza neuraminidase inhibitors. We received an initial \$6.0 million payment from Ortho-McNeil and an additional \$6.0 million common stock equity investment from Johnson & Johnson Development Corporation. The \$48,000 in the third quarter of 1999 represents collaboration work performed for The R.W. Johnson Pharmaceutical Research Institute. Interest and other income increased 15.3% to \$287,000 in the three months ended September 30, 1999 from \$249,000 in the three months ended September 30, 1998. The increase in interest and other income is primarily due to an increase in the average investment in 1999 versus 1998 offset by a decline in interest rates. The increase in the average investment was primarily due to the funds received from Ortho-McNeil and Johnson & Johnson Development Corporation in the fourth quarter of 1998.

Research and development expenses decreased 19.7% to \$1.9 million in the three months ended September 30, 1999 from \$2.4 million in the three months ended September 30, 1998. The decrease is primarily attributable to a decrease in costs associated with conducting clinical trials and one-time costs associated with the influenza neuraminidase license incurred in the third quarter of 1998. These costs tend to fluctuate from period to period depending upon the status of our research projects and collaborative efforts.

General and administrative expenses decreased 46.9% to \$651,000 in the three months ended September 30, 1999 from \$1.2 million in the three months ended September 30, 1998. The decrease is primarily the result of one-time expenses, including the royalty payment to The University of Alabama at Birmingham, associated with the influenza neuraminidase license signed in September 1999.

Interest expense decreased to \$1,184 in the three months ended September 30, 1999 from \$2,880 in the three months ended September 30, 1998. The decrease was primarily due to a decline in capitalized lease obligations resulting in lesser interest expense. We obtained most of our leases in connection with the move to our facilities in April 1992.

RESULTS OF OPERATIONS (NINE MONTHS ENDING SEPTEMBER 30, 1999 COMPARED TO THE NINE MONTHS ENDING SEPTEMBER 30, 1998)

Collaborative and other research and development revenue decreased to \$2.5 million in the first nine months of 1999. This decrease is attributable to the \$2.0 million milestone payment received from Ortho-McNeil in June 1999 and approximately \$0.5 million of research and development work performed for The R.W. Johnson Pharmaceutical Research Institute compared to the \$6.0 license fee from Ortho-McNeil and The R.W. Johnson Pharmaceutical Research Institute in September 1998. The interest and other income did not change primarily due to the increase in the average investment in 1999 versus 1998 being offset by a decline in interest rates in 1999 versus 1998. The difference in the average investment for the nine months ended September 30, 1999 versus 1998 was less than that for the three months ended September 30, 1999 versus 1998.

Research and development expenses decreased 23.5% to \$5.9 million in the first nine months of 1999 from \$7.7 million in the first nine months of 1998. The decrease is primarily attributable to a decrease in costs associated with conducting clinical trials, a reduction in contracted research costs at The University of Alabama at Birmingham and one-time costs associated with the influenza neuraminidase license incurred in the third quarter of 1998. These costs tend to fluctuate from period to period depending upon the status of our research projects and collaborative efforts.

General and administrative expenses decreased 7.4% to \$2.3 million in the first nine months of 1999 from \$2.5 million in the first nine months of 1998. The decrease is primarily the result of one-time expenses, including the royalty payment to The University of Alabama at Birmingham, associated with the influenza neuraminidase license signed in September 1998 offset by increased legal expenses in 1999.

Interest expense decreased to \$3,961 in the first nine months of 1999 from \$12,794 in the first nine months of 1998. The decrease was primarily due to a decline in capitalized lease obligations resulting in lesser interest expense. We obtained most of our leases in connection with the move to our facilities in April 1992.

LIQUIDITY AND CAPITAL RESOURCES

Cash expenditures have exceeded revenues since our inception. Our operations have principally been funded through public offerings and private placements of equity and debt securities, equipment lease financing, facility leases, collaborative and other research and development agreements, licenses and options for licenses, research grants and interest income. In addition, we have attempted to contain costs and reduce cash flow requirements by renting scientific equipment and facilities, contracting with other parties to conduct certain research and development and using consultants. We expect to incur additional expenses, resulting in significant losses, as we continue and expand our research and development activities and undertake additional preclinical studies and clinical trials of compounds which have been or may be discovered. We also expect to incur substantial expenses related to the filing, prosecution, maintenance, defense and enforcement of patent and other intellectual property claims.

