



Providing specialty pharmaceuticals that treat infertility and other women's healthcare conditions in a targeted, patient-friendly way.

# Building Shareholder Value Focused

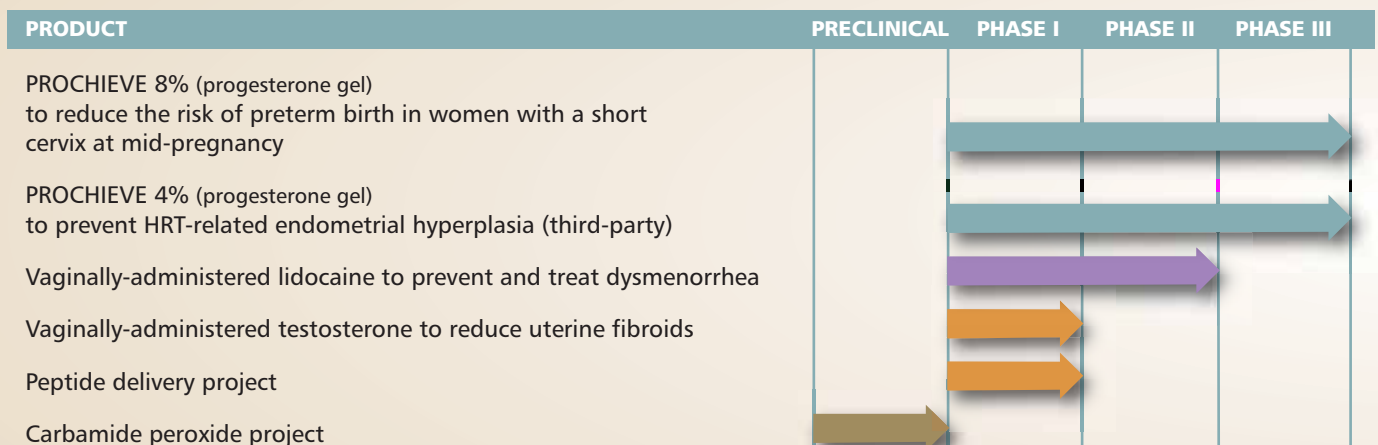
## COMPANY PROFILE

Columbia Laboratories develops and markets specialty pharmaceuticals that utilize our proprietary bioadhesive drug delivery system. We are primarily focused on the U.S. infertility market, to which we promote CRINONE 8% and PROCHIEVE 8%, two brands of our bioadhesive natural progesterone vaginal gel. These products are used as part of an Assisted Reproductive Technology treatment for infertility and to provide pregnancy support throughout the first trimester. We also market STRIANT to treat hypogonadism in men. We derive additional revenues through ex-U.S. marketing agreements for CRINONE 8%, STRIANT, and an OTC product, global agreements for a second OTC product, and a U.S. marketing agreement for PROCHIEVE 4%.

We are building revenues by driving prescription growth and increasing market penetration of CRINONE 8%. We also seek opportunities to market additional products to our physician targets and thereby leverage our sales force; to develop new indications for current products and new products using our drug delivery technology for Columbia or partners; and, to partner or divest products and market segments that fall outside our core women's healthcare focus.

**Our Mission** is to become a leading player in the women's healthcare market, providing patient-friendly solutions for infertility and obstetric, gynecologic, and other medical conditions.

## RESEARCH AND DEVELOPMENT PROGRAMS



## PROGESTERONE PRODUCTS

BRAND	INDICATION	MARKETING:	U.S.	FOREIGN
CRINONE® 8% (progesterone gel)	Infertility and pregnancy support		CBRX	Merck Serono S.A.
PROCHIEVE® 8% (progesterone gel)	Same product, same indications as CRINONE 8%		CBRX	n/a
PROCHIEVE® 4% (progesterone gel)	Secondary amenorrhea		Ascend Therapeutics, Inc.	n/a



## OTHER PRODUCTS

BRAND	INDICATION	MARKETING:	U.S.	FOREIGN
STRIANT® (testosterone buccal system)	Hypogonadism in men		CBRX	Ardana plc (18 European countries) Mipharm SpA (Italy)
RepHresh® Vaginal Gel	OTC feminine hygiene product to eliminate vaginal odor		Lil' Drug Store Products, Inc.	Lil' Drug Store Products, Inc.
Replens® Vaginal Moisturizer	OTC vaginal moisturizer		n/a	Lil' Drug Store Products, Inc.

