

FORM 10-Q

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

For the quarterly period ended March 31, 2002

OR

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

For the transition period from _____ to _____ .

Commission File Number 000-23186

BIOCRYST PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of
incorporation or organization)

62-1413174
(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 No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 17,636,465 shares of the Company's Common Stock, \$.01 par value, were outstanding as of April 26, 2002.

BIOCRYST PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

**BIOCRYST PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS
March 31, 2002 and December 31, 2001
(In thousands, except per share data)**

	2002 (Unaudited)	2001 (Note 1)
Assets		
Cash and cash equivalents	\$ 18,636	\$ 18,865
Securities held-to-maturity	10,621	13,122
Prepaid expenses and other current assets	718	416
	<hr/>	<hr/>
Total current assets	29,975	32,403
Securities held-to-maturity	17,394	20,954
Furniture and equipment, net	5,349	5,396
Patents	453	343
	<hr/>	<hr/>
Total assets	\$ 53,171	\$ 59,096
	<hr/>	<hr/>
Liabilities and Stockholders' Equity		
Accounts payable	\$ 350	\$ 617
Accrued expenses	1,185	1,365
	<hr/>	<hr/>
Total current liabilities	1,535	1,982
Deferred revenue	300	300
Stockholders' equity:		
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 – 17,636 in 2002 and 17,607 in 2001	176	176
Additional paid-in capital	131,807	131,669
Accumulated deficit	(80,647)	(75,031)
	<hr/>	<hr/>
Total stockholders' equity	51,336	56,814
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 53,171	\$ 59,096
	<hr/>	<hr/>

See accompanying notes to condensed financial statements.

**BIOCRYST PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS
Three Months Ended March 31, 2002 and 2001
(In thousands, except per share)
(Unaudited)**

	2002	2001
Revenues:	<hr/>	<hr/>

Collaborative and other research and development	\$ 0	\$ 703
Interest and other	539	1,184
	<hr/>	<hr/>
Total revenues	539	1,887
	<hr/>	<hr/>
Expenses:		
Research and development	5,387	2,530
General and administrative	768	700
Royalty expense	0	40
	<hr/>	<hr/>
Total expenses	6,155	3,270
	<hr/>	<hr/>
Net loss	\$(5,616)	\$(1,383)
	<hr/>	<hr/>
Amounts per common share:		
Net loss (Note 2)	\$ (.32)	\$ (.08)
	<hr/>	<hr/>
Weighted average shares outstanding (Note 2)	17,627	17,539

See accompanying notes to condensed financial statements.

BIOCRYST PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
Three Months Ended March 31, 2002 and 2001
(In thousands)
(Unaudited)

	2002	2001
	<hr/>	<hr/>
Operating activities:		
Net loss	\$(5,616)	\$(1,383)
Depreciation and amortization	287	235
Deferred expense	0	41
Deferred revenue	0	(703)
Non-monetary compensation	37	36
Changes in operating assets and liabilities, net	(749)	(457)
	<hr/>	<hr/>
Net cash used in operating activities	(6,041)	(2,231)
	<hr/>	<hr/>
Investing activities:		
Purchases of furniture and equipment	(240)	(611)
Purchases of patents and licenses	(110)	(13)
Purchases of marketable securities	(560)	(16,433)
Maturities of marketable securities	6,621	27,429
	<hr/>	<hr/>
Net cash provided by investing activities	5,711	10,372
	<hr/>	<hr/>
Financing activities:		
Principal payments of debt and capital lease obligations	0	(7)
Proceeds from sale of common stock	101	20
	<hr/>	<hr/>
Net cash provided by financing activities	101	13
	<hr/>	<hr/>
Increase (decrease) in cash and cash equivalents	(229)	8,154
Cash and cash equivalents at beginning of period	18,865	8,456
	<hr/>	<hr/>
Cash and cash equivalents at end of period	\$ 18,636	\$ 16,610
	<hr/>	<hr/>