At December 31, 1998, our cash, cash equivalents and securities held-to-maturity were \$27.0 million, an increase of \$2.4 million from December 31, 1997, principally due to the \$6.0 million equity investment in us in connection with the influenza neuraminidase license which offset the cash used in operations. At September 30, 1999, our cash, cash equivalents and securities held-to-maturity were \$23.9 million, a decrease of approximately \$3.1 million from December 31, 1998, principally due to the cash used by operations for the nine months ended September 30, 1999 offset by proceeds from the exercise of stock options.

We have financed some of our equipment purchases with lease lines of credit. We currently have a \$500,000 line of credit with our bank to finance capital equipment. In January 1992, we entered into an operating lease for our current facilities which expires on June 30, 2003. We have an option to renew the lease for an additional three years at current market rates. The operating lease requires us to pay monthly rent ranging from \$21,405 and escalating annually to a minimum of \$24,814 per month in the final year, and a pro rata share of operating expenses and real estate taxes in excess of base year amounts.

At December 31, 1998, we had long-term capital lease and operating lease obligations which provide for aggregate minimum payments of \$280,254 in 1999, \$288,128 in 2000 and \$285,816 in 2001. In 1999, we increased the amount of office space we lease by approximately 1,700 square feet. This additional space should increase our annual lease obligations by less than \$15,000 annually.

Under the terms of our license agreement with The R.W. Johnson Pharmaceutical Research Institute and Ortho-McNeil for the development and commercialization of our influenza neuraminidase inhibitors, we received an initial \$6.0 million payment from Ortho-McNeil and an additional \$6.0 million common stock equity investment from Johnson & Johnson Development Corporation. In June 1999, we received a \$2.0 million milestone payment from Ortho-McNeil in connection with the initiation of Phase II clinical testing in the United States. In addition, we may receive cash payments upon specified developmental and regulatory milestones and royalties on product sales, if any. We cannot assure you that The R.W. Johnson Pharmaceutical Research Institute or Ortho-McNeil will continue to develop the product or, if they do so, that such development will result in receiving milestone payments, obtaining regulatory approval or achieving future sales of licensed products.

We previously entered into an exclusive license agreement with Torii under which Torii paid us \$1.5 million in initial license fees and made a \$1.5 million equity investment in us in 1996. The first milestone payment of \$1.0 million was received in 1997. This exclusive license agreement was terminated by Torii in July 1999.

We plan to finance our capital needs principally from the following:

- our existing capital resources and interest earned on that capital;
- payments under collaborative and licensing agreements with corporate partners; and
- through lease or loan financing and future public or private financings.

We believe that our available funds will be sufficient to fund our operations at least through 2000. However, this is a forward-looking statement, and there may be changes that would consume available resources

significantly before such time. Our long-term capital requirements and the adequacy of our available funds will depend upon many factors, including:

- the progress of our research, drug discovery and development programs;
- changes in existing collaborative relationships;
- our ability to establish additional collaborative relationships;
- the magnitude of our research and development programs;
- the scope and results of preclinical studies and clinical trials to identify drug candidates;
- competitive and technological advances;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- our dependence on others, including The R.W. Johnson Pharmaceutical Research Institute and Ortho-McNeil, for development and commercialization of our product candidates, in particular, our neuraminidase inhibitors; and
- successful commercialization of our products consistent with our licensing strategy.

Additional funding, whether through additional sales of securities or collaborative or other arrangements with corporate partners or from other sources, may not be available when needed or on terms acceptable to us. The issuance of preferred or common stock or convertible securities, on terms and prices significantly more favorable than those of the currently outstanding common stock, could have the effect of diluting or adversely affecting the holdings or rights of our existing stockholders. In addition, collaborative arrangements may require us to transfer certain material rights to such corporate partners. Insufficient funds may require us to delay, scale-back or eliminate certain of our research and development programs.

RISKS ASSOCIATED WITH THE YEAR 2000

The year 2000 issue is the result of computer programs being written using two digits rather than four digits to represent the year. Thus, computer software may recognize a date using "00" as the year 1900 rather than the year 2000. This could result in system failures or miscalculations causing disruptions of operations, including a temporary inability to process certain data or engage in similar normal business activities.

PLAN AND STATUS. Our plan to resolve the year 2000 issue involves four phases: assessment, remediation, testing and implementation. We have completed an assessment of our systems. In 1997, we installed a computer network, upgraded our desktop computers and upgraded our information technology software to a common standard. Most of our information technology systems are identified by the manufacturer as year 2000 compliant because of this upgrade. Major vendors and suppliers have been contacted with regard to their year 2000 compliance and we will continue to monitor their compliance. Systems identified as not being year 2000 compliant will be brought into compliance by upgrading either the software or hardware. We have begun remediation and testing and expect our plan to be fully implemented by the end of 1999.

