

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, 1997

OR

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

For the transition period from _____ to _____ .

Commission File Number 000-23186

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

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

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
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Indicate the number of shares outstanding of each of the issuer's classes of
common stock, as of the latest practicable date: 13,804,588 shares of the
Company's Common Stock, \$.01 par value, were outstanding as of October 31,
1997.

BIOCRIST PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOCRYST PHARMACEUTICALS, INC.
 CONDENSED BALANCE SHEETS
 September 30, 1997 and December 31, 1996
 (In thousands, except per share)

ASSETS	1997 (Unaudited)	1996 (Note 1)
	-----	-----
Cash and cash equivalents.....	\$ 5,582	\$ 3,636
Securities held-to-maturity.....	19,286	24,229
Prepaid expenses and other current assets.....	271	233
	-----	-----
Total current assets.....	25,139	28,098
Securities held-to-maturity.....	2,786	7,920
Patents.....	69	
Furniture and equipment, net.....	1,658	1,131
	-----	-----
Total assets.....	\$ 29,652	\$ 37,149
	-----	-----
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable.....	\$ 573	\$ 615
Accrued expenses.....	251	241
Accrued taxes, other than income.....	199	210
Accrued vacation.....	107	83
Current maturities of long-term debt.....		19
Current maturities of capital lease obligations.....	83	219
	-----	-----
Total current liabilities.....	1,213	1,387
Capital lease obligations.....	36	59
Deferred license fee.....	300	300
	-----	-----
Total liabilities.....	1,549	1,746
	-----	-----
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-- 13,805 in 1997 and 13,697 in 1996.....	138	137
Additional paid-in capital.....	73,473	73,032
Accumulated deficit.....	(45,508)	(37,766)
	-----	-----
Total stockholders' equity.....	28,103	35,403
	-----	-----
Total liabilities and stockholders' equity.....	\$ 29,652	\$ 37,149
	-----	-----

See accompanying notes to condensed financial statements.

BIOCRYST PHARMACEUTICALS, INC.
 CONDENSED STATEMENTS OF OPERATIONS
 Periods Ended September 30, 1997 and 1996
 (In thousands, except per share)

	Three Months		Nine Months	
	1997	1996	1997	1996
Collaborative and other research and development.....	\$ 387	\$ 37	\$ 1,000	\$ 1,558
Interest and other.....	387	215	1,266	603
Revenues.....	387	252	2,266	2,161
Research and development.....	2,399	2,221	7,830	5,635
General and administrative.....	491	520	2,138	2,083
Interest.....	10	23	40	79
Expenses.....	2,900	2,764	10,008	7,797
Net loss	\$(2,513)	\$(2,512)	\$(7,742)	\$(5,636)
Net loss per share (Note 2)	\$(.18)	\$(.23)	\$(.56)	\$(.54)
Weighted average shares outstanding (Note 2).....	13,805	10,846	13,770	10,348

See accompanying notes to condensed financial statements.

BIOCRYST PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
Nine Months Ended September 30, 1997 and 1996
(In thousands)

	1997	1996
Operating activities		
Net loss	\$(7,742)	\$(5,636)
Depreciation and amortization.....	483	393
Non-monetary compensation.....	50	
Changes in operating assets and liabilities, net.....	(125)	20
	(7,334)	(5,223)
Investing activities		
Purchases of furniture and equipment.....	(1,010)	(199)
Purchase of marketable securities.....	(5,346)	(10,579)
Maturities of marketable securities.....	15,423	7,245
	9,067	(3,533)
Financing activities		
Principal payments on debt and capital lease obligations.....	(218)	(202)
Proceeds of sale/leaseback.....	40	
Proceeds from sale of common stock, net of issuance cost.....	391	9,305
	213	9,103
Increase in cash and cash equivalents.....	1,946	347
Cash and cash equivalents at beginning of period.....	3,636	6,135
Cash and cash equivalents at end of period.....	\$ 5,582	\$ 6,482

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, 1997 and the condensed statements of operations and cash flows for the nine months ended September 30, 1997 and 1996 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, 1997 and the results of operations and cash flows for the nine months ended September 30, 1997 and 1996. These condensed financial statements should be read in conjunction with the financial statements for the year ended December 31, 1996 and the notes thereto included in the Company's 1996 Annual Report. Interim operating results are not necessarily indicative of operating results for the full year. The balance sheet as of December 31, 1996 has been prepared from the audited financial statements included in the previously mentioned Annual Report.

Note 2. Net Loss Per Share

Net loss per share is computed using the weighted average number of shares of common stock outstanding. Common equivalent shares (from unexercised stock options and warrants) have been excluded from the computation as their effect is anti-dilutive. Because of this exclusion in computing net loss per share, the adoption of Statement of Financial Accounting Standards No. 128, Earnings per Share, is not expected to have a material impact on the Company's reporting in 1998.

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 and Quarterly Reports on Form 10-Q.