# PROCHIEVE 8% The Short Cervix Opportunity

Columbia's research and development pipeline is focused on developing new products and new indications for current products. Each opportunity is for a women's healthcare condition that affects a large patient population with unmet medical need. Our lead program is developing PROCHIEVE 8% to reduce the risk of preterm birth in women with a short cervix at mid-pregnancy.

Preterm birth, defined as birth before 37 weeks gestation, is one of the most serious problems in obstetrics. Over 500,000 babies are born prematurely every year despite intensive preventive measures. Preterm birth causes 60 to 70% of all infant deaths and is a leading cause of healthcare costs throughout the lives of infant survivors. However, there are no FDA-approved therapies to prevent preterm birth.

In recent years, several clinical studies have been published that suggest administering progesterone to women with a short cervix at mid-pregnancy may be a key to reducing the rate of preterm birth:

- A clinical study published in 2003 found that prophylactic use of progesterone extends the time to delivery among patients who had a preterm labor episode<sup>1</sup>;
- A 2006 study found that a short cervix is the most important single predictor of preterm birth<sup>2</sup>; and,
- A 2007 study found that women with a short cervix are the responders to vaginal progesterone therapy<sup>3</sup>.

Then, in October 2007, Columbia published results of a planned secondary analysis from our Phase III study (COL-1620-300) which demonstrated treatment with PROCHIEVE 8% reduced early preterm birth and improved infant outcomes in women with a short cervix at mid-pregnancy<sup>4</sup>.

Based on the growing body of data and positive short cervix findings from COL-1620-300, Columbia is conducting a Phase III clinical trial to further study PROCHIEVE 8% for this indication. We call this randomized, double-blind, placebo-controlled study the PREGNANT (PROCHIEVE Extending Gestation A New Therapy) Study. The primary endpoint is a reduction in the

incidence of preterm birth at less than or equal to 32 weeks gestation versus placebo. We expect to report results of this study in the first half of 2009. We are excited by the high level of interest in our work among maternal-fetal medicine specialists, and are pleased to be at the cutting edge of research in this important area.

The total potential market for short cervix patients is estimated at between \$250 million and \$1.6 billion. If the PREGNANT study is successful, data from this study, coupled with the positive data from the planned secondary analysis of our COL-1620-300 study, would place Columbia in a strong position to influence the full short cervix marketplace.

<sup>1</sup>da Fonseca EB, Bittar RE, Carvalho MH, Zugaib M. Prophylactic administration of progesterone by vaginal suppository to reduce the incidence of spontaneous preterm birth in women at increased risk: a randomized placebo-controlled double-blind study. *Am J Obstet Gynecol.* 2003; 188: 419-424.

<sup>2</sup>To MS, Skentou CA, Royston P, Yu CK, Nicolaidis KH. Prediction of patient-specific risk of early preterm delivery using maternal history and sonographic measurement of cervical length: a population-based prospective study. *Ultrasound Obstet Gynecol.* 2006; 27: 362-367.

<sup>3</sup>da Fonseca EB, Celik E, Parra M, Singh M, Nicolaidis KH. Progesterone and the risk of preterm birth among women with a short cervix. *N Engl J Med.* 2007; 357: 462-469.

<sup>4</sup>DeFranco EA, O'Brien JM, et al. Vaginal progesterone decreases the risk of early preterm birth and improves neonatal outcome in women with a short cervix. *Ultrasound Obstet Gynecol.* 2007; 30: 697-705.