While we have queried our significant suppliers, vendors and other outside parties and will continue to monitor their year 2000 compliance status, we have no means of ensuring that suppliers, vendors and other outside parties will be year 2000 ready. The inability of suppliers, vendors and other outside parties, including the government, to complete their year 2000 compliance process in a timely fashion could materially impact us. We cannot determine the effect on us of non-compliance by suppliers, vendors and outside parties.

COSTS. Our costs incurred to date for year 2000 compliance have not been material and are not expected to be material when completed. We anticipate that we will be able to fund our costs from current funds available for

operations. If, however, the costs are higher than anticipated, this could have a material adverse effect on our business, results of operations and financial condition.

RISKS. While we believe we have an effective program in place to resolve the year 2000 issue in a timely manner, as noted above, we have not completed all necessary phases of the year 2000 program for compliance. In the event that we, or other parties we depend upon, are not fully compliant by the year's end, we may not be able to complete the testing of our compounds and advance our projects into clinical trials as required to support the filings with the FDA which are necessary to our business. In addition, disruptions in the economy generally resulting from year 2000 issues could also materially adversely effect us. We are unable to estimate any potential liability or potential lost revenue at this time. We may not discover year 2000 compliance issues that will have a material adverse effect on our business, results of operations and financial condition.

CONTINGENCY. We have contingency plans for certain critical applications and are working on such plans for others. These contingency plans involve, among other actions, performing the work manually, increasing inventories and adjusting staffing strategies. These contingency plans may not be adequate.

CERTAIN FACTORS THAT MAY AFFECT FUTURE RESULTS, FINANCIAL CONDITION AND THE MARKET PRICE OF SECURITIES

WE HAVE INCURRED SUBSTANTIAL LOSSES SINCE OUR INCEPTION IN 1986, EXPECT TO CONTINUE TO INCUR SUCH LOSSES, MAY NEVER BE PROFITABLE AND MAY NEED ADDITIONAL FINANCING

Since our inception in 1986, we have not been profitable. We expect to incur additional losses for the foreseeable future, and we expect our losses to increase as our research and development efforts progress. As of September 30, 1999, our accumulated deficit was approximately \$58.0 million. To become profitable, we must successfully develop drug candidates, enter into profitable agreements with other parties and our drug candidates must receive regulatory approval. These other parties must then successfully manufacture and market our drug candidates. It will be several years, if ever, before we receive royalties under our existing license agreements or any future license agreements. In addition, we never expect to generate revenue directly from product sales. If we do not generate revenue, or if our drug development expenses increase, we may need to raise additional funds through new or existing collaborations or through private or public equity or debt financings. If financing is not available on acceptable terms, or not available at all, we may not have enough capital to continue our current business strategy.

IF THE R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE AND ORTHO-MCNEIL WERE TO TERMINATE, SUBSTANTIALLY MODIFY OR FAIL TO FULFILL THEIR OBLIGATIONS UNDER THEIR LICENSE AGREEMENT WITH US, WE WOULD LOSE SUBSTANTIALLY ALL OF OUR REVENUE

If The R.W. Johnson Pharmaceutical Research Institute and Ortho-McNeil change their exclusive worldwide license agreement with us, including by terminating it or failing to fulfill their obligations, we would lose substantially all of our revenue. Approximately 72.8% of our revenues for the nine months ended September 30, 1999 and approximately 83.5% of our revenues for the year ended December 31, 1998 resulted from this license agreement. These revenues represent approximately 44.4% of our total revenues since our inception in 1986.

Under this agreement, The R.W. Johnson Pharmaceutical Research Institute and Ortho-McNeil have several rights that could delay or stop the development of our flu drug candidate, including sole discretion on all elements of research and development of BCX-1812, including timing and design of further clinical trials, sole control over the amount of resources devoted to the research and development of BCX-1812 and the right to terminate or cancel the agreement, which they may do at any time on four months notice.

IF OUR DEVELOPMENT COLLABORATIONS WITH OTHER PARTIES FAIL, THE DEVELOPMENT OF OUR DRUG CANDIDATES WILL BE DELAYED OR STOPPED

We rely completely upon other parties for many important stages of our drug development programs, including:

discovery of proteins that cause or enable biological reactions necessary for the progression of the disease or disorder, called enzyme targets;

- execution of preclinical studies and late-stage development for our compounds and drug candidates; and
- manufacturing, sales, marketing and distribution of our drug candidates.

