

Edgar Filing: CYTODYN INC - Form 10QSB

CYTODYN INC  
Form 10QSB  
October 13, 2004

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

FORM 10-QSB

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

For Quarter Ended: August 31, 2004  
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Commission File Number 000-49908  
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CYTODYN, INC.  
(Exact name of small business issuer as specified in its charter)

COLORADO  
(State or other jurisdiction of  
incorporation or organization)

75-3056237  
(I.R.S. Employer Identification No.)

200 W. DeVargas Street, Suite 1, Santa Fe, New Mexico  
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87501  
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(Address of principal executive offices)

(Zip code)

(505) 988-5520  
(Registrant's telephone number, including area code)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes    X    No  
-----    -----

Indicate the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date.

Common stock, no par value  
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8,069,307  
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Class

Number of shares outstanding at October 5, 2004

Transitional Small Business Disclosure Format:

Yes    No    X  
-----    -----

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This document is comprised of 11 pages.  
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INDEX

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Page  
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PART 1 - FINANCIAL INFORMATION

Item 1. Financial Statements

Condensed balance sheet, August 31, 2004 (unaudited).....3  
 Condensed statements of operations, three months ended  
 August 31, 2004 (unaudited) and 2003 (unaudited), and October 28,  
 2003 (inception) through August 31, 2004 (unaudited).....4  
 Condensed statements of cash flows, three months ended  
 August 31, 2004 (unaudited) and 2003 (unaudited) and October 28,  
 2003 (inception) through August 31, 2004 (unaudited).....5  
 Notes to condensed financial statements (unaudited).....6

Item 2. Management's Discussion and Analysis or Plan of Operation.....7

Item 3. Controls and Procedures.....9

PART 2 - OTHER INFORMATION

Item 1. Legal Proceedings.....9  
 Item 2. Changes in Securities and Small Business Issuer Purchases  
 of Equity Securities.....10  
 Item 3. Defaults Upon Senior Securities.....10  
 Item 4. Submission of Matters to a Vote of Security Holders.....10  
 Item 5. Other Information.....10  
 Item 6. Exhibits.....10

Signatures.....11

Part I, Item 1. Financial Statements

CYTODYN, INC.  
 (A Development Stage Company)  
 Condensed Balance Sheet  
 (Unaudited)

August 31, 2004

Assets

Current Assets:	
Cash .....	\$ 76,435
Prepaid expenses .....	9,854
	-----
Total current assets .....	86,289
Property and equipment, less accumulated	
depreciation of \$496 .....	6,006
Deposit .....	495
	-----
	\$ 92,790
	=====

Liabilities and Shareholders' Deficit

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Liabilities:	
Accounts payable .....	\$ 132,084
Accrued liabilities .....	9,327
Indebtedness to related parties (Note 2) .....	71,694
	-----
Total liabilities .....	213,105
	-----
Commitments and contingencies (Note 6) .....	--
Shareholders' deficit (Note 4):	
Preferred stock, no par value; 5,000,000 shares authorized, -0- shares issued and outstanding .....	--
Common stock, no par value; 25,000,000 shares authorized, 8,069,307 shares issued and outstanding .....	1,916,334
Additional paid-in capital .....	24,014
Accumulated deficit .....	(1,601,912)
Deficit accumulated during development stage .....	(458,751)
	-----
Total shareholders' deficit .....	(120,315)
	-----
	\$ 92,790
	=====

See accompanying notes to condensed financial statements

3

CYTODYN, INC.  
(A Development Stage Company)  
Condensed Statements of Operations  
(Unaudited)

	For the Three Months Ended August 31,		October 28, 2003 Through August 31, 2004
	2004	2003	
	-----	-----	-----
Operating expenses:			
General and administrative (Note 8) ....	\$ 120,409	\$ 5,043	\$ 458,139
Depreciation .....	292	--	496
	-----	-----	-----
Total operating expenses	120,701	5,043	458,635
	-----	-----	-----
Operating loss .....	(120,701)	(5,043)	(458,635)
Interest income .....	176	--	519
Interest expense .....	(182)	--	(635)
	-----	-----	-----
Loss before income taxes	(120,707)	(5,043)	(458,751)
Income tax provision (Note 5) .....	--	--	--
	-----	-----	-----