# 2007 Research

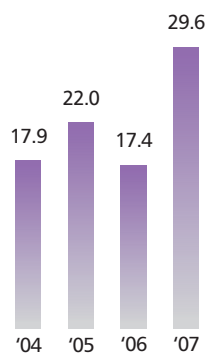
TO MY FELLOW SHAREHOLDERS:

## Seeking Opportunities to Expand Our Product Base



Robert S. Mills  
President and Chief Executive Officer

Annual Revenue  
Snapshot: 2004-2007  
(dollars in millions)



2007 was a landmark year for Columbia Laboratories. We recorded the highest revenues in the Company's history. Revenues increased 70% over 2006 levels, and we hit the top end of our 2007 revenue guidance. Underlying this growth was an 84% increase in revenues from our progesterone franchise: CRINONE® 8%, PROCHIEVE® 8% and PROCHIEVE 4% progesterone vaginal gels. 2007 was our first year marketing CRINONE 8% following the December 2006 acquisition of U.S. marketing rights for that product. We are very pleased with the market response to our efforts.

### Organic Growth in Infertility

We intend to be a major player in the infertility market. Our 2008 strategy is to grow CRINONE 8% revenues by attacking the large market shares held by pharmacy compounded intramuscular progesterone injections and progesterone suppositories. Combined, these two delivery methods represent 75% of the total progesterone market.

Our 35-person sales force is armed with data from 16 clinical studies comparing CRINONE 8% to other forms of progesterone. These studies show that with just one dose per day, CRINONE 8% is equally effective as, and in some cases numerically more effective than, all the other delivery systems for progesterone. More importantly, six of the 16 studies included a preference arm as part of the study. In those six studies, CRINONE 8% was preferred on a statistically significant basis over each of the other delivery systems. This compelling body of data supports our key message that CRINONE 8% is a patient-friendly product that effectively delivers natural progesterone



### Developing New Products

*We continue to explore new applications for our BDS technology. There are many promising products in our development pipeline as well as licensing opportunities to apply BDS to strategic partners' compounds to address indications outside our therapeutic areas of focus.*



# & Development



reach the 14,000-plus physicians who are likely to prescribe progesterone for secondary amenorrhea but who are not on Columbia's infertility target list. We expect sales of PROCHIEVE 4% will increase significantly over the five-year agreement term, while allowing Columbia to remain focused on the specialized infertility market.

### R&D: New Indications

Based on positive results obtained from a planned secondary analysis of data from our Phase III recurrent preterm birth study, COL-1620-300, we are now conducting the PREGNANT (**PROCHIEVE Extending GestatioN A New Therapy**) Study, a Phase III clinical trial evaluating PROCHIEVE 8% to reduce the risk of preterm birth in women with a cervix measuring 1.0 to 2.0 centimeters at mid-pregnancy as measured by transvaginal ultrasound.

This opportunity addresses a market estimated at between \$250 million and \$1.6 billion. We are pleased to be in a position to pursue this lucrative market at a relatively small cost to Columbia, and will aggressively advance the PREGNANT Study in 2008. As of March 31, 2008, seven of the 19 study sites have received Institutional Review Board approvals, and patient recruiting efforts are underway. We expect to fully recruit and complete the treatment phase of this important clinical trial in 2008, with all the babies delivered in time to report results in the first half of 2009. Assuming positive data from the PREGNANT Study, combined with the positive secondary analysis data from our COL-1620-300 study, we should be in a very strong position to influence the short cervix marketplace.

to the uterus. Our Infertility Advisory Committee, comprised of nine leading reproductive endocrinologists, is providing insight on how best to leverage this impressive body of data to increase market penetration of CRINONE 8%.

To support our sales force efforts, we will maintain a high level of visibility with our key audience. We are rolling out our infertility speakers' bureau program in 2008 and look forward to presentations on behalf of CRINONE 8% by key opinion leaders and reproductive endocrinologists throughout the country. We will also maintain a strong presence with the American Society of Reproductive Medicine at its annual meeting in October.