Even more critical to our success is our ability to enter into successful collaborations for the late-stage clinical development, regulatory approval, manufacture, marketing, sales and distribution of our drug candidates. Our strategy is to rely upon other parties for all of these steps so that we can focus exclusively on the key areas of our expertise. This heavy reliance upon third parties for these critical functions presents several risks, including:

- these contracts may expire or the other parties to the contract may terminate them, as was the case with our Torii Pharmaceutical Co., Ltd. contract;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- our partners may not devote sufficient capital or resources towards our drug candidates; and
- our partners may not comply with applicable government regulatory requirements.

If we cannot license enzyme targets from academic institutions or from other biotechnology companies on acceptable terms, we will be unable to develop new drug candidates. If the contract research organizations that conduct our initial clinical trials breach their obligations to us, our inability to replace them would delay or possibly stop the development of our drug candidates. If we are unable to avoid all of these risks with our partners, we will not successfully complete late-stage development of our drug candidates.

IF THE CLINICAL TRIALS OF OUR DRUG CANDIDATES FAIL, WE WILL NOT BE ABLE TO MARKET OUR DRUG CANDIDATES

To receive the regulatory approvals necessary for the sale of our drug candidates, we or our licensees must demonstrate through preclinical studies and clinical trials that each drug candidate is safe and effective. If we or our licensees are unable to obtain regulatory approval of our drug candidates, we will not be able to market our drug candidates, which would result in a decrease in, or complete absence of, revenue.

The clinical trial process is complex, uncertain and expensive. We incur substantial expense for, and devote significant time to, clinical trials, yet cannot be certain that the trials will ever result in the commercial sale of a product. Positive results from preclinical studies and early clinical trials do not ensure positive results in clinical trials designed to permit application for regulatory approval, called pivotal clinical trials. We may suffer significant setbacks in pivotal clinical trials, even after earlier clinical trials show promising results. 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. 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 fail to demonstrate that our drug candidates are safe or effective. Even if we or our licensees successfully complete clinical trials for our product candidates, our licensees might not file the required regulatory submissions in a timely manner and may not receive regulatory approval for the drug candidate.

We licensed our drug candidate, BCX-1812, to Ortho-McNeil and to The R.W. Johnson Pharmaceutical Research Institute, which is in the process of conducting clinical trials. However, the FDA may not accept The R.W. Johnson Pharmaceutical Research Institute's clinical protocols, the Phase III clinical trials may not begin in 1999, or at all, and any Phase III clinical trials may not be successful. Even if The R.W. Johnson Pharmaceutical Research Institute completes the Phase III trials, we do not know when, if ever, it will receive FDA or foreign regulatory agency approvals for, or when Ortho-McNeil will begin marketing of, BCX-1812. If The R.W. Johnson Pharmaceutical Research Institute is unable to begin clinical trials as planned, complete the clinical trials or demonstrate the safety and efficacy of our compounds, we will not receive any revenues from BCX-1812. Even if the results of The R.W. Johnson Pharmaceutical Research Institute's trials are positive, products are not likely to be commercially available for several years, if at all. IF WE OR OUR LICENSEES DO NOT OBTAIN AND MAINTAIN GOVERNMENTAL APPROVALS FOR OUR PRODUCTS UNDER DEVELOPMENT, WE OR OUR PARTNERS WILL NOT BE ABLE TO SELL THESE POTENTIAL PRODUCTS

In the United States, we or our partners must obtain FDA approval for each drug that we intend to commercialize. The FDA approval process is typically lengthy and expensive, and approval is never certain. Products distributed abroad are also subject to foreign government regulation. The FDA or foreign regulatory agencies have not approved any of our drug candidates. Because of the risks and uncertainties in biopharmaceutical development, our drug candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. If the FDA delays regulatory approval of our drug candidates, our management's credibility, our company's value and our operating results may suffer. Even if the FDA or foreign regulatory agencies approve a drug candidate, the approval may limit the indicated uses for a drug candidate and/or may require post-marketing studies.

If we get approval to market our potential products, whether in the United States or internationally, we will continue to be subject to extensive regulatory requirements. These requirements are wide ranging and govern, among other things:

- adverse drug experience reporting regulations;
- product promotion;
- product manufacturing, including good manufacturing practice requirements; and
- product changes or modifications.

Our failure to comply with existing or future regulatory requirements, or our loss of, or changes to, previously obtained approvals, could have a material adverse effect on our business because we will not receive royalty revenues if we do not receive approval of our products for marketing.