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Net loss .....	\$ (120,707)	\$ (5,043)	\$ (458,751)
	=====	=====	=====
Basic and diluted loss per share .....	\$ (0.01)	\$ (0.00)	
	=====	=====	
Basic and diluted weighted average common shares outstanding .....	8,069,307	5,362,640	
	=====	=====	

See accompanying notes to condensed financial statements

4

CYTODYN, INC.  
(A Development Stage Company)  
Condensed Statements of Cash Flows  
(Unaudited)

	For the Three Months Ended August 31,		October 28, 2003 Through August 31, 2004
	2004	2003	
	-----	-----	-----
Net cash used in operating activities .....	\$ (107,874)	\$ (5,043)	\$ (464,769)
	-----	-----	-----
Cash flows from investing activities:			
Property and equipment purchases .....	(3,167)	--	(6,502)
	-----	-----	-----
Net cash used in investing activities .....	(3,167)	--	(6,502)
	-----	-----	-----
Cash flows from financing activities:			
Capital contributions by president (Note 2) ...	512	4,500	512
Proceeds from notes payable issued to related parties (Note 2) .....	--	--	111,194
Repayment of notes payable to related parties (Note 2) .....	--	--	(50,000)
Proceeds from the sale of common stock (Note 4)	--	--	540,000
Payment of offering costs (Note 4) .....	--	--	(54,000)
	-----	-----	-----
Net cash provided by financing activities .....	512	4,500	547,706
	-----	-----	-----
Net change in cash .....	(110,529)	(543)	76,435

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Cash, beginning of period .....	186,964	3,238	--
	-----	-----	-----
Cash, end of period .....	\$ 76,435	\$ 2,695	\$ 76,435
	=====	=====	=====
Supplemental disclosure of cash flow information:			
Income taxes .....	\$ --	\$ --	\$ --
	=====	=====	=====
Interest .....	\$ 182	\$ --	\$ --
	=====	=====	=====

See accompanying notes to condensed financial statements

5

CYTODYN, INC.  
(A Development Stage Company)

Notes to Condensed Financial Statements  
(Unaudited)

Note 1: Basis of Presentation

The condensed financial statements presented herein have been prepared by the Company in accordance with the instructions for Form 10-QSB and the accounting policies in its Form 10-KSB filed for the year ended May 31, 2004 and should be read in conjunction with the notes thereto.

In the opinion of management, the accompanying condensed financial statements contain all adjustments (consisting only of normal recurring adjustments) which are necessary to provide a fair presentation of operating results for the interim periods presented. The results of operations presented for the three months ended August 31, 2004 are not necessarily indicative of the results to be expected for the year.

The Company is in the development stage in accordance with Statements of Financial Accounting Standards (SFAS) No. 7 "Accounting and Reporting by Development Stage Enterprises".

Financial data presented herein are unaudited.

Note 2: Related Party Transactions

During the three months ended August 31, 2004, the Company's president paid administrative expenses on behalf of the Company totaling \$4,500. The payment has been recorded as contributed capital and is included in the accompanying condensed financial statements as "Additional paid-in capital".

Note 3: Income taxes

The Company records its income taxes in accordance with SFAS No. 109, "Accounting for Income Taxes". The Company incurred net operating losses for all periods presented resulting in a deferred tax asset, which was fully allowed for by a valuation allowance; therefore, the net benefit and expense resulted in

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\$-0- income taxes.

6

### Part I. Item 2. Management's Discussion and Analysis or Plan of Operation

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CYTODYN, INC.  
(A Development Stage Company)

#### Plan of Operation

During the next 12 months, our objectives are:

- o To continue our clinical trials of Cytolin,
- o To continue our efforts to protect our technology by obtaining additional patents in The United Kingdom and the European Union,
- o To develop an established market for our shares, and raise funds to support our research and development efforts, the clinical trials relating to Cytolin, and our general and administrative expenses, and
- o To explore joint venture arrangements for other possible pharmaceutical products.