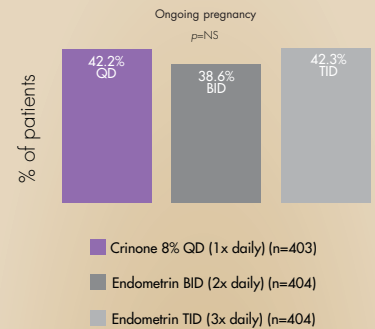
### Growth through Partnerships

We fully expect CRINONE 8% will remain a key revenue driver in 2008. In addition to increased U.S. sales, we anticipate continued growth in the global market. We are particularly excited at the possibility of approval in China, which our partner Merck Serono may receive this year.

On January 1, 2008, Ascend Therapeutics began marketing PROCHIEVE 4% to obstetricians and gynecologists in the U.S. Their 100-person sales force can effectively

### Comparable Efficacy With Fewer Doses

Once daily Crinone 8% is equally effective versus Endometrin® BID/TID<sup>1</sup>



## CRINONE® 8%

“Luteal support with [Crinone 8%] is as effective as the intramuscular route, but in addition has the advantage of being more accepted and tolerated by patients.”

—Saucedo 2000

<sup>1</sup> Doody K, Shamma N, Paulson R, Baker S, Blake E, Yankov V. Endometrin for luteal phase support in a randomized, controlled, open-label, prospective IVF clinical trial using a combination of Menopur and Bravelle. *Fertil Steril.* 2007;87 (Suppl 2): S24. Abstract P-34.

# Broader Markets

# Progesterone

<b>94%</b> found Crinone 8% easier to use than IM progesterone <sup>1</sup>	<b>84%</b> preferred Crinone 8% to IM progesterone <sup>1</sup>	<b>87%</b> preferred Crinone 8% to vaginal suppositories <sup>1</sup>	<b>85%</b> preferred Crinone 8% to vaginally administered capsules <sup>2</sup>
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## R&D: New Products

We continue to advance our vaginal lidocaine candidate to prevent and treat the severe uterine cramps that result in the debilitating pain of dysmenorrhea. In the U.S. alone, this common, painful condition seriously affects about 5.6 million women aged 20 to 45 to the point where they frequently miss work. We estimate the

total market opportunity for this patient group alone could be \$1.7 billion to \$3.4 billion. An additional market segment is menstruating women under age 20, in which group dysmenorrhea can be even more prevalent.

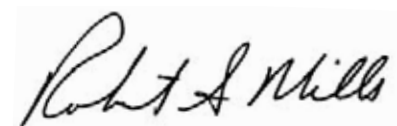
Building on positive results of our multi-dose pharmacokinetic study, which demonstrated safe blood levels from our

ensure maximum market penetration for this product. We would seek to retain the OB/GYN market, while partnering to address the general and family practice markets which fall outside our strategic focus. Our ultimate goal is to file with the FDA, and gain approval, for vaginal lidocaine in 2010.

I am extremely pleased with the progress we made in 2007 and believe that 2008 will be another year of strong performance for Columbia. We expect to again post record revenues, and are targeting 18 to 35% revenue growth year over year. Add to that completion of the Phase II lidocaine trial and completion of patient recruitment in and the treatment phase of the PREGNANT Study and 2008 becomes a pivotal year for Columbia.

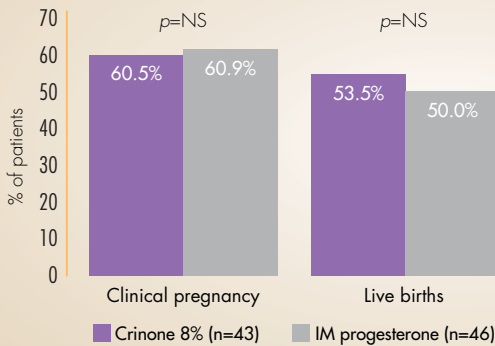
I look forward to the continued dedication from Columbia's many talented employees and the ongoing support of our customers, partners, and loyal shareholders as we continue to attain significant financial milestones and achieve major advances in women's reproductive health.