In June 1995, we notified the FDA that we submitted incorrect efficacy data for our Phase II trials of BCX-34 applied to the skin for the treatment of cutaneous T-cell lymphoma and psoriasis. Cutaneous T-cell lymphoma is a skin cancer in which T-cells, which normally help fight disease in the body, duplicate rapidly and cause skin cancer. Psoriasis is a disease where the immune system attacks the body's own skin cells. The FDA inspected us and issued to us Lists of Inspectional Observations, on Form FDA 483, that cited our failure to follow good clinical practices. The FDA also issued a Form FDA 483 to a principal investigator at a clinical trial site, and the FDA notified us that they will not accept any work performed by this investigator without further validation. Because of these investigations by the FDA, our ongoing and future clinical studies or trials may receive increased scrutiny, which would delay the regulatory review process.

IF OUR DRUG CANDIDATES DO NOT ACHIEVE BROAD MARKET ACCEPTANCE, OUR BUSINESS MAY NEVER BECOME PROFITABLE

Our drug candidates, including our influenza neuraminidase inhibitors, may not gain the market acceptance required for us to be profitable even after they receive approval for sale by the FDA or foreign regulatory agencies. Influenza neuraminidase inhibitors are drugs designed to stop the spread of the flu virus in the body. The degree of market acceptance of any drug candidates that we or our partners develop will depend on a number of factors, including:

- cost-effectiveness of our drug candidates;
- their effectiveness relative to alternative treatment methods, such as the efficacy, cost and ease of use of our flu drug candidate over other products, including vaccines, existing drugs such as amantadine and rimantadine, Hoffmann-La Roche's and Glaxo Wellcome's influenza neuraminidase inhibitors and over-the-counter products;
- reimbursement policies of government and third-party payors; and
- marketing and distribution support for our drug candidates.

Physicians, patients, payors or the medical community in general may not accept or use our drug candidates even after the FDA or foreign regulatory agencies approve the drug candidates. If our drug candidates do not achieve significant market acceptance, we will not have enough revenues to become profitable.

IF COMPETITIVE PRODUCTS FROM OTHER COMPANIES ARE BETTER THAN OUR PRODUCT CANDIDATES, OUR FUTURE REVENUES MIGHT FAIL TO MEET OUR EXPECTATIONS AND THOSE OF FINANCIAL ANALYSTS

If our influenza neuraminidase inhibitor drug candidate, BCX-1812, receives FDA or foreign regulatory approval, it will have to compete with a number of products that are already on the market such as vaccines, the drugs amantadine and rimantadine and over-the-counter products, and with additional products that may beat BCX-1812 to the market. If approved, BCX-1812 will be, at best, the third neuraminidase inhibitor to the market, because the FDA and foreign regulatory agencies approved Glaxo-Wellcome plc's neuraminidase inhibitor product and because the FDA also approved Hoffman-La Roche's neuraminidase inhibitor. Both Glaxo-Wellcome and Hoffmann-La Roche are large multinational pharmaceutical companies that have significant financial, technical and human resources and could therefore establish brand recognition and loyalty with consumers before BCX-1812 is on the market. In addition, a vaccine is currently in preclinical development that may immunize people against all strains of the flu virus, rendering flu drug products like ours obsolete. Products marketed by our competitors may prove to be more effective than our own, and our products, if any, may not offer an economically feasible or preferable alternative to existing therapies.

IF WE FAIL TO ADEQUATELY PROTECT OR ENFORCE OUR INTELLECTUAL PROPERTY RIGHTS OR SECURE RIGHTS TO PATENTS OF OTHERS, THE VALUE OF OUR INTELLECTUAL PROPERTY RIGHTS WOULD DIMINISH

Our success will depend in part on our ability and the abilities of our licensors to obtain patent protection for our products, methods, processes and other technologies to preserve our trade secrets, and to operate without infringing the proprietary rights of other parties. To date, the U.S. Patent and Trademark Office has issued to us nine U.S. patents for our various inventions. We have filed additional patent applications and provisional patent applications with the U.S. Patent and Trademark Office. We have filed a number of corresponding foreign patent applications and intend to file additional foreign and U.S. patent applications, as appropriate. We cannot predict:

- the degree and range of protection any patents will afford against competitors with similar products;
- if and when patents will issue;
- whether or not others will obtain patents claiming aspects similar to those covered by our patent applications; or
- whether we must initiate or defend litigation or administrative proceedings that we may lose and that may be costly even if we win.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to:

- obtain licenses or redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings which may be costly whether we win or lose.