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 March 31, 2002 and the condensed statements of operations and cash flows for the three months ended March 31, 2002 and 2001 have been prepared in accordance with generally accepted accounting principles by the Company and have not been audited. Such financial statements reflect all adjustments that are, in management's opinion, necessary to present fairly, in all material respects, the financial position at March 31, 2002 and the results of operations and cash flows for the three months ended March 31, 2002 and 2001. These condensed financial statements should be read in conjunction with the financial statements for the year ended December 31, 2001 and the notes thereto included in the Company's 2001 Annual Report on Form 10-K. Interim operating results are not necessarily indicative of operating results for the full year. The condensed balance sheet as of December 31, 2001 has been prepared from the audited financial statements included in the previously mentioned Annual Report.

Note 2. Net Loss Per Share

The Company computes net loss per share in accordance with Statement of Financial Accounting Standards No. 128, *Earnings per Share*. Net loss per share is based upon the weighted average number of common shares outstanding during the period. Common equivalent shares from unexercised stock options and warrants are excluded from the computation, as their effect is anti-dilutive. For the three months ended March 31, 2002 and 2001, common stock equivalents of approximately 90,005 and 189,691 shares respectively, were not used to calculate net loss per share because of their anti-dilutive effect. There were no reconciling items in calculating the numerator for net loss per share for any of the periods presented.

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

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- raising capital.

Our revenues have generally been limited to license fees, milestone payments, interest income, collaboration research and development fees. Prior to January 1, 2000, the Company recognized research and development fees,

license fees and milestone payments as revenue when received. Effective January 1, 2000, the Company changed its method of accounting for revenue recognition in accordance with SEC Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* ("SAB 101"). Research and development revenue on cost-reimbursement agreements is recognized as expenses are incurred, up to contractual limits. Research and development fees, license fees and milestone payments are recognized as revenue when the earnings process is complete, the Company has no further continuing performance obligations and has completed its performance under the terms of the agreement, in accordance with SAB 101. License fees and milestone payments received under licensing agreements that are related to future performance are deferred and taken into income as earned over the estimated drug development period. The Company has not received any royalties from the sale of licensed pharmaceutical products. It could be several years, if ever, before we will recognize significant revenue from royalties received pursuant to our license agreements, and we do not expect to ever generate revenue 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 March 31, 2002 was \$80.6 million. We will require substantial expenditures relating to the development of our current and future drug candidates. During the three years ended December 31, 2001, we spent 26.9% 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. For example, in September 1998, we entered a worldwide license agreement with The R.W. Johnson Pharmaceutical Research Institute (RWJPRI) and Ortho-McNeil Pharmaceutical, Inc. (Ortho-McNeil), both Johnson & Johnson companies, to develop and market products to treat and prevent viral influenza. On April 30, 2001, we announced that Ortho-McNeil and RWJPRI gave BioCryst four months prior notice of termination of the worldwide license agreement. The final termination of this agreement was effective on September 21, 2001. Subsequently, we decided to move forward in the United States to complete the Phase III clinical trial of peramivir (RWJ-270201) that was initiated in Europe in February 2000, while we seek a new development partner. During the first quarter 2002, the Company announced that patient enrollment was complete in the first Phase III trial of once-a-day orally administered peramivir and preliminary data from the trial will be available during the third quarter 2002.

Changes in our existing and future research and development and collaborative relationships will also impact the status of our research and development projects. Although 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 research, 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 ended March 31, 2002 compared to the three months ended March 31, 2001)

Revenues decreased 71.4% to \$539,000 in the three months ended March 31, 2002 from \$1,887,000 in the three months ended March 31, 2001. The decrease was primarily due to a change in accounting estimate in the quarter ended June 30, 2001 following termination by Ortho-McNeil and RWJPRI of the worldwide license agreement with BioCryst for peramivir, the Company's neuraminidase inhibitor. As a result of this change, we had no collaborative revenue during the first quarter of 2002 as compared to \$703,000 in the first quarter of 2001. In addition, interest and other income decreased 54.5% to \$539,000 in the first quarter of 2002 from \$1,184,000 in the first quarter of 2001, due to a reduction in cash from funding operations and expansion of our facilities.