Sincerely,



Robert S. Mills  
President and Chief Executive Officer  
Columbia Laboratories, Inc.

## CRINONE 8%: Comparable Clinical Pregnancy and Live Birth Rates versus IM Progesterone



These study results are from a prospective study of 89 women receiving progesterone for an IVF-ET cycle. Patients received either Crinone 8% (90 mg QD) or IM progesterone (50 mg QD). In both groups, progesterone support was begun two days after oocyte retrieval and continued until the pregnancy test was performed and for up to 12 weeks gestation in the case of pregnancy.

Schoolcraft WB, Hesla JS, Gee MJ. Experience with progesterone gel for luteal support in a highly successful IVF programme. *Hum Reprod.* 2000;15:1284-1288.

delivery system, we are conducting a 75-patient Phase II study in dysmenorrhea. We expect to conclude enrollment in April and plan to announce results in the third quarter of 2008. If the Phase II data are positive, we will likely meet with the FDA and begin designing the Phase III program for lidocaine while simultaneously exploring partnership opportunities for this product candidate. Our goal is to co-develop and co-market vaginal lidocaine to



Our bioadhesive vaginal gel products use this pre-filled applicator for simple, patient-friendly administration.



<sup>1</sup>Levine H. Luteal support from the vaginal progesterone (P) gel Crinone 8%: preliminary results of multicenter trial show higher pregnancy rates than historical controls. *J Soc Gynecol Investig.* 2000; 7 (suppl). Abstract 571.

<sup>2</sup>Simunic V, Tomic V, Tomic J, Nizic D. Comparative study of the efficacy and tolerability of two vaginal progesterone formulations, Crinone 8% gel and Utrogestan capsules, used for luteal support. *Fertil Steril.* 2007; 87: 83-87.

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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2007  
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 1-10352

**COLUMBIA LABORATORIES, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**59-2758596**

(I.R.S. Employer  
Identification No.)

**354 Eisenhower Parkway  
Livingston, New Jersey**

(Address of Principal Executive Offices)

**07039**

(Zip Code)

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act:

**Common Stock, \$.01 Par Value**

(Title of Each Class)

**NASDAQ Global Market**

(Name of Exchange on Which Registered)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  
Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.  
Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of Common Stock held by non-affiliates of the registrant on June 30, 2007, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing price on that date of \$2.41, was \$123.1 million.

Number of shares of Common Stock of Columbia Laboratories, Inc. issued and outstanding as of March 3, 2008 are 51,961,789.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Columbia Laboratories, Inc. ("Columbia" or the "Company") Proxy Statement for the 2008 Annual Meeting of Shareholders (the "Proxy Statement") are incorporated by reference into Part III of this Form 10-K. We expect to file our Proxy Statement with the United States Securities and Exchange Commission ("SEC") and mail it to shareholders on or before April 7, 2008.

## **Restatement of Previously Issued Financial Statements**

We restated our historical audited financial statements for the fiscal years ended December 31, 2006, 2005, and 2004 and our unaudited financial information for the quarters ended March 31, 2007, June 30, 2007, September 30, 2007, and March 31, 2006, June 30, 2006 and September 30, 2006. These restatements and revisions primarily reflect adjustments to:

- Correct previously reported interest expense for financing agreements to correct for understatement in 2004 and 2005 and overstatement in 2006, along with the respective increase or decrease in net loss and the impact on outstanding loan balances and to increase or decrease the accumulated deficit.
- Correct the classification of the contingently redeemable Series C Convertible Preferred Stock from Shareholders Equity to temporary equity.



COLUMBIA LABORATORIES, INC.