Continuing Clinical Trials. Phase I clinical trials were conducted by Symbion Research International under the sponsorship of Amerimmune, Inc. during 2002. We believe that the data from these trials support approval by the FDA of Phase II trials, and we intend to seek approval for the Phase II trials. We will work with Symbion International and their Phase I trial data and we plan to submit our application for approval of Phase II/III pivotal studies. If the Phase II/III study is approved, we expect it, together with the pre-Phase II/III efforts, to cost an estimated \$2,050,000 to \$3,350,000, plus estimated manufacturing and supply costs of \$350,000 to \$400,000. These trials can take anywhere from 29 to 42 months. Until we have met with the FDA, which we plan to do within the next 6 months, we cannot be certain what additional studies, assuming that Phase II/III study supports the efficacy and safety of Cytolin, will be required to receive marketing approval.

If we are unable to complete clinical trials on a timely basis, with favorable results, our costs will increase significantly and we may not have enough capital to support further research and development and continue in business. Also, if we incur significant delays in being able to market our product, even if we are ultimately able to do so, we will be delayed in earning revenues and probably will require additional financing to continue in business.

#### Patents

During fiscal year 2004, several European patents were granted with respect to our technology. The new patents are covered by our License Agreement with Allen D. Allen, our president. These patents are designated European Patent No. 94 912826.8, for the United Kingdom, Germany, France, Switzerland, Italy, the Netherlands, Portugal, Spain, and Sweden, and are the counterparts to our United States Patent No. 5424066. Patents are pending in those same countries which, if granted, will be the equivalent of our United States Patent No. 5651970. We estimate the costs associated with these pending patents to be approximately

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\$65,000, including amounts we have already spent. We may file additional patents during the current fiscal year if our research and development efforts warrant them, but we do not have any such potential patents identified at this time.

### Litigation

For a thorough discussion of our pending litigation, please see the section entitled "Legal Proceedings." In Part 2 Item 1.

We were plaintiffs in two pending cases, CytoDyn of New Mexico, Inc. et al., v. Amerimmune Pharmaceuticals, Inc. et al., Case number BC290154 and the other in Ventura County, in a case captioned CytoDyn, Inc., et al. v. Amerimmune, Inc. et al., Case number SC039250., each involving our rights to the patented technology underlying Cytolin and any other products we might wish to develop.

7

### Establishing a Market and Obtaining Funding

We will require funding during the 2005 fiscal year in order to continue our research and development efforts and to stay in business. The amount of that funding is directly related to the clinical trials we are able to conduct and the amounts we will need for our company operations.

We filed a registration statement on Form SB-2 on June 1, 2004, covering the sale of 250,000 shares of common stock at \$0.75 per share, for total proceeds of \$187,500, to be used primarily for general and administrative expense, SEC compliance costs, and legal and accounting fees. This registration statement has not yet gone effective, and we cannot assure that it will or that the shares that would be offered would sell. We intend, if this offering does go effective and if the shares sell, to seek an established market for our securities on an established quotation system, such as the NASD over-the-counter bulletin board, which we hope would give us a wider base of investors. We may not, however, be able to achieve our goals.

In connection with our private placement of securities in late 2003 and early 2004, we granted certain registration rights to the purchasers of our common stock and to our financial representative. The holders of these shares may demand that we register their shares for sale. We estimate that such a registration could cost us approximately \$30,000, for which we would have to find funding.

In addition to operating funds, we will need from approximately \$750,000 to \$3,750,000 for research and development, including clinical trials, and manufacturing and supply costs, depending upon whether we are approved by the FDA to conduct a Phase II/III pivotal study.

We do not have any of this funding arranged or secured, and we do not yet have plans for raising the funding we require. We anticipate that we will seek the funding through further equity offerings, either by private placement or by registered offering, or by possible joint venture arrangements with other parties. If we are unable to secure the necessary funding, we will not be able to conduct our research and development activities or to continue in business.