Overview

Since its inception in 1986, the Company has been engaged in research and development activities (including drug discovery, manufacturing compounds, conducting preclinical studies and clinical trials) and organizational efforts (including recruiting its scientific and management personnel), establishing laboratory facilities, engaging its Scientific Advisory Board and raising capital. The Company has not received any revenue from the sale of pharmaceutical products and does not expect to receive such revenues to a significant extent for at least several years, if at all. The Company has incurred operating losses since its inception. The Company expects to incur significant additional operating losses over the next several years and expects such losses to increase as the Company's research and development and clinical trial efforts expand.

Results of Operations (first nine months of 1997 compared to the first nine months of 1996)

Revenues increased 4.9% to \$2,266,000 in the first nine months of 1997 from \$2,161,000 in the first nine months of 1996. The increase in interest income, primarily due to investing the proceeds from the Company's public offering in September 1996, was partially offset by a decrease in collaborative and other research and development, primarily due to the first milestone payment in 1997 being less than the initial collaboration payment in 1996 from Torii Pharmaceutical Co., Ltd. ("Torii").

Research and development expenses increased 39.0% to \$7,830,000 in the first nine months of 1997 from \$5,635,000 in the first nine months of 1996. The increase is primarily attributable to an increase in costs associated

with conducting additional clinical trials (in 1997 the Company completed two Phase III trials which are larger and more expensive than previous trials the Company has conducted), an increase in personnel costs (generally due to adding additional personnel) and an increase in consulting fees (consultants were used to assist with the Phase III trial results). Preliminary results of the two Phase III trials were announced in September. Those results did not show statistical efficacy and the Company has ceased pursuing the topical cream formulation of BCX-34. The Company is continuing its clinical trials for an oral and an ointment formulation of BCX-34.

General and administrative expenses increased 2.6% to \$2,138,000 in the first nine months of 1997 from \$2,083,000 in the first nine months of 1996. The increase was in several categories, primarily increased personnel costs and the fact that 1996 expenses were reduced by the reversal of a liability recorded in 1995 for use taxes assessed that the Company successfully contested in 1996, and was partially offset by decreased fees and taxes on the Torii milestone in 1997 versus the fees and taxes on the Torii license in 1996.

Interest expense decreased 49.4% to \$40,000 in the first nine months of 1997 from \$79,000 in the first nine months of 1996. The decrease is due to a decline in capitalized lease obligations, along with long-term debt, resulting in lesser interest expense. The Company obtained most of its leases in connection with the move to its new facilities in April 1992.

Liquidity and Capital Resources

Cash expenditures have exceeded revenues since the Company's inception. Operations have principally been funded through public offerings of common stock, private placements of equity and debt securities, equipment lease financing, facility leases, collaborative and other research and development agreements (including a license and options for licenses), research grants and interest income. In addition, the Company has attempted to contain costs and reduce cash flow requirements by renting scientific equipment or facilities, contracting with third parties to conduct certain research and development and using consultants. The Company expects to incur additional expenses, resulting in significant losses, as it continues and expands its research and development activities and undertakes additional preclinical studies and clinical trials of compounds which have been or may be discovered. The Company also expects to incur substantial administrative, manufacturing and commercialization expenditures in the future as it seeks Food and Drug Administration (the "FDA") approval for its compounds and establishes its manufacturing capability under Good Manufacturing Practices ("GMP"), and substantial expenses related to the filing, prosecution, maintenance, defense and enforcement of patent and other intellectual property claims.

At September 30, 1997, the Company's cash, cash equivalents and securities held-to-maturity were \$27.7 million, a decrease of \$8.1 million from December 31, 1996 principally due to the net loss for the nine months ended September 30, 1997.

The Company has financed its equipment purchases primarily with lease lines of credit. The Company currently has a \$500,000 line of credit with its bank to finance capital equipment. In January 1992, the Company entered into an operating lease for its current facilities which, based on an extension signed in March 1997, expires on July 31, 2000, with an option to lease for an additional three years at current market rates. The March 1997 extension also added 5,640 square feet of finished office space. The operating lease requires the Company to pay monthly rent (\$14,562 and escalating annually by the change in the consumer price index, but no more than 6% nor less than 3%), and a pro rata share of operating expenses and real estate taxes in excess of base year amounts.

At December 31, 1996, the Company had long-term capital lease and operating lease obligations which provide for aggregate minimum payments of \$434,561 in 1997, \$205,233 in 1998 and \$148,395 in 1999. The Company is required to expend \$6.0 million, of which approximately \$4.5 million was expended through September 30, 1997, over a period coinciding with funding by the Company to The University of Alabama at Birmingham ("UAB") on its influenza neuraminidase project in order to maintain a worldwide license from UAB.

The Company entered into an exclusive license agreement with Torii under which Torii paid the Company \$1.5 million in license fees and made a \$1.5 million equity investment in the Company in 1996. A milestone payment of \$1.0 million was made in April 1997. While the license agreement provides for potential milestone payments of up

to \$18.0 million and royalties on future sales of licensed products in Japan, there can be no assurance that Torii will continue to develop the product in Japan or that if it does so that it will result in meeting the milestones or achieving future sales of licensed products in Japan.