Research and development expenses increased 112.9% to \$5,387,000 in the three months ended March 31, 2002 from \$2,530,000 in the three months ended March 31, 2001. The increase is primarily attributable to an increase in clinical trial expenses related to the Phase III development of peramivir, plus increased personnel and other research and development expenses related to our other programs.

Liquidity and Capital Resources

Cash expenditures have exceeded revenues since the Company's inception. Our operations have principally been funded through various sources, including the following:

- public offerings and private placements of equity and debt securities,
- equipment lease financing,
- facility leases,
- collaborative and other research and development agreements (including 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, potentially resulting in significant losses, as we continue to 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.

The Company invests its excess cash principally in U.S. marketable securities from a diversified portfolio of institutions with strong credit ratings and in U.S. government and agency bills and notes, and by policy, limits the amount of credit exposure at any one institution. These investments are generally not collateralized and mature within four years. The Company has not realized any losses from such investments. In addition, at March 31, 2002, approximately \$15.1 million was invested in the Merrill Lynch Premier Institutional Fund, which invests primarily in commercial paper, U.S. government and agency bills and notes, corporate notes, certificates of deposit and time deposits. The Merrill Lynch Premier Institutional Fund is not insured. At March 31, 2002, our cash, cash equivalents and securities held-to-maturity were \$46.7 million, a decrease of \$6.3 million from December 31, 2001, principally due to the funding of current operations, which includes continuing Phase III development of peramivir.

We have financed some of our equipment purchases with lease lines of credit. We currently have a \$500,000 general line of credit with our bank, secured by a pledge of \$600,000 in marketable securities. There was nothing drawn against this line as of March 31, 2002. In July 2000, we renegotiated our lease for our current facilities, which will expire on June 30, 2010. We have an option to renew the lease for an additional five years at current market rates. The lease, as amended effective July 1, 2001 for an additional 7,200 square feet, requires us to pay monthly rent starting at \$33,145 per month in July 2001 and escalating annually to a minimum of \$47,437 per month in the final year, plus our pro rata share of operating expenses and real estate taxes in excess of base year amounts. As part of the lease, we have pledged a U.S. Treasury security deposited in escrow for the payment of rent and performance of other obligations specified in the lease. This pledged amount is currently \$455,000, which will be decreased by \$65,000 annually throughout the term of the lease.

During 2000, we remodeled our facilities to gain additional laboratory space, update our existing laboratories, and add a small good manufacturing practices (GMP) clean room. In addition, we updated our general office facility to provide for growth and efficiencies. The total cost of these changes, including furniture and laboratory equipment, was approximately \$2.7 million. This phase of remodeling was completed in December 2000. Another phase of remodeling was completed in February 2002 for approximately \$2.6 million to add two chemistry laboratories and purchase additional equipment. Currently, there are no immediate plans for additional remodeling.

At December 31, 2001, we had long-term operating lease obligations, which provide for aggregate minimum payments of \$567,123 in 2002, \$580,803 in 2003 and \$594,897 in 2004. These obligations include the future rental of our operating facility.

In September 1998, we entered a worldwide license agreement with RWJPRI and Ortho-McNeil, both Johnson & Johnson companies, to develop and market products to treat and prevent viral influenza. Under the terms of the agreement, we received \$6.0 million in cash up front, and \$6.0 million from Johnson & Johnson Development Corporation in the form of a common stock equity investment in 1998, and milestone payments of \$2.0 million and \$4.0 million in 1999 and 2000, respectively. On April 30, 2001, we announced that Ortho-McNeil and RWJPRI gave four months prior notice of termination of the worldwide license agreement. Subsequently, all rights to peramivir and all other patented compounds were returned to the Company. Ortho-McNeil indicated that this business decision was not related to safety or efficacy of the drug, but that other of its drug development programs were of a higher priority. The final termination of this agreement was effective on September 21, 2001.

Subsequently, we decided to move forward in the United States to complete the Phase III clinical trial of peramivir that was initiated in Europe in February 2000, while we seek a new development partner. During the first quarter 2002, the Company announced that patient enrollment was complete in the first Phase III trial of once-a-day orally administered peramivir and preliminary data from the trial will be available during the third quarter 2002.