Our success is also dependent upon the skills, knowledge and experience, none of which is patentable, of our scientific and technical personnel. To help protect our rights, we require all employees, consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the disclosure of confidential information to anyone outside of our company and require disclosure and assignment to us of their ideas, developments, discoveries and inventions. These agreements may not provide or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information, and if any of our proprietary information is disclosed, our business will suffer because our revenues depend upon our ability to license our technology and any such events would significantly impair the value of such a license.

OUR FAILURE TO RETAIN OUR EXISTING KEY PERSONNEL OR OUR FAILURE TO ATTRACT AND RETAIN ADDITIONAL KEY PERSONNEL WILL DELAY OR STOP THE DEVELOPMENT OF OUR DRUG CANDIDATES AND THE EXPANSION OF OUR BUSINESS

We are highly dependent upon our senior management and scientific team, the loss of whose services might impede the achievement of our development and commercial objectives. Although we maintain, and are the beneficiary of, a \$2.0 million key-man insurance policy on the life of Charles E. Bugg, Ph.D., Chairman of the Board of Directors and Chief Executive Officer, we do not believe the proceeds would be adequate to compensate for his loss. We are actively seeking additional members for our senior management team. Competition for key personnel with the experience that we require is intense and we expect it to increase. Our inability to attract and retain the required number of skilled and experienced management, operational and scientific personnel, will harm our business because we rely upon these personnel for many critical functions of our business.

In addition, we rely on members of our scientific advisory board and consultants to assist us in formulating our research and development strategy. All of the members of the scientific advisory board and all of our consultants have jobs and each such member or consultant may have commitments to other entities that may limit their availability to us.

IF USERS OF OUR DRUG CANDIDATES ARE NOT REIMBURSED FOR USE OF OUR DRUG CANDIDATES, FUTURE SALES OF OUR DRUG CANDIDATES WILL DECLINE

Most individuals who buy commercial drug products rely on reimbursement from their insurance provider or the government to cover the cost of the drug product. Many factors may determine whether insurance companies or other third-party payors will reimburse patients for purchasing our flu drug, BCX-1812, including:

- BCX-1812 only alleviates symptoms of, and does not cure, the flu;
- in most cases, the flu is not a life-threatening disease; and
- BCX-1812 may be more expensive than a vaccine or other drug products for treatment of the flu, including over-the-counter products.

IF WE FACE CLINICAL TRIAL LIABILITY CLAIMS RELATED TO THE USE OR MISUSE OF OUR COMPOUNDS EITHER IN CLINICAL TRIALS OR AFTER COMMERCIAL INTRODUCTION, THESE CLAIMS WILL DIVERT OUR MANAGEMENT'S TIME AND WE WILL INCUR LITIGATION COSTS

We face an inherent business risk of liability claims in the event that the use or misuse of our compounds results in personal injury or death. We may experience clinical trial liability claims in the future. We currently maintain clinical trial liability insurance coverage in the amount of \$1.0 million per occurrence and \$2.0 million in the aggregate, with an additional \$5.0 million potentially available under our umbrella policy. The insurance policy may not be sufficient to cover claims that may be made against us. Clinical trial liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, if at all. In addition, after commercial introduction of our products we may experience losses due to product liability claims. Although clinical trial claims are costly, product liability claims are even more complex, expensive and time-consuming and are more difficult to disprove. In clinical trial situations, we or our licensees must warn each participant of the adverse effects of the drug and each participant must sign waivers and acknowledgements. After regulatory authorities approve a drug for marketing, people who take the drug might not be aware of its potential adverse effects, and we would be liable for any harm caused by the drug. Any claims against us, regardless of their merit, could materially and adversely affect our financial condition, because litigation related to these claims would strain our financial resources in addition to consuming the time and attention of our management.

IF, BECAUSE OF OUR USE OF HAZARDOUS MATERIALS, WE VIOLATE ANY ENVIRONMENTAL CONTROLS OR REGULATIONS THAT APPLY TO SUCH MATERIALS, WE MAY INCUR SUBSTANTIAL COSTS AND EXPENSES IN OUR REMEDIATION EFFORTS

Our research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and some waste products. Accidental contamination or injury from these materials could occur. In the event of an accident, we could be liable for any damages that result and any liabilities could exceed our resources. Compliance with environmental laws and regulations could require us to incur substantial unexpected costs which would materially and adversely affect our results of operations.