The Company plans to finance its needs principally from its existing capital resources and interest thereon, from payments under collaborative and licensing agreements with corporate partners, through research grants, and to the extent available, through lease or loan financing and future public or private financings. The Company believes that its available funds will be sufficient to fund the Company's operations at least through 1998. However, this is a forward-looking statement, and no assurance can be given that there will be no change that would consume available resources significantly before such time. The Company's long-term capital requirements and the adequacy of its available funds will depend upon many factors, including results of research and development, results of product testing, relationships with strategic partners, changes in the focus and direction of the Company's research and development programs, competitive and technological advances and the FDA regulatory process. 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 the Company. Insufficient funds may require the Company to delay, scale-back or eliminate certain of its research and development programs or to license third parties to commercialize products or technologies that the Company would otherwise undertake itself.

Certain Factors That May Affect Future Results, Financial Condition and the Market Price of Securities

Early Stage of Development; Uncertainty of Product Development; Technological Uncertainty

BioCryst is at an early stage of development. All of the Company's compounds are in research and development, and no revenues have been generated from sales of its compounds. It will be a number of years, if ever, before the Company will recognize significant revenues from product sales or royalties. To date, most of the Company's resources have been dedicated to the research and development of pharmaceutical compounds based upon its purine nucleoside phosphorylase ("PNP") program for the treatment of T-cell proliferative diseases and disorders and for the development of inhibitors of influenza neuraminidase and enzymes and proteins involved in the complement cascade. The Company is conducting preclinical and clinical studies with its lead drug, BCX-34, and results from these studies may not support future human clinical testing or further development of the compound. Recently completed Phase III trials with a cream formulation of BCX-34 for treatment of Cutaneous T-Cell Lymphoma ("CTCL") and psoriasis did not show statistical efficacy. Accordingly, the Company has discontinued further development of the cream formulation of BCX-34, but is continuing its oral trials for BCX-34 and a Phase I trial for a topical ointment treatment for psoriasis. T-cell proliferative diseases, as well as the other disease indications the Company is studying, are highly complex and their causes are not fully known. The Company's compounds under development will require significant additional, time-consuming and costly research and development, preclinical testing and extensive clinical testing prior to submission of any regulatory application for commercial use. Product development of new pharmaceuticals is highly uncertain, and unanticipated developments, clinical or regulatory delays, unexpected adverse side effects or inadequate therapeutic efficacy could slow or prevent product development efforts and have a material adverse effect on the Company. BioCryst's lead drug, BCX-34, reversibly inhibits T-cell activity, an essential component of the human immune system. In addition to any direct toxicities or side effects the drug may cause, BCX-34, while inhibiting T-cells, may compromise the immune system's ability to fight infection. Although the Company will monitor immunosuppression during drug dosing, there can be no assurance that the drug will not cause irreversible immunosuppression. There can be no assurance that the Company's research or product development efforts as to any particular compound will be successfully completed, that the compounds currently under development will be safe or efficacious, that required regulatory approvals can be obtained, that products can be manufactured at acceptable cost and with appropriate quality or that any approved products can be successfully marketed or will be accepted by patients, health care providers and third-party payors. Few drugs discovered by use of structure-based drug design have been successfully developed, approved by the FDA or marketed. Within the pharmaceutical industry, treatment of the disease indications being pursued by the Company, especially T-cell proliferative diseases such as CTCL and psoriasis, have proven difficult. There can be no assurance that drugs resulting from the approach of structure-based drug design employed by the Company will overcome the difficulties of drug discovery and development or result in commercially successful products.

Uncertainty Associated with Preclinical and Clinical Testing

Before obtaining regulatory approvals for the commercial sale of any of its products, BioCryst must undertake extensive preclinical and clinical testing to demonstrate their safety and efficacy in humans. The Company has limited experience in conducting clinical trials. To date, the Company has conducted initial preclinical testing of certain of its compounds and is testing oral and topical ointment formulations of BCX-34 in various clinical trials. The results of initial preclinical and clinical testing of compounds under development by the Company are neither necessarily predictive of results that will be obtained from subsequent or more extensive preclinical and clinical testing nor necessarily acceptable to the FDA to support applications for marketing permits. However, the Company recently completed two Phase III trials of a topical cream formulation of BCX-34 which did not show statistical efficacy. Even if the results of subsequent clinical tests are positive, products, if any, resulting from the Company's research and development programs are not likely to be commercially available for several years. Additionally, the Company has made and may in the future make changes to the formulation of its drugs and/or to the processes for manufacturing its drugs. Any such future changes in formulation or manufacturing processes could result in delays in conducting further preclinical and clinical testing, in unexpected adverse events in further preclinical and clinical testing, and/or in additional development expenses. Furthermore, there can be no assurance that clinical studies of products under development will be acceptable to the FDA or demonstrate the safety and efficacy of such products at all or to the extent necessary to obtain regulatory approvals of such products. Companies in the industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to comply with data integrity (Good Clinical Practice ("GCP")) requirements or to adequately demonstrate the safety and efficacy of a therapeutic product under development could delay or prevent regulatory approval of the product, and would have a material adverse effect on the Company.