### Exploring Joint Ventures

While we continue to pursue FDA approval of our Cytolin product, we are also considering entering into joint ventures to develop other types of products. We have, for instance, entered into a nondisclosure agreement with another development stage biotech company to discuss the possibility of the joint development of drugs to treat neuropsychiatric diseases or disorders. These

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discussions are in the early stages and we do not know if we will enter into a joint venture or other arrangement with this company or if any products might ensue from our efforts.

We may also pursue joint ventures or other arrangements to obtain funding for our Cytolin-related endeavors, but we have not pursued this possibility and do not have any prospects at this time.

Other Matters

We do not expect, in the next 12 months, to make any significant expenditures for equipment, nor do we expect to make any significant changes in the number of employees that we have. We have no off-balance sheet arrangements.

Part I. Item 3. Controls and Procedures

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(a) Evaluation of disclosure controls and procedures

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We maintain controls and procedures designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission. Based upon their evaluation of those controls and procedures performed within 90 days of the filing date of this report, our chief executive officer and the chief financial officer concluded that our disclosure controls and procedures were adequate.

(b) Changes in internal controls

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There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the evaluation of those controls by the chief executive officer and chief financial officer.

Part 2. Other Information

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Item 1 - Legal Proceedings.

CytoDyn, Inc.. v. Amerimmune, Inc. et al., Los Angeles Superior Court

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Case No. BC 290154.

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The court dismissed the case stating that our attorney did not present the evidence in an orderly and logical fashion. We may appeal this decision if it is cost effective in comparison to our other remedies available to us. The officer and directors of CytoDyn of New Mexico will continue to defend the cross-complaint. Management believes the cross-complaint is without merit and chances of an unfavorable outcome are remote.

CytoDyn, Inc., et al. v. Amerimmune, Inc. et al., Case number SC039250,

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California Superior Court in and for the County of Ventura.  
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The principal relief sought was a declaration that the license granted and the assignment of the technology, patents and drug application made pursuant to the Conditional License Agreement were terminated no later than September 12, 2001, and that Allen and we are the owners of the technology, patents and investigational new drug application, free of any claims of the defendants. Costs, attorney's fees, and other "just and proper" relief also were sought.

This case was decided in favor of the plaintiffs, CytoDyn and Allen, on October 4, 2004 and the plaintiffs were awarded the declaratory relief sought and attorneys' fees.

Symbion Research International, Inc., v. Amerimmune, Inc. et al., Case  
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number SC035668, California Superior Court in and for the County of  
-----  
Ventura.  
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We were not a party to this action; however the action affects intellectual property which is important to us.

A default was entered against Amerimmune, Inc. on December 18, 2003. A judgment was entered in favor of Symbion International on September 17, 2004 granting the declarative relief sought.

9

The intellectual property generated in the early phase FDA clinical trials is necessary to obtain approval for, and to conduct, further FDA clinical tests of Cytolin. Because a satisfactory result was obtained in this action, we anticipate negotiating an agreement with Symbion that will allow the use in subsequent phases of clinical test of Cytolin of the research data generated in the early phases.

Item 2 - Changes in Securities and Small Business Issuer Purchases of Equity Securities.

No response required.

Item 3 - Defaults Upon Senior Securities.

No response required.

Item 4 - Submission of Matters to a Vote of Security Holders.

No response required.

Item 5 - Other Information.

No response required.

Item 6 - Exhibits and Reports on Form 8-K.

(a) Exhibits:

- 1. 31.1: Certification by the CEO
- 2. 31.2: Certification by the CFO

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- 3. 32.1: Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 - CEO
- 4. 32.2: Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 - CFO

(b) Reports on Form 8-K:

None.

10

SIGNATURES

The financial information furnished herein has not been audited by an independent accountant; however, in the opinion of management, all adjustments (only consisting of normal recurring accruals) necessary for a fair presentation of the results of operations for the three months ended August 31, 2004 have been included.

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

CYTODYN, INC.  
(Registrant)

DATE: October 12, 2004  
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BY: /s/ Allen D. Allen  
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Allen D. Allen  
President and CEO

11