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Fiscal Year Ended December 31, 2007

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\* Items 11, 12, 13, 14 and portions of Item 10 are incorporated by reference to the Company’s 2008 Proxy Statement.

The “Company,” “Columbia,” “we,” “our” and “us” as used in this Annual Report on Form 10-K refer to Columbia Laboratories, Inc., a Delaware corporation, and its subsidiaries.

“CRINONE®,” “PROCHIEVE®” and “STRIANT®” are registered trademarks of Columbia Laboratories, Inc. RepHresh®, Replens® and Advantage-S® are registered trademarks of Lil’ Drug Store Products, Inc. Other brands, names and trademarks contained in this Annual Report are the property of their respective owners.

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## PART I

### Item 1. Business

#### General

We are in the business of developing, manufacturing and selling pharmaceuticals products that utilize our proprietary bioadhesive drug delivery technologies. We are focused predominantly on the women's reproductive healthcare market but our product development projects address the broader women's healthcare market. Our bioadhesive vaginal gel products provide patient-friendly solutions for infertility, pregnancy support, amenorrhea, and other obstetric, gynecologic and medical conditions.

Our U.S. sales organization currently promotes two natural progesterone gel products, CRINONE® 8% and PROCHIEVE® 8% in the United States. CRINONE and PROCHIEVE are approved in the U.S. for supplementation or replacement of progesterone as part of an Assisted Reproductive Technology ("ART") treatment for infertile women with progesterone deficiency and for treatment of secondary amenorrhea. Outside the U.S. CRINONE has been approved for marketing for one or more medical indications including supplementation or replacement as part of an ART treatment for infertile women, treatment of secondary amenorrhea, the prevention of hyperplasia in postmenopausal women receiving hormone replacement therapy ("HRT"), the reduction of symptoms of premenstrual syndrome ("PMS"), menstrual irregularities, dysmenorrhea, and dysfunctional uterine bleeding. We reacquired the U.S. marketing rights to CRINONE in December 2006, and can now promote these products to a full range of reproductive endocrinologists, obstetricians and gynecologists who treat infertility. We also promote STRIANT® testosterone buccal system for the treatment of hypogonadism in men, however, our continuing focus in fiscal 2008 is to increase prescriptions of our infertility products.

We derive additional revenues from our established marketing partnerships, through which certain of our products are commercialized in global territories outside the U.S. and U.S. markets on which we are not currently focused.

We also seek opportunities to develop new products using our drug delivery technology, both proprietary projects and for strategic partners; to expand our product base and thereby leverage our sales force; and, to partner or divest products that fall outside our core women's healthcare focus.

All of our products and product candidates utilize our Bioadhesive Delivery System ("BDS"), which consists principally of a polymer (polycarbophil) and an active ingredient. The BDS is based upon the principle of bioadhesion, a process by which the polymer adheres to epithelial surfaces or mucosa. Our vaginal products adhere to the vaginal epithelium and the buccal products adhere to the mucosal membrane of the gum and cheek. The polymer remains attached to epithelial surfaces or mucosa and is discharged upon normal cell turnover, a physiological process that, depending upon the area of the body, occurs every 12 to 72 hours, or longer. Both vaginal and buccal BDS products provide sustained and controlled delivery of active drug ingredients. Its extended period of attachment permits use of BDS in products when extended duration of effectiveness is desirable or required. The Company intends to continue to leverage the advantages of BDS drug delivery by developing new BDS products that improve the delivery of approved drugs that have low oral bioavailability, or where systemic levels of the active ingredient must be curtailed. In addition, this delivery system is particularly useful for active drug ingredients that cannot be ingested.

We have focused on infertility but our development pipeline also focuses on the broader women's reproductive healthcare market because we believe that vaginal delivery is a particularly effective way to deliver active ingredients to the female reproductive organs.

