CURTIS DEAN WILSON
Form SC 13G
October 03, 2002

**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

# SCHEDULE 13G

**(Rule 13d-102)**

**INFORMATION TO BE INCLUDED IN STATEMENTS FILED PURSUANT TO RULE 13d-1(c) AND AMENDMENTS THERETO FILED PURSUANT TO RULE 13d-2(d)**

**(Amendment No. _____)**[1]

ONCOLYTICS BIOTECH INC.

(Name of Issuer)

COMMON STOCK

(Title of Class of Securities)

6823 10-10-7

(CUSIP Number)

ANDREW D. GRASBY, SUITE 3300, 421-7TH AVENUE S.W.
CALGARY, ALBERTA T2P 4K9 (403) 260-3530

WITH COPY TO:

ALAN TALKINGTON, 400 SANSOME STREET
SAN FRANCISCO, CA 94111 (415) 392-1122

(Name, Address and Telephone Number of Person Authorized to Receive Notices and Communications)

JUNE 14, 2002 AND JUNE 25, 2002*

(Date of Event which Required Filing of this Statement)

Check the appropriate box to designate the rule pursuant to which this Schedule is filed:

¨ Rule 13d-1(b)

x Rule 13d-1(c)

¨ Rule 13d-1(d)

* On July 3, 2002 these reporting persons erroneously filed a Schedule 13D disclosing certain information about their acquisition of interests in the Issuer on June 14, 2002 and June 25, 2002. Upon recognizing this error, they have filed this Schedule 13G.

[1] The remainder of this cover page shall be filled out for a reporting person s initial filing on this form with respect to the subject class of securities, and for any subsequent amendment containing information which would alter the disclosures provided in a prior cover page.

The information required in the remainder of this cover page shall not be deemed to be filed for the purpose of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act

(however, *see* the *Notes*).

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| | | | |
|---|---|---|---|
| 1. | Name of Reporting Person<br>I.R.S. Identification No. of above person (entities only)<br><br>Dean Wilson Curtis | | |
| 2. | Check the Appropriate Box if a Member of a Group*<br><br>(a) ¨<br>(b) ¨ | | |
| 3. | SEC Use Only | | |
| 4. | Citizenship or Place of Organization<br><br>Canadian | | |
| NUMBER OF SHARES BENEFICIALLY OWNED BY EACH REPORTING PERSON WITH | 5. | Sole Voting Power<br><br>1,387,500** | |
| | 6. | Shared Voting Power<br><br>576,389 | |
| | 7. | Sole Dispositive Power<br><br>1,387,500** | |
| | 8. | Shared Dispositive Power<br><br>576,389 | |
| 9. | Aggregate Amount Beneficially Owned by Each Reporting Person<br><br>1,963,889*** | | |
| 10. | Check Box if the Aggregate Amount in Row (9) Excludes Certain Shares* | | ¨ |
| 11. | Percent of Class Represented by Amount in Row (9)<br><br>9.3% | | |
| 12. | Type of Reporting Person<br><br>IN | | |

** Includes 1,384,500 shares described in the Schedule 13D filed July 3, 2002 and 3,000 shares acquired on August 7, 2002.
*** Includes 1,960,889 shares described in Schedule 13D filed July 3, 2002 and 3,000 shares acquired on August 7, 2002.