The rate of completion of clinical trials is dependent upon, among other factors, the rate of enrollment of patients. Patient accrual is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study and the existence of competitive clinical trials. Delays in planned patient enrollment in the Company's current trials or future clinical trials may result in increased costs and/or program delays which could have a material adverse effect on the Company.

Government Regulation; No Assurance of Product Approval

The research, testing, manufacture, labeling, distribution, advertising, marketing and sale of drug products are subject to extensive regulation by governmental authorities in the United States and other countries. Prior to marketing, compounds developed by the Company must undergo an extensive regulatory approval process required by the FDA and by comparable agencies in other countries. This process, which includes preclinical studies and clinical trials of each compound to establish its safety and effectiveness and confirmation by the FDA that good laboratory, clinical and manufacturing practices were maintained during testing and manufacturing, can take many years, requires the expenditure of substantial resources and gives larger companies with greater financial resources a competitive advantage over the Company. To date, no compound or drug candidate being evaluated by the Company has been submitted for approval to the FDA or any other regulatory authority for marketing, and there can be no assurance that any such product or compound will ever be approved for marketing or that the Company will be able to obtain the labeling claims desired for its products or compounds. The Company is and will continue to be dependent upon the laboratories and medical institutions conducting its preclinical studies and clinical trials to maintain both good laboratory and good clinical practices and, except for the formulating and packaging of small quantities of its drug formulations which the Company is currently undertaking, upon the manufacturers of its compounds to maintain compliance with current GMP requirements. Data obtained from preclinical studies and clinical trials are subject to varying interpretations which could delay, limit or prevent FDA regulatory approval. Delays or rejections may be encountered based upon changes in FDA policy for drug approval during the period of development and FDA regulatory review. Similar delays also may be encountered in foreign countries. Moreover, even if approval is granted, such approval may entail commercially unacceptable limitations on the labeling claims for which a compound may be marketed. Even if such regulatory approval is obtained, a marketed drug or compound and its manufacturer are subject to continual review and inspection, and later discovery of previously unknown problems with the product or manufacturer may result in restrictions or sanctions on such product or manufacturer, including withdrawal of the product from the market, and other enforcement actions.

In June 1995 the Company notified the FDA that it had submitted incorrect efficacy data to the FDA pertaining to its Phase II dose-ranging studies of BCX-34 for CTCL and psoriasis. The FDA inspected the Company in November 1995 in relation to a study involving the topical application of BCX-34 concluded in early 1995, and in June 1996 the FDA inspected the Company and one of its clinical sites in relation to a Phase II dose-ranging study of BCX-34 for CTCL and a Phase II dose ranging study for psoriasis, both of which were concluded in early 1995. After each inspection, the FDA issued to the Company a Form FDA 483 setting forth certain deficient GCP procedures followed by the Company, some of which resulted in submission to the FDA of efficacy data which reported false statistical significance. The FDA also issued a Form FDA 483 to the principal investigator at one of the Company's clinical sites citing numerous significant deficiencies in the conduct of the Phase II dose-ranging studies of BCX-34 for CTCL and psoriasis. These deficiencies included improper delegations of authority by the principal investigator, failures to follow the protocols, institutional review board deviations, and discrepancies or deficiencies in documentation and reporting. As a consequence of the FDA inspections and such resulting Form FDA 483s, the Company's ongoing clinical studies are likely to receive increased scrutiny since the same clinical site which received the Form FDA 483 is involved in the Company's oral trials; this may delay the regulatory review process or require the Company to increase the number of patients at other sites to obtain approval (which can not be assured on a timely basis or at all). The Company has adjusted certain of its procedures, but there can be no assurance that the FDA will find such adjustments to be in compliance with FDA requirements or that, even if it does find such adjustments to be in compliance, it will not seek to impose administrative, civil or other sanctions in connection with the earlier studies. Administrative sanctions could include refusing to accept earlier studies and requiring the Company to repeat one or more clinical studies, which would be the only studies the FDA would accept for purposes of substantive scientific review of any New Drug Application ("NDA") by the agency.

Such sanctions or other government regulation may delay or prevent the marketing of products being developed by the Company, impose costly procedures upon the Company's activities and confer a competitive advantage to larger companies or companies that are more experienced in regulatory affairs and that compete with the Company. There can be no assurance that FDA or other regulatory approval for any products developed by the Company will be granted on a timely basis, or at all. Delay in obtaining or failure to obtain such regulatory approvals will materially adversely affect the marketing of any products which may be developed by the Company, as well as the Company's results of operations.

