

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

**Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended March 31, 2005

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

**BIOCRYSST PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**DELAWARE**

(State of other jurisdiction of incorporation or organization)

**62-1413174**

(I.R.S. employer identification no.)

**2190 Parkway Lake Drive; Birmingham, Alabama 35244**

(Address 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 a 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 by a check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2).

Yes  No

The number of shares of Common Stock, par value \$.01, of the Registrant outstanding as of April 26, 2005 was 26,149,427.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

**BIOCRYST PHARMACEUTICALS, INC.**  
**CONDENSED BALANCE SHEETS**  
**March 31, 2005 and December 31, 2004**  
(In thousands, except per share data)

	2005	2004
	(Unaudited)	(Note 1)
<b>Assets</b>		
Cash and cash equivalents	\$ 22,049	\$ 8,838
Securities held-to-maturity	18,988	14,335
Prepaid expenses and other current assets	671	699
<b>Total current assets</b>	<b>41,708</b>	<b>23,872</b>
Securities held-to-maturity	4,889	5,530
Furniture and equipment, net	2,634	2,817
Patents	258	249
<b>Total assets</b>	<b>\$ 49,489</b>	<b>\$ 32,468</b>
<b>Liabilities and Stockholders' Equity</b>		
Accounts payable	\$ 1,672	\$ 1,970
Accrued expenses	1,011	864
<b>Total current liabilities</b>	<b>2,683</b>	<b>2,834</b>
Deferred revenue	300	300
<b>Total liabilities</b>	<b>2,983</b>	<b>3,134</b>
Stockholders' equity:		
Preferred stock: shares authorized – 5,000		
Series A Convertible Preferred stock, \$.01 par value; shares authorized – 1,800; shares issued and outstanding – none		
Series B Junior Participating Preferred Stock, \$.001 par value; shares authorized – 21.5; shares issued and outstanding - none		
Common stock, \$.01 par value; shares authorized - 45,000; shares issued and outstanding - 26,149 in 2005 and 21,758 in 2004	262	218
Additional paid-in capital	177,653	154,880
Accumulated deficit	(131,409)	(125,764)
<b>Total stockholders' equity</b>	<b>46,506</b>	<b>29,334</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 49,489</b>	<b>\$ 32,468</b>

See accompanying notes to condensed financial statements.

**BIOCRIST PHARMACEUTICALS, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
**Three Months Ended March 31, 2005 and 2004**  
(In thousands, except per share)  
(Unaudited)

	2005	2004
<b>Revenues:</b>		
Collaborative and other research and development	\$ 41	\$ 0
<b>Expenses:</b>		
Research and development	5,175	4,983
General and administrative	696	660
	5,871	5,643
Loss from operations	(5,830)	(5,643)
Interest and other income	185	181
	\$ (5,645)	\$ (5,462)
<b>Amounts per common share:</b>		
Basic and diluted net loss (Note 2)	\$ (.24)	\$ (.28)
Weighted average shares outstanding (Note 2)	23,620	19,587

See accompanying notes to condensed financial statements.

**BIOCRIST PHARMACEUTICALS, INC.**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
**Three Months Ended March 31, 2005 and 2004**  
(In thousands)  
(Unaudited)

	2005	2004
<b>Operating activities:</b>		
Net loss	\$ (5,645)	\$ (5,462)
Depreciation and amortization	224	244
Non-monetary compensation	7	13
Changes in operating assets and liabilities, net	(123)	986
	<b>(5,537)</b>	<b>(4,219)</b>
<b>Investing activities:</b>		
Purchases of furniture and equipment	(41)	(123)
Purchases of patents and licenses	(9)	(6)
Purchases of marketable securities	(5,812)	(12,818)
Maturities of marketable securities	1,800	5,870
	<b>(4,062)</b>	<b>(7,077)</b>
<b>Financing activities:</b>		
Employee stock purchase plan sales	65	59
Exercise of stock options	41	91
Sale of common stock, net of issuance costs	22,704	20,280
	<b>22,810</b>	<b>20,430</b>
Increase in cash and cash equivalents	13,211	9,134
Cash and cash equivalents at beginning of period	8,838	8,348
	<b>\$ 22,049</b>	<b>\$ 17,482</b>

See accompanying notes to condensed financial statements.