We have projected to spend approximately \$7 to \$9 million more than our normal annual operating expenses on the Phase III clinical trial, which began in the quarter ended December 31, 2001. If we are able to find a new corporate partner to continue and complete the development of peramivir, our future costs associated with this drug will be limited. We cannot assure you that we will find a new corporate partner that 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 royalties from sales of licensed products.

We plan to finance our 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 financing.

We believe that our available funds will be sufficient to fund our operations at least through 2004. 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;

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- 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 for development and commercialization of our product candidates, in particular, peramivir, our influenza neuraminidase inhibitor, 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, with 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.

Critical Accounting Policies

We have established various accounting policies that govern the application of accounting principles generally accepted in the United States in the preparation of our financial statements. Our significant accounting policies are described in the footnotes to the financial statements of the Company's most recent Annual Report on Form 10-K. Certain accounting policies involve significant judgments and assumptions by management that have a material impact on the carrying value of certain assets and liabilities; management considers such accounting policies to be critical accounting policies. The judgments and assumptions used by management are based on historical experience and other factors, which are believed to be reasonable under the circumstances. Because of the nature of the judgments and assumptions made by management, actual results could differ from these judgments and estimates which could have a material impact on the carrying values assets and liabilities and the results of operations.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Effective January 1, 2000, we changed our method of accounting for revenue recognition in accordance with SEC Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* ("SAB 101"). Research and development revenue on cost-reimbursement agreements is recognized as expenses are incurred, up to contractual limits. Research and development fees, license fees and milestone payments are recognized as revenue when the earnings process is complete, the Company has no further continuing performance obligations and has completed its performance under the terms of the agreement, in accordance with SAB 101. License fees and milestone payments received under licensing agreements that are related to future performance are deferred and taken into income as earned over the estimated drug development period. Recognized revenues and profit are subject to revisions as these contracts or agreements progress to completion. Revisions to revenue or profit estimates are charged to income in the period in which the facts that give rise to the revision became known.

Valuation of Financial Instruments

We carry our held-to-maturity securities at amortized cost, as adjusted for other-than-temporary declines in market value. In determining if and when a decline in market value below amortized cost is other-than-temporary, we evaluate the market conditions and other key measures for our held-to-maturity investments. Future adverse changes in market conditions could result in losses or an inability to recover the carrying value of the held-to-maturity investments that may not be reflected in an investment's current carrying value, thereby possibly requiring an impairment charge in the future.

Deferred Taxes

We have not had taxable income since incorporation and, therefore, we have not paid any income tax. We have deferred tax assets related to net operating loss carryforwards and research and development carryforwards. We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, in the event we were to determine that we would be able to realize the deferred tax assets in the future in excess of the net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of the net deferred tax asset in the future, an adjustment to the deferred tax asset would be charged to income in the period such determination was made.

Certain Risk 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 our losses could increase as our research and development efforts progress. As of March 31, 2002, our accumulated deficit was approximately \$80.6 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 could be several years, if ever, before we receive royalties from 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 financing. 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.

Because Ortho-McNeil Pharmaceutical, Inc. (Ortho-McNeil) and The R.W. Johnson Pharmaceutical Research Institute (RWJPRI) terminated their worldwide license agreement with us, our future revenue generation is uncertain

On April 30, 2001, we announced that Ortho-McNeil and RWJPRI gave BioCryst four months prior notice of termination of the worldwide license agreement with us to develop and market products to treat and prevent viral influenza. The final termination of this agreement was effective on September 21, 2001. As a result, we have lost a substantial amount of our expected revenue. After applying SAB 101 on a pro forma basis, none of our revenues for the three months ended March 31, 2002; approximately 69.3% of our revenues for the year ended December 31, 2001 and approximately 43.3% of our revenues for the year ended December 31, 2000 resulted from this license agreement. These revenues represent approximately 39.1% of our total revenues since our inception in 1986. Because of the termination of this agreement, we will not receive any future milestone or other payments from RWJPRI or Ortho-McNeil.