#### Our Strategy

Our goal is to become a significant player in the women's reproductive healthcare market, providing patient-friendly solutions for infertility, obstetric, gynecologic and other women's medical conditions. The key elements of our strategy are:

*Focus on building revenues from our products for the treatment of infertility in women.* Since 2002, Columbia has been increasingly focused on products for the treatment of infertility in women. In 2006, we reacquired U.S. marketing rights for CRINONE® progesterone gel from Merck Serono S.A. ("Merck Serono").

Our CRINONE 8% and PROCHIEVE® 8% progesterone gels form the core to build a broader infertility business. We aim to build progesterone gel prescriptions by building relationships with reproductive endocrinologists; leveraging those relationships to influence prescribing habits of obstetricians and gynecologists who prescribe clomiphene citrate to treat infertility; proactively addressing obstetricians and gynecologists who regularly prescribed CRINONE before 2001; using an interim analysis of a pregnancy study being conducted by the Brigham and Women's Hospital to support the use of CRINONE to assist the infertility cycle and for pregnancy support; and utilizing direct to consumer marketing. These products currently generate over 55,000 U.S. prescriptions per year. Over 1.2 million infertility treatments are performed every year in the U.S. In each instance, the reproductive endocrinologist (RE), obstetrician or gynecologist (OB/GYN) could improve the likelihood of successful implantation by using supplemental progesterone. CRINONE 8% and PROCHIEVE 8% are also used for pregnancy support during the first 10 to 12 weeks of gestation. This largely untapped market provides growth potential over and above infertility cycle supplementation. In 2007 we expanded our sales force and sales force management from 25 to 35 to more effectively call on those physicians that treat over 80% of all infertility patients.

*Develop a preterm birth prevention indication for PROCHIEVE® 8%.* Our lead R&D opportunity is the study of PROCHIEVE 8% to reduce the risk of preterm birth in women with a short cervix as measured by transvaginal ultrasound in mid-pregnancy. This opportunity arose from significant positive data obtained from secondary analyses of our earlier recurrent Phase III preterm study. Based on those positive data and our discussions with the FDA, we designed the Phase III PREGNANT (PR OCHIEVE® E xtending G estatio N A N ew T herapy) study. The Company is conducting the Phase III clinical study with PROCHIEVE® 8% progesterone gel to prevent preterm birth and improve infant outcomes for those women with a short cervix at mid-pregnancy. This randomized, double-blind, placebo-controlled clinical trial will evaluate the effect of PROCHIEVE® 8% on reducing the risk of preterm birth in women with a cervical length between 1.0 and 2.0 centimeters as measured by transvaginal ultrasound at mid-pregnancy. The primary endpoint is a reduction in the incidence of preterm birth at less than or equal to 32 weeks gestation vs. placebo. If successful, we would apply to FDA for approval of a label indication for this use. In the fourth quarter of 2007 we recruited 19 sites, filed the protocol with the Institutional Review Boards ("IRB") and trained their staff in the study protocol. We expect to begin the recruiting efforts in the PREGNANT study in the first quarter of 2008. If we are able to meet our enrollment timeline for this trial, we expect to enroll and complete this clinical trial in 2008, with all the babies delivered in time to report results in the first half of 2009.

*Focus research and development resources on vaginally-administered lidocaine.* Throughout 2007 we continued to invest in our vaginal lidocaine drug candidate, which we are evaluating to prevent and treat the severe uterine cramps that result in the debilitating pain of dysmenorrhea. In the U.S. alone, this common, painful condition seriously affects about 5.6 million women in the age range of 20 to 45 to the point where they frequently miss work. In mid 2007 we completed a multi-dose pharmacokinetic study of the lidocaine candidate and reported positive results demonstrating safe blood levels from our delivery system. We subsequently initiated a 75-patient Phase II study in patients with dysmenorrhea. We expect to conclude enrollment in April 2008 and we expect to announce data and results from this clinical trial in the third quarter of 2008.