***SEE INSTRUCTIONS BEFORE FILLING OUT!**

**SCHEDULE 13G**



| | | | |
|---|---|---|---|
| 1. | Name of Reporting Person<br>I.R.S. Identification No. of above person (entities only)<br><br>Curtis Investment Corporation | | |
| 2. | Check the Appropriate Box if a Member of a Group*<br><br>(a) ¨<br>(b) ¨ | | |
| 3. | SEC Use Only | | |
| 4. | Citizenship or Place of Organization<br><br>Canada | | |
| NUMBER OF SHARES BENEFICIALLY OWNED BY | 5. | Sole Voting Power<br><br>576,389 | |
| | 6. | Shared Voting Power<br><br>1,387,500** | |
| EACH REPORTING PERSON WITH | 7. | Sole Dispositive Power<br><br>576,389 | |
| | 8. | Shared Dispositive Power<br><br>1,387,500** | |
| 9. | Aggregate Amount Beneficially Owned by Each Reporting Person<br><br>1,963,889*** | | |
| 10. | Check box if the Aggregate Amount in Row (9) Excludes Certain Shares*<br><br>¨ | | |
| 11. | Percent of Class Represented by Amount in Row (9)<br><br>9.3% | | |
| 12. | Type of Reporting Person*<br><br>CO | | |

** Includes 1,384,500 shares described in the Schedule 13D filed July 3, 2002 and 3,000 shares acquired on August 7, 2002.
*** Includes 1,960,889 shares described in the Schedule 13D filed July 3, 2002 and 3,000 shares acquired on August 7, 2002.

***SEE INSTRUCTIONS BEFORE FILLING OUT!**

**SCHEDULE 13G**



**Item 1(a).** ***Name of Issuer:***

Oncolytics Biotech Inc. ( Oncolytics )

**Item 1(b).** ***Address of Issuer s Principal Executive Offices:***

Suite 210, 1167 Kensington Crescent N.W., Calgary, Alberta T2N 1X7

**Item 2(a).** ***Name of Person Filing:***

Dean Wilson Curtis ( Curtis ) and Curtis Investment Corporation ( CIC )

**Item 2(b).** ***Address of Principal Business Office or, if None, Residence:***

The residential address of Curtis and the business address of CIC is 902D, 500 Eau Claire Ave. S.W., Calgary, Alberta T2P 3R8

**Item 2(c).** ***Citizenship:***

Curtis is a Canadian citizen. CIC is an Alberta, Canada corporation.

**Item 2(d).** ***Title of Class of Securities:***

Common Stock

**Item 2(e).** ***CUSIP Number:***

682310-10-7

**Item 3.** ***If this statement is filed pursuant to Rules 13d-1(b), or 13d-2(b) or (c), check whether the person filing is a:***

(a) ¨ Broker or dealer registered under Section 15 of the Exchange Act.

(b) ¨ Bank as defined in Section 3(a)(6) of the Exchange Act.

(c) ¨ Insurance company as defined in Section 3(a)(19) of the Exchange Act.

(d) ¨ Investment company registered under Section 8 of the Investment Company Act.

(e) ¨ An adviser in accordance with Rule 13d-1(b)(1)(ii)(E).

(f) ¨ An employee benefit plan or endowment fund in accordance with Rule 13d-1(b)(1)(ii)(F).

(g) ¨ A parent holding company or control person in accordance with Rule 13d-1(b)(ii)(G).

(h) ¨ A savings association as defined in Section 3(b) of the Federal Deposit Insurance Act.

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(i) ¨ A church plan that is excluded from the definition of an investment company under Section 3(c)(14) of the Investment Company Act.

(j) ¨ Group, in accordance with Rule 13d-1(b)(1)(ii)(J)

If this statement is filed pursuant to Rule 13d-1(c), check this box. x

**Item 4.** ***Ownership.***

(a) Amount beneficially owned:

Curtis: 1,387,500 Common Shares**
CIC: 576,389 Common Shares

(b) Total percentage of class: 9.3%

(c) Number of shares as to which such person has:

(i) Sole power to vote or to direct the vote:

Curtis: 1,387,500 Common Shares**
CIC: 576,389 Common Shares

(ii) Shared power to vote or to direct the vote:

Curtis: 576,389 Common Shares
CIC: 1,387,500 Common Shares**

(iii) Sole power to dispose or to direct the disposition of

Curtis: 1,387,500 Common Shares**
CIC: 576,389 Common Shares

(iv) Shared power to dispose or to direct the disposition of

Curtis: 576,389 Common Shares
CIC: 1,387,500 Common Shares**

**Item 5.** ***Ownership of Five Percent or Less of a Class.***

Not Applicable

**Item 6.** ***Ownership of More than Five Percent on Behalf of Another Person.***

Not Applicable

**Item 7.** ***Identification and Classification of the Subsidiary Which Acquired the Security Being Reported on by the Parent Holding Company.***

Not Applicable

**Includes 1,384,500 shares described in the Schedule 13D filed July 3, 2002 and 3,000 shares acquired on August 7, 2002.