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

Our failure to engage in successful collaborations at any one of these stages would greatly impact our business. For example, we cannot assure you that we will license our proprietary influenza neuraminidase inhibitor peramivir to a new corporate partner to facilitate final development and potential commercialization on acceptable terms, if at all. If we do not license enzyme targets from academic institutions or from other biotechnology companies on acceptable terms, our product development efforts would suffer. Similarly, if the contract research organizations that conduct our initial or late-stage clinical trials breached their obligations to us, this would delay or prevent the development 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, manufacturing, 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;
- 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.

Any problems encountered with our current or future partners could delay or prevent the development of our compounds, which would severely affect our business, because if our compounds do not reach the market in a timely manner, or at all, we will experience a significant decrease in milestone payments received by us and may never receive any royalty payments.

If the clinical trials of our drug candidates fail, our drug candidates will not be marketed, which would result in a decrease in, or complete absence of, revenue

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 demonstrate that our drug candidates are safe and effective, our drug candidates will not receive regulatory approval and will not be marketed, which would result in a decrease in, or complete absence of, revenue. The clinical trial process is complex and uncertain. 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. These side effects could also result in the FDA or foreign regulatory authorities refusing to approve the drug candidate for any targeted indications. We, our licensees, 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.

Clinical trials are lengthy and expensive. We or our licensees incur substantial expense for, and devote significant time to, preclinical testing and clinical trials, yet cannot be certain that the tests and trials will ever result in the commercial sale of a product. For example, clinical trials require adequate supplies of drug and sufficient patient enrollment. Delays in patient enrollment can result in increased costs and longer development times. 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.

In 1998, we signed an agreement to license our flu drug candidate to Ortho-McNeil and to RWJPRI, who conducted clinical trials. On April 30, 2001, BioCryst announced that Ortho-McNeil and RWJPRI gave four months prior notice of termination of the worldwide license agreement with BioCryst to develop and market products to treat and prevent viral influenza. Ortho-McNeil returned all rights to BioCryst's proprietary influenza neuraminidase inhibitors, including peramivir, back to the Company. Ortho-McNeil transferred to BioCryst all improvements, information, data and materials connected to the licensed product including, but not limited to, clinical and chemical data, regulatory filings, specifications and third party agreements. Ortho-McNeil indicated that this business decision was not related to safety or efficacy of peramivir, but that other of its drug development programs were of a higher priority. The final termination of this agreement was effective on September 21, 2001.

During the first quarter 2002, the Company completed patient enrollment in the first Phase III trial of once-a-day orally administered peramivir, and we continue to seek a new corporate partner to facilitate the final development and potential commercialization of this drug candidate. Even if we or any potential licensee continues certain Phase III clinical trials, the trials may not be successful. We do not know when, if ever, our drug candidate will complete all the required Phase III clinical trials, or when, if ever, it will receive FDA or foreign regulatory agency approvals for, or when, if ever, marketing of peramivir will begin. If we or any partners are unable to complete the clinical trials or demonstrate the safety and efficacy of our compounds, the loss of our future revenues that depend on the success of peramivir will harm our business. Even if the results of the Phase III trials are positive, a product is not likely to be commercially available for three or more 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, which would significantly harm our business because we will receive no revenue

We or our licensees must obtain regulatory approval before marketing or selling our future drug products. If we or our licensees are unable to receive regulatory approval and do not market or sell our future drug products, we will never receive any revenue from such product sales. 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. If we or our licensees fail to obtain regulatory approval we will be unable to market and sell our future drug products. We have several drug products in various stages of preclinical and clinical development; however, we are unable to determine when, if ever, any of these products will be commercially available. 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.

The FDA regulates, among other things, the record keeping and storage of data pertaining to potential pharmaceutical products. We currently store most of our preclinical research data at our facility. While we do store duplicate copies of most of our clinical data offsite, we could lose important preclinical data if our facility incurs damage. 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:

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- 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 our licensees do not receive approval of our products for marketing.