**BIOCRIST PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS (UNAUDITED)**

Note 1. Basis of Preparation

The condensed balance sheet as of March 31, 2005, the condensed statements of operations for the three months ended March 31, 2005 and 2004, and the statements of cash flows for the three months ended March 31, 2005 and 2004 have been prepared by the Company in accordance with accounting principles generally accepted in the United States 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, 2005, the results of operations for the three months ended March 31, 2005 and 2004, and cash flows for the three months ended March 31, 2005 and 2004. There were no adjustments other than normal recurring adjustments. The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements. Examples include accrued clinical and preclinical expenses. Actual results could differ from those estimates.

These condensed financial statements should be read in conjunction with the financial statements for the year ended December 31, 2004 and the notes thereto included in the Company's 2004 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, 2004 has been derived from the audited financial statements included in the previously mentioned Annual Report.

Certain amounts in the Condensed Statement of Cash Flows for the three months ended March 31, 2004 have been reclassified to conform to the Condensed Statement of Cash Flows for the three months ended March 31, 2005. The changes had no effect on the results of operations previously reported.

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. Diluted loss per share is equivalent to basic net loss per share for all periods presented herein because common equivalent shares from unexercised stock options and common shares expected to be issued under the Company's employee stock purchase plan were anti-dilutive.

Note 3. Stock-Based Compensation

The Company accounts for stock-based compensation under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB No. 25"). Under APB No. 25, the Company's stock option and employee stock purchase plans qualify as noncompensatory plans. Under Financial Accounting Standards Board Interpretation 44, *Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB No. 25*, outside directors are considered employees for purposes of applying APB No. 25, if they are elected by the shareholders. Consequently, no compensation expense for employees and directors is recognized unless there has been a modification to their grants as was the case for the directors in May 2004, resulting in a recognized expense of \$457,000 during 2004. Stock issued to non-employees is compensatory and compensation expense is recognized under Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* ("Statement No. 123") as amended by Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*.

The following table illustrates the pro forma effect on net loss and net loss per share had the Company applied the fair value recognition provisions of Statement No. 123 for the three month periods ended March 31, 2005 and 2004.

	Three Months Ended March 31	
	2005	2004
Net loss as reported	\$ (5,645)	\$ (5,462)
Add stock-based employee compensation expense included in reported net loss	7	13
Deduct stock-based employee compensation expense determined under Statement No. 123	(426)	(313)
<b>Pro forma net loss</b>	<b>\$ (6,064)</b>	<b>\$ (5,762)</b>
<b>Amounts per common share:</b>		
Net loss per share, as reported	\$ (.24)	\$ (.28)
Pro forma net loss per share	\$ (.26)	\$ (.29)

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment* ("Statement No. 123R"), which is a revision of Statement No. 123 and supersedes APB No. 25. The Statement addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. The Statement eliminates the ability to account for share-based compensation transactions using APB No. 25, and generally would require instead that such transactions be accounted for using a grant date fair-value based method. Companies will now be required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. In March 2005, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 107, *Share-Based Payment* ("SAB 107"), which provided further clarification on the implementation of Statement No. 123R. In April 2005, the SEC announced a deferral of the effective date of Statement No. 123R for calendar year companies until January 1, 2006. It is expected that the new rules of Statement No. 123R will be applied on a modified prospective basis. The Company is currently evaluating option valuation methodologies and assumptions in light of Statement No. 123R and SAB 107. Current estimates of option values using the Black-Scholes method (as shown above) may not be indicative of results from valuation methodologies ultimately adopted by the Company.

#### Note 4. Stockholders' Equity

In February 2005, the Company entered into a Placement Agency Agreement with Leerink Swann & Company in connection with a registered direct offering of 4,350,000 shares of its common stock at an offering price of \$5.50 per share. The common stock was issued pursuant to a prospectus supplement filed with the SEC in connection with a shelf takedown from the Company's registration statement on Form S-3.

In February 2005, the Company entered into stock purchase agreements with a number of institutional investors for an aggregate of 4,350,000 shares of common stock at a gross purchase price of \$5.50 per share or \$23.9 million.

One of these agreements was with Baker Brothers Investments, L.P., Baker Brothers Investments II, L.P., Baker Biotech Fund I, L.P., Baker Biotech Fund II, L.P., Baker Biotech Fund II (Z), L.P., Baker Biotech Fund III, L.P., Baker Biotech Fund III (Z), L.P., Baker/Tisch Investments, L.P., and 14159, L.P., or the Baker investors, for a total of 1,454,545 shares. As part of this agreement, the Company has granted the Baker investors the right to appoint a member to its board of directors effective as of the closing of the offering, or for a period of twelve months following the closing. The Baker investors have not exercised this right.