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**Item 8.** ***Identification and Classification of Members of the Group.***

Not Applicable

**Item 9.** ***Notice of Dissolution of Group.***

Not Applicable

**Item 10.** ***Certification.***

By signing below I certify that, to the best of my knowledge and belief, the securities referred to above were not acquired and are not held for the purpose of or with the effect of changing or influencing the control of the issuer of the securities and were not acquired and are not held in connection with or as a participant in any transaction having that purpose or effect.

**SIGNATURE**

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct.

Date: October 3, 2002

/s/ Dean Wilson Curtis

**Dean Wilson Curtis**

Curtis Investment Corporation

By: /s/ Dean Wilson Curtis

**Dean Wilson Curtis**
**President**

The original statement shall be signed by each person on whose behalf the statement is filed or his authorized representative. If the statement is signed on behalf of a person by his authorized representative (other than an executive officer or general partner of this filing person), evidence of the representative s authority to sign on behalf of such person shall be filed with the statement, provided, however, that a power of attorney for this purpose which is already on file with the Commission may be incorporated by reference. The name and any title of each person who signs the statement shall be typed or printed beneath his signature.

**Attention: Intentional misstatements or omissions of fact constitute Federal criminal violations (See 18 U.S.C. 1001)**

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the progress and magnitude of our research, drug discovery and development programs;

changes in existing collaborative relationships or government contracts;

our ability to establish additional collaborative relationships with academic institutions, biotechnology or pharmaceutical companies and governmental agencies or other third parties;

the extent to which our partners, including governmental agencies will share in the costs associated with the development of our programs or run the development programs themselves;

our ability to negotiate favorable development and marketing strategic alliances for certain drug candidates; or our ability to build or expand internal development and commercial capabilities;

our ability to achieve successful commercialization of marketed products by either us or a partner;

the scope and results of preclinical studies and clinical trials to identify and evaluate drug candidates;

our ability to enroll sites and patients in our clinical trials;

the scope of manufacturing of our drug candidates to support our preclinical research and clinical trials;

increases in personnel and related costs to support the development of our drug candidates;

the scope of validation for the manufacturing of our drug substance and drug products required for future NDA filings;

competitive and technological advances;

the time and costs involved in obtaining regulatory approvals; and

the costs involved in all aspects of intellectual property strategy and protection including the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;

We expect that 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, including governmental agencies, in general and from the HHS contract specifically, 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.

***If HHS were to eliminate, reduce or delay funding from our contract or dispute some of our incurred costs, this would have a significant negative impact on our anticipated revenues and cash flows and the development of peramivir.***

Our projections of revenues and incoming cash flows for 2007 are substantially dependent upon HHS reimbursement for the costs related to our peramivir program. If HHS were to eliminate, reduce or delay the funding for this program or disallow some of our incurred costs, we would have to obtain additional funding for development of this drug candidate or significantly reduce or stop the development effort.

In contracting with HHS, we are subject to various U.S. government contract requirements, including general clauses for a cost-reimbursement research and development contract, which may limit our reimbursement or if we are found to be in violation could result in contract termination. U.S. government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion. The U.S. government may terminate its contract with us either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms, which would have a significant negative impact on our cash flows and operations.

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***Our contract with HHS has special contracting requirements, which create additional risks of reduction or loss of funding.***

We have entered into a contract with HHS for the advanced development of our neuraminidase inhibitor, peramivir. In contracting with HHS, we are subject to various U.S. government contract requirements, including general clauses for a cost-reimbursement research and development contract. U.S. government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which subjects us to additional risks. These risks include the ability of the U.S. government to unilaterally:

terminate or reduce the scope of our contract; and

audit and object to our contract-related costs and fees, including allocated indirect costs.