BECAUSE STOCK OWNERSHIP IS CONCENTRATED, YOU AND OTHER INVESTORS WILL HAVE MINIMAL INFLUENCE ON STOCKHOLDER DECISIONS

Prior to this offering, our directors, executive officers and some principal stockholders and their affiliates, including Johnson & Johnson Development Corporation, beneficially own approximately 40.7% of our outstanding common stock. As a result, these holders, if acting together, are able to significantly influence matters requiring stockholder approval, including the election of directors. This concentration of ownership may delay, defer or prevent a change in our control.

WE HAVE ANTI-TAKEOVER PROVISIONS IN OUR CORPORATE CHARTER DOCUMENTS THAT MAY RESULT IN OUTCOMES WITH WHICH YOU DO NOT AGREE

Our board of directors has the authority to issue up to 5,000,000 shares of undesignated preferred stock and to determine the rights, preferences, privileges and restrictions of those shares without further vote or action by our stockholders. The rights of the holders of any preferred stock that may be issued in the future may adversely affect the rights of the holders of common stock. The issuance of preferred stock could make it more difficult for third parties to acquire a majority of our outstanding voting stock.

In addition, our certificate of incorporation provides for staggered terms for the members of the board of directors and super majority approval of the removal of any member of the board of directors and prevents our stockholders from acting by written consent. Our certificate also requires supermajority approval of any amendment of these provisions. These provisions and other provisions of our by-laws and of Delaware law applicable to us could delay or make more difficult a merger, tender offer or proxy contest involving us.

OUR STOCK PRICE IS LIKELY TO BE HIGHLY VOLATILE AND THE VALUE OF YOUR INVESTMENT COULD DECLINE SIGNIFICANTLY

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. Moreover, our stock has fluctuated frequently, and these fluctuations are often not related to our financial results. The 52-week range of the market price of our stock has ranged from \$5.50 to \$35.31 per share, which is a significantly greater change than that experienced by many other companies. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- developments or disputes concerning patents or proprietary rights;
- our licensees achieving or failing to achieve development milestones;
- publicity regarding actual or potential medical results relating to products under development by us or our competitors;
- regulatory developments in both the United States and foreign countries;
- public concern as to the safety of pharmaceutical products;
- actual or anticipated fluctuations in our operating results;

- changes in financial estimates or recommendations by securities analysts;
- economic and other external factors or other disasters or crises; and
- period-to-period fluctuations in our financial results.

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ITEM 1. LEGAL PROCEEDINGS:

None.

ITEM 2. CHANGES IN SECURITIES:

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES:

None

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS:

None

ITEM 5. OTHER INFORMATION:

On September 23, 1999, the Company filed a Form S-3 for 2,000,000 shares of common stock.

- ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K:
- a. Exhibits:

NUMBER

DESCRIPTION

3.1	Composite Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 10-Q for the second quarter ending June 30, 1995 dated August 11, 1995.
3.2	Bylaws of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 10-Q for the second quarter ending June 30, 1995 dated August 11, 1995.
4.1	See Exhibits 3.1 and 3.2 for provisions of the Composite Certificate of Incorporation and Bylaws of the Registrant defining rights of holders of Common Stock of the Registrant.
10.1	1991 Stock Option Plan, as amended and restated. Incorporated by reference to Exhibit 99.1 to the Company's Form S-8 Registration Statement (Registration No. 333-30751).
10.2	Amendment No. 1 to the 1991 Stock Option Plan, as amended and restated. Incorporated by reference to Exhibit 10.2 to the Company's Form 10-Q for the second quarter ending June 30, 1999 dated August 12, 1999.
10.3	Form of Notice of Stock Option Grant and Stock Option Agreement. Incorporated by reference to Exhibit 99.2 and 99.3 to the Company's Form S-8 Registration Statement (Registration No. 33-95062).
10.4	Warehouse Lease dated January 17, 1992 between Principal Mutual Life Insurance Company and the Registrant. Incorporated by reference to Exhibit 10.21 to the Company's Form S-1 Registration Statement (Registration No. 33-73868).
10.5	First Amendment to Lease Agreement between Registrant and Principal Mutual Life Insurance Company, Inc. for office/warehouse space. Incorporated by reference to Exhibit 10.21 to the Company's Form 10-K for the year ending December 31, 1994 dated March 28, 1995.
10.6	Second Amendment to Lease Agreement between Registrant and Principal Mutual Life Insurance Company, Inc. for office/warehouse space. Incorporated by reference to Exhibit 10.24 to the Company's Form 10-Q for the first quarter ending March 31, 1997 dated May 12, 1997.
10.7	Third Amendment to Lease Agreement between Registrant and Principal Mutual Life Insurance Company, Inc. for office/warehouse space. Incorporated by reference to Exhibit 10.24 to the Company's Form 10-Q for the first quarter ending March 31, 1998 dated April 29, 1998.