The Company also issued an additional 41,140 shares during the three months ended March 31, 2005 as a result of exercises related to the Company's stock option plan and employee stock purchase plan.

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

*This Quarterly Report on Form 10-Q contains certain statements of a forward-looking nature relating to future events or the future financial performance of the Company. Such statements are only predictions and the actual events or results may differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include those discussed below as well as those discussed in other filings made by the Company with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K.*

### Overview

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

- identification and licensing of enzyme targets;
- drug discovery;
- structure-based design of drug candidates;
- small-scale synthesis of compounds;
- conducting preclinical studies and clinical trials;
- recruiting our scientific and management personnel;
- establishing laboratory facilities; and
- raising capital.

Our revenues have generally been limited to license fees, milestone payments, interest income, and collaboration research and development fees. The Company recognizes revenue in accordance with SEC Staff Accounting Bulletin No. 104, *Revenue Recognition* ("SAB No. 104"). 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 No. 104. License fees and milestone payments received under licensing agreements that are related to future performance are deferred and recognized as earned over the estimated drug development period. The Company has not received any revenues or 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 or 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, 2005 was \$131.4 million. We will require substantial expenditures relating to the development of our current and future drug candidates. During the three years ended December 31, 2004, we spent 45.5% of our research and development expenses on contract research and development, including:

- payments to consultants;
- funding of research at academic institutions;
- large scale synthesis and formulation of compounds;
- preclinical studies;
- engaging investigators to conduct clinical trials;
- hiring contract research organizations for regulatory and clinical functions; 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, during the first quarter of 2004, we entered a Phase II trial for our lead drug candidate, Fodosine™ (“forodesine hydrochloride”, or “BCX-1777”), an inhibitor of purine nucleoside phosphorylase. In addition, during the fourth quarter of 2004, we initiated a Phase I trial for Fodosine™ in cutaneous T-cell lymphoma (“CTCL”) and a Phase I trial with BCX-4208 in healthy volunteers. As these trials progress and additional trials are started in other indications, our costs for clinical studies will increase significantly. In addition, the costs associated with the manufacturing of Fodosine™ and BCX-4208 will increase as we scale up to the larger production runs required for both clinical development and additional toxicology studies.

Changes in our existing and future research and development and collaborative relationships also will 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 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, 2005 compared to the three months ended March 31, 2004)**

Collaborative and other research and development revenues increased to \$41,000 in the three months ended March 31, 2005 compared to \$0 in the three months ended March 31, 2004, due to revenue from the National Institutes of Health related to an SBIR grant for support of our hepatitis C program. Interest and other income increased 2.2% to \$185,000 in the first quarter of 2005 compared to \$181,000 in the first quarter of 2004.

Research and development expenses increased 3.9% to \$5,175,000 in the three months ended March 31, 2005 from \$4,983,000 in the three months ended March 31, 2004. The increase is primarily attributable to increased expenses related to the clinical trials for our lead drug candidates, Fodosine™ and BCX-4208. These increases were partially offset by a decrease in preclinical testing related to BCX-4208 incurred in 2004 prior to its clinical development.

General and administrative expenses for the three months ended March 31, 2005 increased 5.5% to \$696,000 as compared to \$660,000 for the same period in 2004, primarily due to additional compensation cost which included the hiring of a Vice President of Business Development in February 2005.

#### **Liquidity and Capital Resources**

Cash expenditures have exceeded revenues since the Company’s inception. Our operations have principally been funded through public offerings and private placements of equity and debt securities. For example, during February 2005, we raised \$23.9 million (approximately \$22.7 million net of expenses) through the sale of 4,350,000 shares of our common stock. Other sources of funding have included the following:

- 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 pursue 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 three years. The Company has not realized any losses from such investments. In addition, at March 31, 2005, approximately \$19.9 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, 2005, our cash, cash equivalents and securities held-to-maturity were \$45.9 million, which included \$2.1 million in certificates of deposit at two financial institutions.