The U.S. government may terminate its contract with us either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms. Termination for convenience provisions generally enable us to recover only our costs incurred or committed, and settlement expenses and profit on the work completed prior to termination. Termination for default provisions do not permit these recoveries.

As a U.S. government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices and are subject to periodic audits and reviews. As part of any such audit or review, the U.S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U.S. government may adjust our contract-related costs and fees, including allocated indirect costs. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. In addition, under U.S. government purchasing regulations, some of our costs may not be reimbursable or allowed under our contracts. Further, as a U.S. government contractor, we are subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities as compared to private sector commercial companies.

***If we fail to successfully commercialize or establish collaborative relationships to commercialize certain of our drug product candidates or if any partner terminates or fails to perform its obligations under agreements with us, potential revenues from commercialization of our product candidates could be reduced, delayed or eliminated.***

Our business strategy is to increase the asset value of our drug candidate portfolio. We believe this is best achieved by retaining full product rights or through collaborative arrangements with third parties as appropriate. As needed, potential third party alliances could include preclinical development, clinical development, regulatory approval, marketing, sales and distribution of our drug product candidates.

Currently, we have established collaborative relationships with four pharmaceutical companies, Roche, Mundipharma, and Shionogi and Green Cross for development and commercialization of BCX-4208, Fodosine$^{tm}$ and peramivir, respectively. The process of establishing and implementing collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons;

our contracts for collaborative arrangements may expire;

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;

we do not have day to day control over the activities of our partners and have limited control over their decisions;

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our ability to generate future event payments and royalties from our partners depends upon their abilities to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and achieve market acceptance of products developed from our drug candidates;

we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;

our partners may not devote sufficient capital or resources towards our product candidates; and

our partners may not comply with applicable government regulatory requirements.

If any partner fails to fulfill its responsibilities in a timely manner, or at all, our commercialization efforts related to that collaboration could be reduced, delayed or terminated, or it may be necessary for us to assume responsibility for activities that would otherwise have been the responsibility of our partner. If we are unable to establish and maintain collaborative relationships on acceptable terms, we may have to delay or discontinue further development of one or more of our product candidates, undertake commercialization activities at our own expense or find alternative sources of funding. Any delay in the development or commercialization of our compounds would severely affect our business, because if our compounds do not progress through the development process or reach the market in a timely manner, or at all, we may not receive additional future event payments and may never receive product or royalty payments.

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

We have not 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 event or other collaborative payments.

Our ability to receive revenue from products we commercialize presents several risks, including:

we or our collaborators may fail to successfully complete clinical trials sufficient to obtain FDA marketing approval;

many competitors are more experienced and have significantly more resources;

we may fail to employ a comprehensive and effective intellectual property strategy which could result in decreased commercial value of our company and our products;

we may fail to employ a comprehensive and effective regulatory strategy which could result in a delay or failure in commercialization of our products;

our ability to successfully commercialize our products are affected by the competitive landscape, which cannot be fully known at this time;

reimbursement is constantly changing which could greatly affect usage of our products; and

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 contract research organizations do not successfully carry out their duties or if we lose our relationships with contract research organizations, our drug development efforts could be delayed.***

We depend on contract research organizations, third-party vendors and investigators for preclinical testing and clinical trials related to our drug discovery and development efforts, including the HHS contract. We intend to depend on them to assist in our future discovery and development efforts. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. If they

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fail to devote sufficient time and resources to our drug development programs or if their performance is substandard, it will delay the approval of our products. The parties with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our products. Moreover, these parties may also have relationships with other commercial entities, some of which may compete with us. If they assist our competitors it could harm our competitive position.