History of Operating Losses; Accumulated Deficit; Uncertainty of Future Profitability

BioCryst, to date, has generated no revenue from product sales and has incurred losses since its inception. As of September 30, 1997, the Company's accumulated deficit was approximately \$45.5 million. Losses have resulted principally from costs incurred in research activities aimed at discovering, designing and developing the Company's pharmaceutical product candidates and from general and administrative costs. These costs have exceeded the Company's revenues, which to date have been generated primarily from collaborative arrangements, licenses, research grants and from interest income. The Company expects to incur significant additional operating losses over the next several years and expects such losses to increase as the Company's research and development and clinical trial efforts expand. The Company's ability to achieve profitability depends upon its ability to develop drugs and to obtain regulatory approval for its products, to enter into agreements for product development, manufacturing and commercialization, and to develop the capacity to manufacture, market and sell its products. There can be no assurance that the Company will ever achieve significant revenues or profitable operations.

Additional Financing Requirements; Uncertainty of Additional Funding

The Company has incurred negative cash flows from operations in each year since its inception. The Company expects that the funding requirements for its operating activities will increase substantially in the future due to expanded research and development activities (including preclinical studies and clinical trials), the development of manufacturing capabilities and the development of marketing and distribution capabilities. The Company anticipates that its capital resources are adequate to satisfy its capital requirements at least through 1998. However, this is a forward-looking statement, and no assurance can be given that there will be no change that would consume available resources significantly before such time. The Company's future capital requirements will depend on many factors, including continued scientific progress in its research, drug discovery and development programs, the

magnitude of these programs, progress with preclinical studies and clinical trials, prosecuting and enforcing patent claims, competing technological and market developments, changes in existing collaborative research or development relationships, the ability of the Company to establish additional collaborative relationships, and the cost of manufacturing scale-up and effective marketing activities and arrangements. The Company anticipates, based on its current business plan, that it will be necessary to raise additional funds in 1999 or earlier. Additional funds, if any, may possibly be raised through financing arrangements or collaborative relationships and/or 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, which could have the effect of diluting or adversely affecting the holdings or rights of existing stockholders of the Company. In addition, collaborative arrangements may require the Company to transfer certain material rights to such corporate partners. If adequate funds are not available, the Company will be required to delay, scale back or eliminate one or more of its research, drug discovery or development programs or attempt to obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish some or all of its rights to certain of its intellectual property, product candidates or products. No assurance can be given that additional financing will be available to the Company on acceptable terms, if at all.

Competition

The Company is engaged in the pharmaceutical industry, which is characterized by extensive research efforts, rapid technological progress and intense competition. There are many public and private companies, including well-known pharmaceutical companies, chemical companies, specialized biotechnology companies and academic institutions, engaged in developing synthetic pharmaceuticals and biotechnological products for human therapeutic applications that represent significant competition to the Company. Existing products and therapies and improvements thereto will compete directly with products the Company is seeking to develop and market, and the Company is aware that other companies or institutions are pursuing development of new drugs and technologies directly targeted at applications for which the Company is developing its drug compounds. Many of the Company's competitors have substantially greater financial and technical resources and production and marketing capabilities and experience than does the Company. The Company has granted Novartis Pharmaceuticals Corporation, formerly Ciba-Geigy Corporation, ("Novartis"), a worldwide exclusive license to several compounds in the Company's sixth group of PNP inhibitors. Such arrangement with Novartis does not include BCX-34 or most of the Company's other compounds. No assurance can be given that Novartis will or will not develop compounds under such arrangements, will be able to obtain FDA approval for any licensed compounds, that any such licensed compounds if so approved will be able to be commercialized successfully, or that the Company will realize any revenues pursuant to such arrangements. If commercialized, these compounds could compete directly against other compounds, including BCX-34, being developed by the Company.

Many of the Company's competitors have significantly greater experience in conducting preclinical studies and clinical trials of new pharmaceutical products and in obtaining FDA and other regulatory approvals for health care products. Accordingly, BioCryst's competitors may succeed in obtaining approvals for their products more rapidly than the Company and in developing products that are safer or more effective or less costly than any that may be developed by the Company and may also be more successful than the Company in the production and marketing of such products. Many of the Company's competitors also have current GMP facilities and significantly greater experience in implementing GMP or in obtaining and maintaining the requisite regulatory standards for manufacturing. Moreover, other technologies are, or may in the future become, the basis for competitive products. Competition may increase further as a result of the potential advances from structure-based drug design and greater availability of capital for investment in this field. There can be no assurance that the Company's competitors will not succeed in developing technologies and products that are more effective than any being developed by the Company or that would render the Company's technology and product candidates obsolete or noncompetitive.