We have financed some of our equipment purchases with lease lines of credit. 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 the current market rate in effect on June 30, 2010 and a one-time option to terminate the lease on June 30, 2008 for a termination fee of approximately \$124,000. 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 deposited a U.S. Treasury security in escrow for the payment of rent and performance of other obligations specified in the lease. This pledged amount is currently \$265,000, which can be decreased by \$65,000 annually throughout the term of the lease. Currently, we have approximately 14,000 square feet of space available for sublease, of which 3,600 square feet are currently being leased.

We have not incurred any significant charges related to new equipment or building renovations since 2001 and currently have no plans for any significant additional purchases or renovations.

At December 31, 2004, we had long-term operating lease obligations, which provide for aggregate minimum payments of \$622,105 in 2005, \$580,027 in 2006 and \$535,746 in 2007. These obligations include the future rental of our operating facility.

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
- 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 2006. However, this is a forward looking statement, and there may be changes that would consume available resources significantly before such time. Our long-term capital requirements and the adequacy of our available funds will depend upon many factors, including:

- the progress of our research, drug discovery and development programs;
- changes in existing collaborative relationships;
- our ability to establish additional collaborative relationships;

- the magnitude of our research and development programs;
- the scope and results of preclinical studies and clinical trials to identify drug candidates;
- competitive and technological advances;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- our dependence on others for development and commercialization of our product candidates, and
- successful commercialization of our products consistent with our licensing strategy.

In 2004, our operations consumed approximately \$1,500,000 per month, but we expect that our monthly cash used by operations will continue to increase for the next several years. During 2005, we plan to both expand our existing clinical programs and initiate clinical programs for several new disease indications. These additional trials and the related manufacturing, personnel resources and testing required to support these studies will consume significant capital resources and significantly increase our expenses and our net loss. As of March 31, 2005, we had \$45.9 million in cash, cash equivalents and securities. We raised \$23.9 million gross (approximately \$22.7 million net of expenses) of capital during February 2005 to provide the resources necessary to continue the development of our existing programs, while prudently maintaining our cash position. We expect our monthly burn rate to increase to approximately \$2 million during 2005, as our lead candidates advance through the clinical trials planned for 2005. This monthly burn rate could increase more as the year progresses and in future years depending on many factors, including our ability to raise additional capital, the progress of our current and proposed clinical trials for both Fodosine™ and BCX-4208, and the progression of our discovery programs.

We will be required to raise additional capital to complete the development and commercialization of our current product candidates. 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.

#### **Off-Balance Sheet Arrangements**

As part of our ongoing business, we do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities (“SPEs”), which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of March 31, 2005, we are not involved in any material unconsolidated SPE or off-balance sheet arrangements.

#### **Contractual Obligations**

A summary of our obligations to make future payments under contracts existing as of December 31, 2004 is included in Item 7, Management’s Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2004. For the three months ended March 31, 2005, the Company has entered into various contracts in the ordinary course of business for several R&D related items, including manufacturing of various compounds, additional toxicology studies and clinical trials and has already paid for some of the obligations disclosed at December 31, 2004. The net effect of these changes was to decrease the purchase obligations disclosed at December 31, 2004 by a total of approximately \$1.0 million. These obligations could change during the course of the year depending on the status of each of our development programs.

## **Critical Accounting Policies**

We have established various accounting policies that govern the application of accounting principles generally accepted in the United States, which were utilized in the preparation of our financial statements. 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 of 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***

The Company recognizes revenue in accordance with SAB No. 104. 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 No. 104. License fees and milestone payments received under licensing agreements that are related to future performance are deferred and recognized as earned over the estimated drug development period. Revisions to revenue or profit estimates as a result of changes in the estimated drug development period are recognized prospectively.

### ***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. We have not incurred any other-than-temporary declines in market value that would require an impairment charge.

### ***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 credit carryforwards, and have recorded 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. For the current year, the Company has recorded a valuation allowance equivalent to the amount of deferred tax assets.

### ***Patents and Licenses***

Patents and licenses are recorded at cost and amortized on a straight-line basis over their estimated useful lives or 20 years, whichever is lesser. These costs are reviewed periodically in accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* to determine any impairment that needs to be recognized. For 2004, we recognized an impairment charge of \$8,339.

