ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
September 17, 2002

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): September 17, 2002
(September 17, 2002)

ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

DELAWARE	39040	13-4022871
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

100 Painters Drive
Chadds Ford, Pennsylvania 19317

(Address of principal executive offices) (Zip Code)

(610) 558-9800

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Item 7. Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.

Not applicable.

(b) Pro Forma Financial Information.

Not applicable.

(c) Exhibits.

Exhibit Number	Description
99.1	Slide Presentation of Endo Pharmaceuticals Holdings Inc. dated September 17, 2002

Item 9. Regulation FD Disclosure.

On September 17, 2002, the Registrant intends to make a slide presentation at the Bear Stearns 15th Annual Healthcare Conference in New York, New York, a copy of which presentation is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

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, hereunto duly authorized.

ENDO PHARMACEUTICALS HOLDINGS INC.
(Registrant)

By: /s/ CAROL A. AMMON

Name: Carol A. Ammon
Title: Chairman & Chief Executive Officer

Dated: September 17, 2002

INDEX TO EXHIBITS

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Exhibit 99.1

COVER SLIDE

[ENDO LOGO]

Endo Pharmaceuticals

Bear Stearns
15th Annual Healthcare Conference

September 17, 2002

SLIDE 1

Forward-Looking Statements
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This presentation contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on management's beliefs and assumptions, current expectations, estimates and projections. These statements are subject to risks and uncertainties and, therefore, actual results may differ materially from those expressed or implied by these forward-looking statements. Forward-looking statements are not historical facts and include information regarding the Company's possible or assumed results of operations. Also, statements or expressions that are preceded by, followed by, or that include, the words "believes," "anticipates," "plans," "expects," "intends," "estimates" or similar expressions are forward-looking statements. Endo's estimated or anticipated future results, product performance or other non-historical facts are forward-looking and reflect Endo's current perspective on existing trends and information. Many of the factors that will determine the Company's future results are beyond the ability of the Company to control or predict. The reader should not rely on any forward-looking statement. The Company undertakes no obligations to update any forward-looking statements whether as a result of new information, future events or otherwise. Several important factors, in addition to the specific factors discussed in connection with these forward-looking statements individually, could affect the future results of Endo and could cause those results to differ materially from those expressed in the forward-looking statements contained herein. Important factors that may affect future results include, but are not limited to: the Company's ability to successfully develop, commercialize and market new products; results of clinical trials on new products; competition for the business of the Company's branded and generic products, and in connection with the Company's acquisition of rights to intellectual property assets; market acceptance of the Company's future products; government regulation of the pharmaceutical industry; the Company's dependence on a small number of products; the Company's dependence on outside manufacturers for the manufacture of its products; the Company's dependence on third parties to supply raw materials and to provide services for the core aspects of its business; new regulatory action or lawsuits relating to the Company's use of narcotics in most of its core products; the Company's exposure to product liability claims and product recalls and the possibility that the Company may not be able to adequately insure itself; the Company's ability to protect its proprietary technology; the Company's ability to successfully implement its acquisition strategy; the availability of controlled substances that constitute the active ingredients of some of the Company's products and products in development; the availability of third-party reimbursement for the Company's products; the Company's dependence on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of its total net sales; and other risks and uncertainties detailed in Endo's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on June 9, 2000, as amended, and in Endo's Registration Statement on Form S-3 dated October 17, 2001. Readers should evaluate any statement in light of these important factors.

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Profile
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- Endo is a specialty pharmaceutical company engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat and manage pain

- Endo will leverage its strengths to capture growth opportunities in the rapidly growing pain management market and other complementary areas

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Company History
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1920	Endo founded
1950	Percodan(R) launched
1969	Endo sold to DuPont
1971	Percocet(R) launched
1997	Management buyout of Endo from DuPont Merck
1998	Lidoderm(R) licensed from Hind Healthcare
2000	Endo goes public; Algos acquired
2001	October: Follow-on offering completed

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Aggressive Pain Focus
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- Pain Management is a tremendous growth area:
  - Compounded growth rate of >28% annually
  - Pain community is extremely aggressive
  - Prescribing physician base highly concentrated

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Total Prescription Pain Market
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Bar Chart Reflecting Data Below:

	1998	1999	2000	2001
Sales (billions)	$6.8	$9.3	$11.9	$14.3

Graph Shows a Compounded Annual Growth Rate of 28%

Source: IMS

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Key Drivers of Market Growth

- Changing attitudes toward pain management
  - Physicians
  - Patients
- Changing environment toward treatment of pain
  - Guideline changes
  - Pain management now recognized as a board certified specialty
- Favorable demographics
  - Aging population
- Increase in number of surgical procedures

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Analgesics: 2001 the second most prescribed medication