Dependence on Collaborative Partners; Relationship with The University of Alabama at Birmingham

The Company's strategy for research, development and commercialization of certain of its products is to rely in part upon various arrangements with corporate partners, licensees and others. As a result, the Company's products are

dependent in large part upon the subsequent success of such third parties in performing preclinical studies and clinical trials, obtaining regulatory approvals, manufacturing and marketing. The Company entered into an exclusive license agreement with Torii in May 1996 to develop, manufacture and commercialize in Japan BCX-34 and certain other PNP inhibitor compounds for three indications. The Company has also entered into collaborative arrangements with Novartis and intends to pursue additional collaborations in the future. There can be no assurance that the Company will be able to negotiate additional acceptable collaborative arrangements or that such arrangements will be successful. No assurance can be given that the Company's collaborative partners will be able to obtain FDA approval for any licensed compounds, that any such licensed compounds, if so approved, will be able to be commercialized successfully, or that the Company will realize any revenues pursuant to such arrangements. Although the Company believes that parties to collaborative arrangements generally have an economic motivation to succeed in performing their contractual responsibilities, the amount and timing of resources which they devote to these activities are not within the control of the Company. There can be no assurance that such parties will perform their obligations as expected or that current or potential collaborators will not pursue treatments for other diseases or seek alternative means of developing treatments for the diseases targeted by collaborative programs with the Company or that any additional revenues will be derived from such arrangements. If any of the Company's collaborators breaches or terminates its agreement with the Company or otherwise fails to conduct its collaborative activities in a timely manner, the development or commercialization of the product candidate or research program under such collaboration agreement may be delayed, the Company may be required to undertake unforeseen additional responsibilities or to devote unforeseen additional resources to such development or commercialization, or such development or commercialization could be terminated. The termination or cancellation of collaborative arrangements could also adversely affect the Company's financial condition, intellectual property position and operations. In addition, disagreements between collaborators and the Company have in the past and could in the future lead to delays in the collaborative research, development or commercialization of certain product candidates, or could require or result in legal process or arbitration for resolution. These consequences could be time-consuming, expensive and could have material adverse effects on the Company.

The successful commercialization of the Company's compounds and product candidates is also dependent upon the Company's ability to develop collaborative arrangements with academic institutions and consultants to support research and development efforts and to conduct clinical trials. The Company's primary academic collaboration is with UAB. The Company is highly dependent upon its collaborative arrangements with UAB to support its ongoing research and development programs and the termination or cessation of such relationship could have a material adverse effect upon the Company. There can be no assurance that the Company's current arrangements with UAB will continue or that the Company will be able to develop successful collaborative arrangements with academic institutions and consultants in the future.

Uncertainty of Protection of Patents and Proprietary Rights

The Company's success will depend in part on its ability to obtain and enforce patent protection for its products, preserve its trade secrets, and operate without infringing on the proprietary rights of third parties, both in the United States and in other countries. In the absence of patent protection, the Company's business may be adversely affected by competitors who develop substantially equivalent technology. Because of the substantial length of time and expense associated with bringing new products through development and regulatory approval to the marketplace, the pharmaceutical and biotechnology industries place considerable importance on obtaining and maintaining patent and trade secret protection for new technologies, products and processes. To date, the Company has been issued seven United States patents related to its PNP inhibitor compounds. One of these compounds is under a patent issued to Warner-Lambert Company ("Warner-Lambert") and the Company may require a license from Warner-Lambert to market a product containing one or both of these compounds. The Company has the right of first refusal to negotiate a license from Warner-Lambert for that compound, however, there can be no assurance that such a license would be available or obtainable on terms acceptable to the Company. A patent has also been issued by the U.S. Patent and Trademark Office ("PTO") on a new process to prepare BCX-34 and other PNP inhibitors and an additional patent application has been filed for another new process to prepare BCX-34 and other PNP inhibitors. In addition, one patent has issued by the PTO and two patent applications have been filed with the PTO relating to inhibitors of influenza neuraminidase. Also, two provisional United States patent applications have been filed with the PTO on complement inhibitors. The Company has filed certain corresponding foreign patent applications and

intends to file additional foreign patent applications and additional United States patent applications, as appropriate. There can be no assurance that patents will be issued from such applications, that the Company will develop additional products that are patentable or that present or future patents will provide sufficient protection to the Company's present or future technologies, products and processes. In addition, there can be no assurance that others will not independently develop substantially equivalent proprietary information, design around the Company's patents or obtain access to the Company's know-how or that others will not successfully challenge the validity of the Company's patents or be issued patents which may prevent the sale of one or more of the Company's product candidates, or require licensing and the payment of significant fees or royalties by the Company to third parties in order to enable the Company to conduct its business. Legal standards relating to the scope of claims and the validity of patents in the fields in which the Company is pursuing research and development are still evolving, are highly uncertain and involve complex legal and factual issues. No assurance can be given as to the degree of protection or competitive advantage any patents issued to the Company will afford, the validity of any such patents or the Company's ability to avoid infringing any patents issued to others. Further, there can be no guarantee that any patents issued to or licensed by the Company will not be infringed by the products of others. Litigation and other proceedings involving the defense and prosecution of patent claims can be expensive and time consuming, even in those instances in which the outcome is favorable to the Company, and can result in the diversion of resources from the Company's other activities. An adverse outcome could subject the Company to significant liabilities to third parties, require the Company to obtain licenses from third parties or require the Company to cease any related research and development activities or sales.