## **Research and Development Expenses**

Major components of R&D expenses consist of personnel costs, including salaries and benefits, clinical, regulatory and toxicology services performed by contract research organizations (“CRO’s”), materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. We charge clinical and preclinical study costs to expense when incurred, consistent with Statement of Financial Accounting Standards No. 2, *Accounting for Research and Development Costs*. These costs are a significant component of R&D expenses. Most of our clinical and preclinical studies are performed by third-party CRO’s. We accrue costs for studies performed by CRO’s over the service periods specified in the contracts and adjust our estimates, if required, based upon our on-going review of the level of services actually performed by the CRO.

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

*An investment in our stock involves a high degree of risk. You should consider carefully the following risks, along with all of the other information included in our other filings with the Securities and Exchange Commission, before deciding to buy our common stock. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also impair our business operations. If we are unable to prevent events that have a negative effect from occurring, then our business may suffer. Negative events are likely to decrease our revenue, increase our costs, make our financial results poorer and/or decrease our financial strength, and may cause our stock price to decline. In that case, you may lose all or a part of your investment in our common stock.*

## **Risks Relating to Our Business**

***We have incurred substantial losses since our inception in 1986, expect to continue to incur such losses and may never be profitable***

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, 2005, our accumulated deficit was approximately \$131.4 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. We or 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 or revenues directly from product sales.

***If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates or continue our research and development programs.***

To date, we have financed our operations primarily from sale of our equity securities and, to a lesser extent, revenues from collaborations and interest. In 2004, our operations consumed approximately \$1,500,000 per month, but we expect that our monthly cash used by operations will continue to increase for the next several years. During 2005, we plan to both expand our existing clinical programs and initiate clinical programs for several new disease indications. These additional trials and the related manufacturing, personnel resources and testing required to support these studies will consume significant capital resources and significantly increase our expenses and our net loss.

As of March 31, 2005, we had \$45.9 million in cash, cash equivalents and securities. We raised \$23.9 million gross (approximately \$22.7 million net of expenses) of capital during February 2005 to provide the resources necessary to continue the development of our existing programs, while prudently maintaining our cash position. We expect our monthly burn rate to increase to approximately \$2 million during 2005, as our lead candidates advance through the clinical trials planned for 2005. This monthly burn rate could increase more as the year progresses and in future years depending on many factors, including our ability to raise additional capital, the progress of our current and proposed clinical trials for both Fodosine™ and BCX-4208, and the progression of our discovery programs. Our long-term capital requirements and the adequacy of our available funds will depend upon many factors, including:

- the progress of our research, drug discovery and development programs;
- changes in existing collaborative relationships;

- our ability to establish additional collaborative relationships;
- the magnitude of our research and development programs;
- the scope and results of preclinical studies and clinical trials to identify drug candidates;
- competitive and technological advances;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- our dependence on others for development and commercialization of our product candidates; and
- successful commercialization of our products consistent with our licensing strategy.

We will be required to raise additional capital to complete the development and commercialization of our current product candidates. 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.

***We have not commercialized any products or technologies and our future revenue generation is uncertain***

We have not yet commercialized any products or technologies, and we may never be able to do so. Our revenue from collaborative agreements is dependent upon the status of our preclinical and clinical programs. If we fail to advance these programs to the point of being able to enter into successful collaborations, we will not receive any future milestone or other collaborative payments.

Any future revenue directly from product sales would depend on our ability to successfully complete clinical studies, obtain regulatory approvals, manufacture, market and commercialize any approved drugs.

***If our development collaborations with other parties fail, the development of our drug candidates will be delayed or stopped***

We rely heavily 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;
- licensing or design of enzyme inhibitors for development as drug candidates;
- execution of some preclinical studies and late-stage development for our compounds and drug candidates;
- management of our clinical trials, including medical monitoring and data management;
- management of our regulatory function; 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. If we do not license enzyme targets or inhibitors 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 or manage our regulatory function 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 general 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. For some smaller niche markets, we may perform these steps ourselves and outsource those functions where we do not have the internal 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;
- our partners may not comply with applicable government regulatory requirements; and
- our manufacturing partners may not be able to manufacture our compounds in the quantities required or to the specifications required by the regulatory authorities.

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 may never receive any milestone, product or royalty payments.

***If the clinical trials of our drug candidates fail, our drug candidates will not be marketed, which would result in a complete absence of product related 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 complete absence of product related revenue. The clinical trial process is complex and uncertain. Because of the cost and duration of clinical trials, we may decide to discontinue development of product candidates that are either unlikely to show good results in the trials or unlikely to help advance a product to the point of a meaningful collaboration. 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, we or our licensees might not file the required regulatory submissions in a timely manner and may not receive regulatory approval for the drug candidate.