- 10.8 Fourth Amendment to Lease Agreement between Registrant and Principal Mutual Life Insurance Company, Inc. for office/warehouse space. Incorporated by reference to Exhibit 10.22 to the Company's Form 10-Q for the second quarter ending June 30, 1998 dated April 29, 1998.
- 10.9 Fifth Amendment to Lease Agreement between Registrant and Principal Mutual Life Insurance Company, Inc. for office/warehouse space. Incorporated by reference to Exhibit 10.9 to the Company's Form 10-Q for the second quarter ending June 30, 1999 dated August 12, 1999.
- 10.10 Employment Agreement dated December 17, 1996 between the Registrant and Charles E. Bugg, Ph.D. Incorporated by reference to Exhibit 10.11 to the Company's Form 10-K for the year ended December 31, 1996 dated March 28, 1997.
 10.11 Employment Agreement dated December 18, 1996 between the
- 10.11 Employment Agreement dated December 18, 1996 between the Registrant and J. Claude Bennett. Incorporated by reference to Exhibit 10.12 to the Company's Form 10-K for the year ended December 31, 1996 dated March 28, 1997.
- 10.12# License Agreement dated April 15, 1993 between Ciba-Geigy Corporation (now merged into Novartis) and the Registrant. Incorporated by reference to Exhibit 10.40 to the Company's Form S-1 Registration Statement (Registration No. 33-73868).
- 10.13 Employee Stock Purchase Plan. Incorporated by reference to Exhibit 99.4 to the Company's

Form S-8 Registration Statement (Registration No. 33-95062). 10.14 Form of Stock Purchase Agreement dated May 1995 between

- Registrant and various parties to purchase 1,570,000 shares of common stock. Incorporated by reference to Exhibit 10.22 to the Company's Form 10-Q for the second quarter ending June 30, 1995 dated August 11, 1995.
- 10.15 Form of Registration Rights Agreement dated May 1995 between Registrant and various parties. Incorporated by reference to Exhibit 10.23 to the Company's Form 10-Q for the second quarter ending June 30, 1995 dated August 11, 1995.
- 10.16 Form of Stock Purchase Agreement dated March 22, 1996 among Registrant and certain investors to purchase 1,000,000 shares of common stock. Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K dated March 22, 1996.
- 10.17 Form of Registration Rights Agreement dated March 22, 1996 among Registrant and certain investors. Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K dated March 22, 1996.
- 10.18# License Agreement, dated May 31, 1996, between Registrant and Torii Pharmaceutical Co., Ltd. ("Torii"). Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K/A dated May 3, 1996 and filed August 2, 1996.
- 10.19# Stock Purchase Agreement, dated May 31, 1996, between Registrant and Torii. Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K/A dated May 3, 1996 and filed August 2, 1996.
- 10.20# License Agreement dated as of September 14, 1998 between Registrant and The R.W. Johnson Pharmaceutical Research Institute and Ortho-McNeil Pharmaceutical, Inc. Incorporated by reference to Exhibit 10.23 to the Company's Form 10-Q for the third quarter ending September 30, 1998 dated November 10, 1998.
- 10.21 Stock Purchase Agreement dated as of September 14, 1998 between Registrant and Johnson & Johnson Development Corporation. Incorporated by reference to Exhibit 10.24 to the Company's Form 10-Q for the third quarter ending September 30, 1998 dated November 10, 1998.
- 10.22 Stockholder's Agreement dated as of September 14, 1998 between Registrant and Johnson & Johnson Development Corporation. Incorporated by reference to Exhibit 10.25 to the Company's Form 10-Q for the third quarter ending September 30, 1998 dated November 10, 1998.
- 27.1 Financial Data Schedule.

Confidential treatment granted.

b. Reports on Form 8-K:

None.

SIGNATURES

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

BIOCRYST PHARMACEUTICALS, INC.

Date: October 29, 1999	/s/ Charles E. Bugg
	Charles E. Bugg
	Chairman and Chief Executive Officer

Date: October 29, 1999 /s/ Ronald E. Gray Ronald E. Gray Chief Financial Officer and Chief Accounting Officer

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This schedule contains summary financial information extracted from the BioCryst Pharmaceuticals, Inc. Financial Statements, and is qualified in its entirety by reference to such financial statements.

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