If we lose our relationship with any one or more of these parties, we could experience a significant delay in both identifying another comparable provider and then contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to current Good Laboratory Practices ( cGLP ), current Good Manufacturing Practices ( cGMP ), or current Good Clinical Practices ( cGCP ), and similar foreign standards and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our product candidates could be delayed.

***If our development collaborations with third parties, such as our development partners and contract research organizations, fail, the development of our drug product candidates will be delayed or stopped.***

We rely heavily upon other parties for many important stages of our drug development programs, including but not limited to:

- discovery of compounds 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 product candidates;
- execution of some preclinical studies and late-stage development for our compounds and product candidates;
- management of our clinical trials, including medical monitoring and data management;
- obtaining, shipping, testing and storing patient samples from our clinical trials;
- execution of additional toxicology studies that may be required to obtain approval for our product candidates;
- manufacturing the starting materials and drug substance required to formulate our drug products and the drug products to be used in both our clinical trials and toxicology studies; and
- management of our regulatory function.

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, conduct our toxicology studies, manufacture our starting materials, drug substance and drug products or manage our regulatory function breached their obligations to us, this would delay or prevent the development of our product candidates.

***Our development of both intravenous and intramuscular dosing of peramivir for avian and seasonal influenza is subject to all disclosed drug development and potential commercialization risks and numerous additional risks. Any potential revenue benefits to us are highly speculative.***

Further development and potential commercialization of peramivir is subject to all the risks and uncertainties disclosed in our other risk factors relating to drug development and commercialization. In

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addition, potential commercialization of peramivir is subject to further risks, including but not limited to the following:

- the injectable versions of peramivir are currently in Phase II clinical development, have been tested in a limited number of humans, and may not be safe or effective;
- necessary government or other third party funding for clinical testing and further development of peramivir may not be available timely, at all, or in sufficient amounts;
- the avian flu prevention or treatment concerns may not materialize at all, or in the near future;
- advances in flu vaccines could substantially replace potential demand for an antiviral such as peramivir;
- any substantial demand for avian flu treatments may occur before peramivir can be adequately developed and tested in clinical trials;
- injectable forms of peramivir may not prove to be accepted by patients and physicians as a treatment for seasonal influenza compared to the other currently marketed antiviral drugs, which would limit revenue from non-governmental entities;
- numerous large and well-established pharmaceutical and biotech companies will be competing to meet the market demand for avian flu drugs and vaccines;
- regulatory authorities may not make needed accommodations to accelerate the drug testing and approval process for peramivir; and
- in the next few years, it is expected that a limited number of governmental entities will be the primary potential customers for peramivir and if we are not successful at marketing peramivir to these entities for any reason, we will not receive substantial revenues.

If any or all of these and other risk factors occur, we will not attain significant revenues or gross margins from peramivir and our stock price will be adversely affected.

***Because we have limited manufacturing experience, we depend on third-party manufacturers to manufacture our drug product candidates and the materials for our product candidates. If we cannot rely on third-party manufacturers, we will be required to incur significant costs and potential delays in finding new third-party manufacturers.***

We have limited manufacturing experience and only a small scale manufacturing facility. We currently rely upon third-party manufacturers to manufacture the materials required for our drug product candidates and most of the preclinical and clinical quantities of our product candidates. We depend on these third-party manufacturers to perform their obligations in a timely manner and in accordance with applicable governmental regulations. Our third-party manufacturers may encounter difficulties with meeting our requirements, including but not limited to problems involving:

- inconsistent production yields;
- difficulties in scaling production to commercial and validation sizes;

interruption of the delivery of materials required for the manufacturing process;

scheduling of plant time with other vendors or unexpected equipment failure;

potential catastrophes that could strike their facilities;

potential impurities in our drug substance or drug products that could affect availability of product for our clinical trials or future commercialization;

poor quality control and assurance or inadequate process controls; and

lack of compliance with regulations and specifications set forth by the FDA or other foreign regulatory agencies.