***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:

- 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 product or royalty revenues if we or 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 CTCL 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 CTCL 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. We are 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.

***We may be unable to establish sales, marketing and distribution capabilities necessary to successfully commercialize products we may successfully develop***

We currently have no marketing capability and no direct or third-party sales or distribution capabilities. If we successfully develop a drug candidate and decide to commercialize it ourselves rather than relying on third parties, as we currently intend to do in the United States for Fodosine™, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for that product.



***If our drug candidates do not achieve broad market acceptance, our business may never become profitable***

Our drug candidates may not gain the market acceptance required for us to be profitable even if they successfully complete initial and final clinical trials and 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;
- 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.

***We face intense competition, and if we are unable to compete effectively, the demand for our products, if any, may be reduced***

The biotechnology and pharmaceutical industries are highly competitive and subject to rapid and substantial technological change. We face, and will continue to face, competition in the licensing of desirable disease targets, licensing of desirable drug candidates, and development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. Competition may also arise from, among other things:

- other drug development technologies;
- methods of preventing or reducing the incidence of disease, including vaccines; and
- new small molecule or other classes of therapeutic agents.

Developments by others may render our product candidates or technologies obsolete or noncompetitive.

We are performing research on or developing products for the treatment of several disorders including T-cell mediated disorders (T-cell cancers, psoriasis, and rheumatoid arthritis), cardiovascular, oncology, and hepatitis C, and there are a number of competitors to products in our research pipeline. If one or more of our competitors' products or programs are successful, the market for our products may be reduced or eliminated.

Compared to us, many of our competitors and potential competitors have substantially greater:

- capital resources;
- research and development resources, including personnel and technology;
- regulatory experience;
- preclinical study and clinical testing experience;
- manufacturing and marketing experience; and
- production facilities.

Any of these competitive factors could reduce demand for our products.

***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 could limit or restrict reimbursement for our product candidates and would materially and adversely affect our business, because future product sales would decline and we would receive less product or 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 \$5.0 million per occurrence and \$5.0 million in the aggregate, with an additional \$2.0 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 most 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.

**Risks Relating to Our Common Stock**

***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, 2005, the 52-week range of the market price of our stock was from \$4.32 to \$11.25 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.

***Because stock ownership is concentrated, you and other investors will have limited influence on stockholder decisions***

As of March 31, 2005, our directors, executive officers and some principal stockholders and their affiliates beneficially owned approximately 43.9% (directors and officers, together with their relevant affiliates owned 25.6%) 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 3,178,500 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.

In June 2002, our board of directors adopted a stockholder rights plan and, pursuant thereto, issued preferred stock purchase rights (“Rights”) to the holders of our common stock. The Rights have certain anti-takeover effects. If triggered, the Rights would cause substantial dilution to a person or group of persons who acquires more than 15% (19.9% for William W. Featheringill, a Director who owned approximately 11% as of February 23, 2005, but owned more than 15% at the time the Rights were put in place) of our common stock on terms not approved by the board of directors.

***We have never paid dividends on our common stock and do not anticipate doing so in the foreseeable future***

We have never paid cash dividends on our stock. We currently intend to retain all future earnings, if any, for use in the operation of our business. Accordingly, we do not anticipate paying cash dividends on our common stock in the foreseeable future.

**Information Regarding Forward-Looking Statements**

This discussion contains forward-looking statements, which are subject to risks and uncertainties. These forward-looking statements can generally be identified by the use of words such as “may,” “will,” “intends,” “plans,” “believes,” “anticipates,” “expects,” “estimates,” “predicts,” “potential,” the negative of these words or similar expressions. Statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects are also forward-looking statements. Discussions containing these forward-looking statements are principally contained in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” above, as well as any amendments we make to those sections in filings with the SEC.

These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in “Risk Factors.” Also, these forward-looking statements represent our estimates and assumptions only as of the date of this document.

You should read this discussion completely and with the understanding that our actual future results may be materially different from what we expect. We may not update these forward-looking statements, even though our situation may change in the future. We qualify all of our forward-looking statements by these cautionary statements.