In June 1995, we notified the FDA that we submitted incorrect data for our Phase II studies of BCX-34 applied to the skin for cutaneous T-cell lymphoma and psoriasis. The FDA inspected us in November 1995 and issued us a

List of Inspectional Observations, Form FDA 483, which cited our failure to follow good clinical practices. The FDA also inspected us in June 1996. The focus was on the two 1995 Phase II dose-ranging studies of topical BCX-34 for the treatment of cutaneous T-cell lymphoma and psoriasis. As a result of the investigation, the FDA issued us a Form FDA 483, which cited our failure to follow good clinical practices. BioCryst is no longer developing BCX-34; however, as a consequence of these two investigations, our ongoing and future clinical studies may receive increased scrutiny, which may 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 peramivir, our influenza neuraminidase inhibitor, may not gain the market acceptance required for us to be profitable even if they receive approval for sale by the FDA or foreign regulatory agencies. 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 safety and effectiveness relative to alternative treatments, such as Hoffmann-La Roche's and GlaxoSmithKline's influenza neuraminidase inhibitors, amantadine, rimantadine, or vaccines for prevention of influenza;
- reimbursement policies of government and third-party payers; and
- marketing and distribution support for our drug candidates.

Physicians, patients, payers 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 expectations

The biotechnology and pharmaceutical industries are highly competitive and are subject to rapid and substantial technological change. Other products and therapies that either currently exist on the market or are under development could compete directly with some of the compounds that we are seeking to develop and market. These other products may render some or all of our compounds under development noncompetitive or obsolete.

If our influenza neuraminidase inhibitor drug candidate, peramivir, 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 two influenza neuraminidase inhibitors already on the market, the drugs amantadine and rimantadine and with additional products that may beat peramivir to the market. If approved, peramivir will be, at best, the third neuraminidase inhibitor to the market, because the FDA has approved both GlaxoSmithKline's and Hoffman-La Roche's neuraminidase inhibitors in the U.S. and both companies have also obtained approval in several other countries. Both GlaxoSmithKline and Hoffmann-La Roche, the companies responsible for the development and marketing of Relenza® and Tamiflu®, the two neuraminidase inhibitors that reached the market before peramivir, are large multinational pharmaceutical companies that have significant financial, technical and human resources and could therefore establish brand recognition and loyalty with consumers before peramivir is on the market. 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 those 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 third parties. If we or our partners are unable to adequately protect or enforce our intellectual property rights for our products, methods, processes and other technologies, the value of the drug candidates that we license to derive revenue would diminish. Additionally, if our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs. The U.S. Patent and Trademark Office has issued to us a number of U.S. patents for our various inventions and we have in-licensed several patents from various institutions. 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 assure you as to:

- the degree and range of protection any patents will afford against competitors with similar products;
- if and when patents will issue; or

- whether or not others will obtain patents claiming aspects similar to those covered by our patent applications.

If the U.S. Patent and Trademark Office upholds patents issued to others or if the U.S. Patent and Trademark Office grants patent applications filed by others, we may have to:

- obtain licenses or redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in those patents; or
- pay damages.

We may initiate, or others may bring against us, litigation or administrative proceedings related to intellectual property rights, including proceedings before the U.S. Patent and Trademark Office. Any judgment adverse to us in any litigation or other proceeding arising in connection with a patent or patent application could materially and adversely affect our business, financial condition and results of operations. In addition, the costs of any such proceeding may be substantial whether or not we are successful.

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 adequate protection for our 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, 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.

If we fail to retain our existing key personnel or fail to attract and retain additional key personnel, the development of our drug candidates and the expansion of our business will be delayed or stopped

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. Competition for key personnel with the experience that we require is intense and is expected to continue 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 are otherwise employed and each such member or consultant may have commitments to other entities that may limit their availability to us.