2000	2001
1. Vascular agents	1. Anti-infectives
2. Psychotherapeutics	2. Analgesics
3. Anti-infective	3. Psychotherapeutics
4. Analgesics	4. Vascular agents
5. Hormones	5. Hormones
6. Respiratory Therapy	6. Respiratory Therapy
7. Gastrointestinal	7. Cough/Cold Preps
8. Anti-arthritics	8. Anti-arthritics
9. Diuretics	9. Gastrointestinal
10. Diabetes Therapy	10. Cholesterol Reducers & Lipotropics
Narcotics comprise approximately 75% of analgesic prescriptions	Narcotics comprise approximately 76% of analgesic prescriptions

Source: IMS Prescription Data

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Narcotic Analgesics

Bar Chart Reflecting Data Below:

	1998	1999	2000	2001
Sales (billions)	$1.6	$2.1	$2.7	$3.6

Graph Shows a Compounded Annual Growth Rate of 31%

Source: IMS

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Endo's Products Address the Pain Continuum

	Mild	Moderate	Moderately Severe	Severe
Marketed Products		Lidoderm(R) Nubain(R) Zydone(R)	Percocet(R) Percodan(R) Endocet(R) Endodan(R)	Numorphan(R) Percolone(R) Hydromorphone Morphine ER
Pipeline Products		HydrocoDex(TM)	PercoDex(TM)	MorphiDex(R) Oxymorphone IR/ER OxycoDex(TM) Oxycodone ER

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Endo's Pain Management Product Offering

- Established Portfolio of Branded Products:
  - Percocet(R)
  - Lidoderm(R)
  - Other established brands including:
    - Percodan(R)
    - Zydone(R)
- Difficult-to-Develop Generics:
  - MS Contin generic

> Oxycontin generic
  - subject of litigation
  - tentative approval granted by FDA July 2002

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Established Portfolio of Brands: Percocet(R)

1971	o Percocet(R) 5.0/325 launched
1999	o Endo launches new strengths of Percocet(R)
2001	o April 2001 - Generics of 7.5/500 and 10.0/650 introduced
2001	o November 2001 - New strengths approved and launched:
	> Percocet(R) 7.5/325 and Percocet(R) 10.0/325

"Gold Standard"
in pain
management

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Percocet(R) Prescriptions

Line Graph Reflecting Data Below:

	1994	1995	1996	1997	1998	1999	2000	2001
Prescriptions (millions)	2.0	1.8	1.6	1.4	1.4	1.3	2.0	2.2

Source: IMS

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Percocet(R) Net Sales

Bar Chart Reflecting Data Below:

	1999	2000	2001	1H 2001	1H2002
(in millions)	$51.5	$92.4	$101.0	$56.4	$64.1

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Established Portfolio of Brands: Lidoderm(R)

- First FDA-approved drug for the treatment of post-herpetic neuralgia (PHN), a form of neuropathic pain
- Herpes Zoster ("shingles") afflicts ~ one million patients annually
- Approximately 70% experience some pain:
  - Acute
  - Chronic (PHN)
- PHN occurs in about 20% of shingles patients
- Lidoderm(R) provides analgesia

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Lidoderm(R) Prescriptions

Line Graph Reflecting Data Below:

	Quarter Ended									
	Mar-00	Jun-00	Sep-00	Dec-00	Mar-01	Jun-01	Sep-01	Dec-01	Mar-02	Jun-02
Prescriptions (thousands)	28	39	49	60	68	81	96	119	139	170

Source: IMS

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Lidoderm(R) Net Sales

Bar Chart Reflecting Data Below:

1999 2000 2001 1H 2001 1H 2002

(in millions)	$5.7	$22.5	$40.9	$10.7	$ 35.8

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Sales by Product

Bar Chart Reflecting Data Below:

	1998	1999	2000	2001
		(in millions)		
Generics	$33.7	$44.8	$47.1	$ 84.3
Other Brands	$30.1	$36.5	$35.4	$ 25.8
Lidoderm(R)	$ 0.0	$ 5.7	$22.5	$ 40.9
Percocet(R)	$44.6	$51.5	$92.4	$101.0
	$108.4	$138.5	$197.4	$252.0

Graph Shows a Compounded Annual Growth Rate of 33%

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Targeted Sales and Marketing

- Direct marketing through national dedicated sales force:
  - 160 community-based field representatives (contract)
  - 70 specialty institutional representatives (internal)
- Focus on high-prescribing physicians in:
  - Pain management
  - Surgery
  - Oncology
  - Primary care

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Management Expertise

- Average of approximately 20 years of experience in the pharmaceutical industry
- Senior leadership instrumental in buy-out from DuPont Merck and formation of independent company
- Proven track record

> Have received FDA approval on more than 15 new products and product extensions since 1997