**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 expected 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.

**Item 4. Controls and Procedures**

We maintain a set of disclosure controls and procedures that are designed to ensure that information relating to BioCryst Pharmaceuticals, Inc. required to be disclosed in our periodic filings under the Securities Exchange Act is recorded, processed, summarized and reported in a timely manner under the Securities Exchange Act of 1934. We carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2005, the Company’s disclosure controls and procedures are effective to ensure that information required to be disclosed by BioCryst in the reports filed or submitted by it under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and include controls and procedures designed to ensure that information required to be disclosed by BioCryst in such reports is accumulated and communicated to the Company’s management, including the Chairman and Chief Executive Officer and Chief Financial Officer of BioCryst, as appropriate to allow timely decisions regarding required disclosure.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2005 that have materially affected, or are reasonably likely to materially affect, BioCryst’s internal control over financial reporting.

## PART II. OTHER INFORMATION

**Item 1. Legal Proceedings:**

None

**Item 2. Unregistered Sales of Equity 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:**

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 as amended March 7, 2005. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed March 9, 2005.
4.1	Rights Agreement, dated as of June 17, 2002, by and between the Company and American Stock Transfer & Trust Company, as Rights Agent, which includes the Certificate of Designation for the Series B Junior Participating Preferred Stock as Exhibit A and the form of Rights Certificate as Exhibit B. Incorporated by reference to Exhibit 4.1 to the Company's Form 8-A dated June 17, 2002.
10.1	1991 Stock Option Plan, as amended and restated effective March 8, 2004. Incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q for the second quarter ending June 30, 2004 dated August 10, 2004.
10.2#	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).
10.3	Employee Stock Purchase Plan. Incorporated by reference to Exhibit 99.1 to the Company's Form S-8 Registration Statement dated June 14, 2002 (Registration No. 333-90582).
10.4#	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.
10.5#	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.

- 10.6 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.
- 10.7 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 for the second quarter ending June 30, 2002 dated August 7, 2002.
- 10.8 Stock Purchase Agreement, dated as of February 17, 2004, by and among BioCryst Pharmaceuticals, Inc., Caduceus Private Investments II, LP, Caduceus Private Investments II (QP), LP and UBS Juniper Crossover Fund, L.L.C. Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K dated February 17, 2004.
- 10.9 Employment Agreement dated March 17, 2004 between the Registrant and Charles E. Bugg, Ph.D. Incorporated by reference to Exhibit 10.9 to the Company's Form 10-Q for the first quarter ending March 31, 2004 dated May 11, 2004.
- 10.10 Employment Agreement dated February 1, 2005 between the Registrant and Randall B. Riggs. Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K dated February 7, 2005.
- 10.11 Stock Purchase Agreement, dated as of February 17, 2005, by and among BioCryst Pharmaceuticals, Inc., Baker Bros. Investments, L.P., Baker Biotech Fund II, L.P., Baker Bros. Investments II, L.P., Baker Biotech Fund II (Z), L.P., Baker/Tisch Investments, L.P., Baker Biotech Fund III, L.P., Baker Biotech Fund I, L.P., Baker Biotech Fund III (Z), L.P. and 14159, L.P. Incorporated by reference to Exhibit 4.1 to the Company's Form 8-K dated February 17, 2005.
- 31.1 Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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# Confidential treatment granted.

**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 on this 2nd day of May, 2005.

BIOCRIST PHARMACEUTICALS, INC.

/s/ CHARLES E. BUGG

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**Charles E. Bugg, Ph.D.**  
*Chairman and Chief Executive Officer*

/s/ MICHAEL A. DARWIN

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**Michael A. Darwin**  
*Chief Financial Officer (Principal Financial  
and Accounting Officer), Secretary and Treasurer*



## CERTIFICATIONS

I, Charles E. Bugg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioCryst Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 2, 2005

/s/ CHARLES E. BUGG

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Charles E. Bugg  
Chairman and Chief Executive Officer

## CERTIFICATIONS

I, Michael A. Darwin, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioCryst Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 2, 2005

/s/ MICHAEL A. DARWIN

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Michael A. Darwin  
Chief Financial Officer and Chief Accounting Officer

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of BioCryst Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Charles E. Bugg, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ CHARLES E. BUGG

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Charles E. Bugg  
Chief Executive Officer  
May 2, 2005

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of BioCryst Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael A. Darwin, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ MICHAEL A. DARWIN

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Michael A. Darwin  
Chief Financial Officer  
May 2, 2005