The Company's success is also dependent upon the skills, knowledge and experience (none of which is patentable) of its scientific and technical personnel. To help protect its rights, the Company requires all employees, consultants, advisors and collaborators to enter into confidentiality agreements which prohibit the disclosure of confidential information to anyone outside the Company and requires disclosure and assignment to the Company of their ideas, developments, discoveries and inventions. There can be no assurance, however, that these agreements will provide adequate protection for the Company's trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information.

The Company's management and scientific personnel have been recruited primarily from other pharmaceutical companies and academic institutions. In many cases, these individuals are continuing research in the same areas with which they were involved prior to joining BioCryst and may be restricted by agreement from disclosing to the Company trade secrets they learned elsewhere. As a result, the Company could be subject to allegations of violation of such agreements and similar claims and litigation regarding such claims could ensue.

Dependence on Key Management and Qualified Personnel

The Company is highly dependent upon the efforts of its senior management and scientific team. The loss of the services of one or more members of the senior management and scientific team could significantly impede the achievement of development objectives. Although the Company maintains, and is 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, the Company does not believe the proceeds would be adequate to compensate for his loss. Due to the specialized scientific nature of the Company's business, the Company is also highly dependent upon its ability to attract and retain qualified scientific, technical and key management personnel. There is intense competition for qualified personnel in the areas of the Company's activities, and there can be no assurance that the Company will be able to continue to attract and retain qualified personnel necessary for the development of its existing business and its expansion into areas and activities requiring additional expertise, such as production and marketing. The loss of, or failure to recruit, scientific, technical and managerial personnel could have a material adverse effect on the Company. In addition, the Company relies on members of its Scientific Advisory Board and consultants to assist the Company in formulating its research and development strategy. All of the members of the Scientific Advisory Board and all of the Company's consultants are employed by other employers, and each such member or consultant may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to the Company.

Lack of Manufacturing, Marketing or Sales Capability

The Company has not yet manufactured or marketed any products and currently does not have the facilities to manufacture its product candidates in commercial quantities under GMP as prescribed and required by the FDA. To be successful, the Company's products must be manufactured in commercial quantities under GMP and at acceptable costs. Although the Company is formulating and packaging under GMP conditions small amounts of certain drug formulations which are the subject of preclinical studies and clinical trials, the current facilities of the Company are not adequate for commercial scale production. Therefore, the Company will need to develop its own GMP manufacturing facility and/or depend on its collaborators, licensees or contract manufacturers for the commercial manufacture of its products. The Company has no experience in such commercial manufacturing and no assurance can be given that the Company will be able to make the transition to commercial production successfully or at an acceptable cost. In addition, no assurance can be given that the Company will be able to make arrangements with third parties to manufacture its products on acceptable terms, if at all. The inability of the Company to manufacture or provide for the manufacture of any products it may develop on a cost-effective basis would have a material adverse effect on the Company.

The Company has no experience in marketing, distributing or selling pharmaceutical products and will have to develop a pharmaceutical sales force and/or rely on its collaborators, licensees or arrangements with others to provide for the marketing, distribution and sales of any products it may develop. There can be no assurance that the Company will be able to establish marketing, distribution and sales capabilities or make arrangements with collaborators, licensees or others to perform such activities.

Uncertainty of Third-Party Reimbursement and Product Pricing

Successful commercialization of any pharmaceutical products the Company may develop will depend in part upon the availability of reimbursement or funding from third-party health care payors such as government and private insurance plans. There can be no assurance that third-party reimbursement or funding will be available for newly approved pharmaceutical products or will permit price levels sufficient to realize an appropriate return on the Company's investment in its pharmaceutical product development. The U.S. Congress is considering a number of legislative and regulatory reforms that may affect companies engaged in the health care industry in the United States. Although the Company cannot predict whether these proposals will be adopted or the effects such proposals may have on its business, the existence and pendency of such proposals could have a material adverse effect on the Company in general. In addition, the Company's ability to commercialize potential pharmaceutical products may be adversely affected to the extent that such proposals have a material adverse effect on other companies that are prospective collaborators with respect to any of the Company's pharmaceutical product candidates.

Third-party payors are continuing their efforts to contain or reduce the cost of health care through various means. For example, third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations, such as health maintenance organizations, which can control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for pharmaceutical products. The cost containment measures that health care providers are instituting and the effect of any health care reform could materially adversely affect the Company's ability to sell its products if successfully developed and approved.

Risk of Product Liability; Availability of Insurance

The Company's business may be affected by potential product liability risks which are inherent in the testing, manufacturing and marketing of pharmaceutical and other products under development by the Company. There can be no assurance that product liability claims will not be asserted against the Company, its collaborators or licensees. The use of products developed by the Company in clinical trials and the subsequent sale of such products is likely to cause BioCryst to bear all or a portion of those risks. The Company does not have product liability insurance but does maintain coverage for clinical trials in the amount of \$6.0 million per occurrence and in the aggregate. No assurance can be given that such insurance will be adequate to cover claims made with respect to the clinical trials.