If users of our drug products are not reimbursed for use, future sales of our drug products will decline

The lack of reimbursement for the use of our product candidates by hospitals, clinics, patients or doctors will harm our business. Medicare, Medicaid, health maintenance organizations and other third-party payers may not authorize or otherwise budget for the reimbursement of our products. Governmental and third-party payers are increasingly challenging the prices charged for medical products and services. We cannot be sure that third-party payers would view our product candidates as cost-effective, that reimbursement will be available to consumers or that reimbursement will be sufficient to allow our product candidates to be marketed on a competitive basis. Changes in reimbursement policies, or attempts to contain costs in the health care industry, limit or restrict reimbursement for our product candidates, would materially and adversely affect our business, because future product sales would decline and we would receive less royalty revenue.

If we face clinical trial liability claims related to the use or misuse of our compounds in clinical trials, our management's time will be diverted 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 have not experienced any clinical trial liability claims to date, but we may experience these claims in the future. After commercial introduction of our products we may experience losses due to product liability claims. 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 may not be available in the future on acceptable terms, if at all. 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 our computer systems fail, our business will suffer

Our drug development activities depend on the security, integrity and performance of the computer systems supporting them, and the failure of our computer systems could delay our drug development efforts. We currently store most of our preclinical and clinical data at our facility. Duplicate copies of all critical data are stored off-site in a bank vault. Any significant degradation or failure of our computer systems could cause us to inaccurately calculate or lose our data. Loss of data could result in significant delays in our drug development process and any system failure could harm our business and operations.

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

Our directors, executive officers and some principal stockholders and their affiliates, including Johnson & Johnson Development Corporation, beneficially own approximately 42% (directors and officers own 28%) of our outstanding common stock and common stock equivalents. 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 supermajority 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 price has fluctuated frequently, and these fluctuations are often not related to our financial results. For the twelve months ended March 31, 2002, the 52-week range of the market price of our stock has been from \$3.00 to \$8.00 per share. 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;
- status of new or existing licensing or collaborative agreements;
- we or 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.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The primary objective of our investment activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing our risk. We invest excess cash principally in U.S. marketable securities from a diversified portfolio of institutions with strong credit ratings and in U.S. government and agency bills and notes, and by policy, limit the amount of credit exposure at any one institution. Some of the securities we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, we schedule our investments to have maturities that coincide with our cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, we believe we have no material exposure to interest rate risk arising from our investments. Therefore, no quantitative tabular disclosure is provided.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings:

None

Item 2. Changes in Securities and Use of Proceeds:

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 as of March 6, 2000. Incorporated by reference to Exhibit 99.1 to the Company's Form S-8 Registration Statement dated June 16, |

- 10.2 Employment Agreement dated December 27, 1999 between the Registrant and Charles E. Bugg, Ph.D. Incorporated by reference to Exhibit 10.10 to the Company's Form 10-K for the year ending December 31, 1999 dated March 24, 2000.
- 10.3# 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).
- 10.4 Employee Stock Purchase Plan. Incorporated by reference to Exhibit 99.4 to the Company's Form S-8 Registration Statement (Registration No. 33-95062).
- 10.5# 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.
- 10.6# 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.
- 10.7# 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.
- 10.8 Warehouse Lease dated July 12, 2000 between RBP, LLC an Alabama Limited Liability Company and the Registrant for office/warehouse space. Incorporated by reference to Exhibit 10.8 to the Company's Form 10-Q for the second quarter ending June 30, 2000 dated August 8, 2000.
- 10.9# Termination Agreement dated as of September 21, 2001 between Registrant and The R.W. Johnson Pharmaceutical Research Institute and Ortho-McNeil Pharmaceutical, Inc. Incorporated by reference to Exhibit 10.9 to the Company's Form 10-Q/A for the third quarter ending September 30, 2001 dated January 15, 2002.
- 10.10 Change of Control Agreement dated May 25, 2001 between the Registrant and W. Randall Pittman. Incorporated by reference to Exhibit 10.10 to the Company's Form 10-K for the year ending December 31, 2001 dated March 22, 2002.

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: May 3, 2002

By: /s/ CHARLES E. BUGG

Charles E. Bugg
Chairman and Chief Executive Officer

Date: May 3, 2002

By: /s/ W. RANDALL PITTMAN