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These contract manufacturers may not be able to manufacture the materials required or our drug product candidates at a cost or in quantities necessary to make them commercially viable. We also have no control over whether third-party manufacturers breach their agreements with us or whether they may terminate or decline to renew agreements with us. To date, our third party manufacturers have met our manufacturing requirements, but they may not continue to do so. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the drug is manufactured or a change of a third-party manufacturer, may require prior review and approval in accordance with the FDA s cGMPs, and comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a product. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. If we or our contract manufacturers are unable to comply, we or they may be subject to regulatory action, civil actions or penalties.

If we are unable to enter into agreements with additional manufacturers on commercially reasonable terms, or if there is poor manufacturing performance on the part of our third party manufacturers, we may not be able to complete development of, or market, our product candidates.

Our raw materials, drug substances, and drug products are manufactured by a limited group of suppliers and some at a single facility. If any of these suppliers were unable to produce these items, this could significantly impact our supply of drugs for further preclinical testing and clinical trials.

***If the clinical trials of our drug product candidates fail, our product candidates will not be marketed, and we will not realize product related revenue.***

To receive the regulatory approvals necessary for the sale of our product candidates, we or our partners must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective. If we or other third party partners are unable to demonstrate that our product candidates are safe and effective, our product candidates will not receive regulatory approval and will not be marketed, and we will not realize 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 unlikely to show good results in the trials, unlikely to help advance a product to the point of a meaningful collaboration, or unlikely to have a reasonable commercial potential. 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 product 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 product candidate. These side effects could also result in the FDA or foreign regulatory authorities refusing to approve the product candidate for any targeted indications. We, our partners, 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 product candidates are safe or effective.

We negotiated a special protocol assessment, or SPA, with the FDA for the planned pivotal clinical trial of our lead anti-cancer compound, Fodosine$^{tm}$, for treatment of CTCL. A previous pivotal clinical trial under an SPA of Fodosine$^{tm}$ for treatment of T-cell acute lymphoblastic leukemia was voluntarily put on hold by us. An SPA is an agreement between an applicant and the FDA on the design and the size of clinical trials that is intended to form the basis of a New Drug Application ( NDA ). Once the FDA and an applicant reach an agreement on an SPA, the SPA cannot be changed after the clinical trial begins, except in limited circumstances such as a change in the science or clinical knowledge about the conditions being studied. Any significant change to the protocols for a clinical trial subject to an SPA would require prior FDA approval, which could delay implementation of such a change and

continuation and completion of the related clinical trial. Receipt of the SPA does not ensure that Fodosine[tm] will receive FDA approval or that the process will be accelerated.

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Clinical trials are lengthy and expensive. We or our partners 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 partners successfully complete clinical trials for our product candidates, we or our partners might not file the required regulatory submissions in a timely manner and may not receive regulatory approval for the product candidate.

***If we or our partners 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 partners must obtain regulatory approval before marketing or selling our future drug products. If we or our partners 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. Neither the FDA nor foreign regulatory agencies have approved any of our drug product candidates. 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 product 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 product 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 product candidate, the approval may limit the indicated uses for a product 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, our clinical data and our manufacturing data at our facility. While we do store duplicate copies of most of our clinical data offsite and a significant portion of our data is included in regular backups of our systems, we could lose important 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 partners 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. In November 1995, the FDA issued 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.

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***If we fail to meet certain registration deadlines for common stock sold in August 2007, we face substantial liquidated damages.***

We have agreed to meet certain registration deadlines relating to the common stock, warrants and underlying common stock we sold in August 2007. If we fail to meet such deadlines, we face liquidated damages of up to approximately $7.8 million in cash. This would adversely affect our cash resources and our stock price.

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

Our drug product 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 product candidates that we or our partners develop will depend on a number of factors, including but not limited to:

our clinical evidence of safety and efficacy;

cost-effectiveness, convenience and ease of use of our product candidates;

their safety, availability and effectiveness relative to alternative treatments;

the actual and potential side effects or other reactions;

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