There can be no assurance that the Company will be able to obtain or maintain adequate product liability insurance on acceptable terms or that such insurance will provide adequate coverage against potential liabilities. Furthermore, there can be no assurance that any collaborators or licensees of BioCryst will agree to indemnify the Company, be sufficiently insured or have a net worth sufficient to satisfy any such product liability claims.

Hazardous Materials; Compliance with Environmental Regulations

The Company's research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. Although the Company believes that its safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, the Company could be held liable for any damages that result and any such liability could exceed the resources of the Company. The Company may incur substantial costs to comply with environmental regulations if the Company develops manufacturing capacity.

Control by Existing Management and Stockholders; Effect of Certain Anti-Takeover Considerations

The Company's directors, executive officers and certain principal stockholders and their affiliates own beneficially approximately 24.8% of the Common Stock. Accordingly, such holders, if acting together, may have the ability to exert significant influence over the election of the Company's Board of Directors and other matters submitted to the Company's stockholders for approval. The voting power of these holders may discourage or prevent any proposed takeover of the Company unless the terms thereof are approved by such holders. Pursuant to the Company's Composite Certificate of Incorporation (the "Certificate of Incorporation"), shares of Preferred Stock may be issued by the Company in the future without stockholder approval and upon such terms as the Board of Directors may determine. The rights of the holders of Common Stock will be subject to, and may be adversely affected by, the rights of the holders of any Preferred Stock that may be issued in the future. The issuance of Preferred Stock could have the effect of discouraging a third party from acquiring a majority of the outstanding Common Stock of the Company and preventing stockholders from realizing a premium on their shares. The Company's Certificate of Incorporation also provides for staggered terms for the members of the Board of Directors. A staggered Board of Directors and certain provisions of the Company's by-laws and of Delaware law applicable to the Company could delay or make more difficult a merger, tender offer or proxy contest involving the Company.

Price Volatility

The securities markets have from time to time experienced significant price and volume fluctuations that have often been unrelated to the operating performance of particular companies. In addition, the market prices of the common stock of many publicly traded emerging pharmaceutical and biopharmaceutical companies have in the past been, and can in the future be expected to be, especially volatile. Announcements of technological innovations or new products by the Company or its competitors, developments or disputes concerning patents or proprietary rights or collaboration partners, achieving or failing to achieve development milestones, publicity regarding actual or potential medical results relating to products under development by the Company or its competitors, regulatory developments in both U.S. and foreign countries, public concern as to the safety of pharmaceutical products and economic and other external factors, as well as period-to-period fluctuations in the Company's financial results, may have a significant impact on the market price of the Common Stock.

PART II. OTHER INFORMATION

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:

NONE

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	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).
10.3	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).
10.4	Equipment Leases dated February 25, 1993, August 25, 1993, and November 25, 1993 between Ventana Leasing, Inc. and the Registrant. Incorporated by reference to Exhibit 10.23 to the Company's Form S-1 Registration Statement (Registration No. 33-73868).
10.5	Common Stock Purchase Warrants issued in connection with the issuance of Series A Convertible Preferred Stock. Incorporated by reference to Exhibit 10.32 to the Company's Form S-1 Registration Statement (Registration No. 33-73868).
10.6	Fourth Amended and Restated Registration Rights Agreement among the Registrant and certain securityholders. Incorporated by reference to Exhibit 10.35 to the Company's Form S-1 Registration Statement (Registration No. 33-73868).
10.7	Common Stock Purchase Warrants issued in connection with the issuance of Series B Convertible Preferred Stock. Incorporated by reference to Exhibit 10.36 to the Company's Form S-1 Registration Statement (Registration No. 33-73868).

- 10.8 Common Stock Purchase Warrants dated December 7, 1993 to purchase 49,400 shares of Common Stock issued to each of John Pappajohn, Lindsay A. Rosenwald and William M. Spencer. Incorporated by reference to Exhibit 10.37 to the Company's Form S-1 Registration Statement (Registration No. 33-73868).
- 10.9 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.
- 10.10 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.
- 10.11# 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).
- 10.12 Employee Stock Purchase Plan. Incorporated by reference to Exhibit 99.4 to the Company's Form S-8 Registration Statement (Registration No. 33-95062).
- 10.13 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.
- 10.14 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 Second Amendment to Lease Agreement between Registrant and Principal Mutual Life Insurance Company, Inc. for office/warehouse space.
- 27.1 Financial Data Schedule.

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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 31, 1997

/s/ Charles E. Bugg

Charles E. Bugg
Chairman and Chief Executive Officer

Date: October 31, 1997

/s/ Ronald E. Gray

Ronald E. Gray
Chief Financial Officer and Chief
Accounting Officer

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.

9-MOS		
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