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R&D Expertise

- Core expertise in narcotic analgesics
  - Pipeline products launched in the past four years contributed 54% of 2001 net sales
- Four NDA products in Phase III and three NDA products in Phase II clinical trials
- Successful and proven record with the FDA

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Substantial Pipeline

Key Pipeline Products	Branding	Development stage
MorphiDex(R)	Branded	Phase III
Oxymorphone ER	Branded	Phase III
Oxymorphone IR	Branded	Phase III
Immunol(TM)	Branded	Phase III
HydrocoDex(TM)	Branded	Phase II
OxycoDex(TM)	Branded	Phase II
PercoDex(TM)	Branded	Phase II
Oxycodone ER	Generic	Tentative FDA approval; subject to litigation

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MorphiDex(R) (morphine + dextromethorphan)

- Dextromethorphan enhances morphine analgesia
- Pivotal chronic dosing study previously completed
  - "Morphine sparing"
  - "Longer duration of pain relief"
- Long-term clinical experience: Safety established

In response to Algos' "not-approvable" letter:

o Multiple-dose Phase III studies in chronic pain underway

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MorphiDex(R) (morphine + dextromethorphan)
==========

o Multiple dose Phase III studies in chronic pain

> three-month treatment period

> 200-300 patients per study

> primary objective:
- morphine sparing (2 studies)
- superior analgesia (1 study)

> secondary objectives:
- define lowest fixed-dose MS/DM ratio (1 study)
- "tolerance" (3 studies)

o First study (announced 6/24/02) did not meet primary or secondary endpoint

o Anticipate announcement of results from second and third studies in Q4 2002

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Oxymorphone ER/IR
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o Pure opioid agonist; marketed in U.S. since 1960 as injection and suppository

o New oral extended and immediate release formulations

> ER version co-developed with Penwest Pharmaceuticals

o First "new" opioid in decades

o Efficacy demonstrated

> 1,500+ cancer and non-cancer patients in clinical program

o Abstracts presented at 2002 World Pain Congress in August

o Currently expect to file NDA applications in second half of 2002

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Historical Financial Summary

Bar Chart Reflecting Data Below:

	1999*	2000*	2001
		(in millions)	
Net Sales	$138.5	$197.4	$252.0
Gross profit	$ 80.3	$134.4	$177.1
Consolidated EBITDA**	$ 27.7	$ 62.1	$ 79.5

* Pro-forma for Algos acquisition.
** Excludes non-cash COGS.

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YTD June Financial Summary

Bar Chart Reflecting Data Below:

	1H 2001	1H 2002
	(in millions)	
Net Sales	$ 107.2	$ 174.9
Gross profit	$ 73.6	$ 128.2
Consolidated EBITDA (1)	$ 31.1	$ 60.9

(1) Excludes non-cash COGS.

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Projected Financial Summary

Bar Chart Reflecting Data Below:

	2001	2002E		2001	2002E
	(in millions)			(in millions)	
Net Sales	$252.0	$350.0	Consolidated EBITDA*	$79.5	$125.0

* Excludes non-cash COGS.

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Recent Developments

- Added new Phase III pipeline product through acquisition of BML Pharmaceuticals
  - prescription oral rinse for management of oral mucositis
- Internalized specialty sales force
  - strengthens our sales capabilities
  - reflects continuing strength of Lidoderm(R) and Percocet(R)
- Announced tentative FDA approval for Oxycodone Extended Release Tablets
  - final approval contingent upon favorable litigation outcome
- Amended manufacturing agreement with BMS
  - ensures smooth transition to Novartis Consumer Health
- Repaid BMS Promissory Notes
  - strengthens balance sheet - debt free

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Proven Track Record

Strategy	Achievement
o Leverage brand equity of products	|X| Launched new strengths of Percocet(R) in November 1999 and November 2001
o Line extensions	|X| Launched Zydone(R) in February 1999
o Develop difficult generics	|X| Only AB-rated generic of all five strengths of MS Contin(R) on the market |X| First to file 10, 20 and 40 mg generic version of Oxycontin(R)
o Acquire products in pain management and related areas	|X| Launched Lidoderm(R) for PHN in September 1999 |X| Immunol in late-stage development

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2002 Expected Milestones
==========

o Completion of our second and third Phase III clinical studies on MorphiDex(R)

o File NDAs for extended-release and immediate-release oxymorphone

o Continue to advance future product line through:

> Advancement of other pipeline projects

> Acquire and in-license complementary products, compounds and technologies

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Summary
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Endo is well positioned to capture profitable growth in the fast-expanding pain management market through our:

|X| Established portfolio of branded products

|X| Targeted national sales and marketing infrastructure

|X| Experienced, successful management team

|X| Research and development expertise

|X| Substantial pipeline

|X| Strong financial position

END SLIDE 32

[ENDO LOGO]

Endo Pharmaceuticals

(Nasdaq: ENDP)