*License and acquire products to leverage our sales force.* In addition to collaborations, we also seek opportunistically to license and acquire under-promoted FDA-approved pharmaceuticals that complement our current women's infertility product offering to generate additional near-term revenues from our commercial infrastructure.

*Continue existing and establish new collaborations to develop and commercialize selected drugs.* Collaborations with pharmaceutical companies have played an important role in helping us develop and commercialize our products. These collaborations enable us to address markets, and commercialize products, that fall outside our core focus. We plan to continue to rely on collaborators to commercialize certain of our drugs and drug candidates, either outside the U.S. or in U.S. markets in which we are not currently concentrating our resources. We also seek opportunities to apply our technology to approved compounds manufactured and sold by potential strategic partners for therapeutic areas outside our focus.

*Continue existing and establish new collaborations to develop selected drug candidates.* Collaborations with pharmaceutical companies and third-party researchers have played an important role in helping us advance the development of certain investigational drug candidates. We plan to continue to seek strategic partners for certain investigational projects to cost-effectively advance our clinical projects while retaining U.S. marketing rights for Columbia.

## **Segments**

The Company is currently engaged solely in one business segment — the development, licensing and sale of pharmaceutical products. In certain foreign countries these products may be classified as medical devices or cosmetics by those countries' regulatory agencies. See Note 10 to the consolidated financial statements for information on foreign operations.

## **Operations**

Our sales and marketing organization operates solely in the United States, and is specifically focused on a select group of obstetricians, gynecologists, reproductive endocrinologists. We also market STRIANT to general endocrinologists, urologists and a select number of primary care physicians. Our marketing and sales efforts for STRIANT are primarily focused on maintaining the current prescription levels. We have entered into partnerships to commercialize our products outside the United States and within certain markets in the United States, and seek to enter into additional partnerships to commercialize our products in new countries and with additional audiences in the United States that we do not currently address.

We are substantially dependent on three manufacturers for the products that we sell to marketing partners around the world and commercialize ourselves in the United States. We sell five vaginal gel products that are each manufactured in bulk by Fleet Laboratories Limited, Watford, Herts, United Kingdom ("Fleet") and filled into overwrapped single-use disposable applicators by Maropack AG, Zell, Switzerland ("Maropack"). Our single buccal product is manufactured for us by Mipharm S.p.A., Milan, Italy ("Mipharm").

Our wholly owned subsidiary, Columbia Laboratories (Bermuda) Ltd., entered into an agreement dated July 12, 1996, with Fleet to manufacture our progesterone vaginal gel products for delivery in bulk containers. Pursuant to the agreement Fleet built and operates a dedicated suite for the manufacture of hormone products. Fleet may pass on increases in the cost of materials on three months notice and increases in labor on the anniversaries of the agreement. The original term of the agreement was 10 years after which either party may terminate the agreement on twelve (12) months prior written notice. Payments under the agreement are made in pounds sterling. Fleet also manufactures the Company's non-progesterone vaginal gel products for delivery in bulk containers pursuant to individual purchase orders.

Our then wholly owned subsidiary, Columbia Laboratories (Ireland) Ltd., entered into an agreement dated October 28, 1993 (which agreement was later transferred to our wholly owned subsidiary, Columbia Laboratories (Bermuda) Ltd.), with Maropack to fill our bulk vaginal gel products into overwrapped single-use disposable applicators. The original term of the agreement was one (1) year with automatic one (1) year renewals. Either party may terminate the agreement on six (6) months prior written notice before the end of any renewal term. Prices are renegotiated annually based on forecasted production volumes. Payments under the agreement are made in Swiss francs.

Our wholly owned subsidiary, Columbia Laboratories (Bermuda) Ltd., entered into an agreement dated May 7, 2002 with Mipharm to manufacture at least eighty-five percent (85%) of our requirements for our STRIANT® testosterone buccal product for sale in the United States, Europe and Latin America. Pursuant to the agreement Mipharm built and operates a dedicated suite for the manufacture of hormone products, one-half the cost of which was paid by us. The original term of the agreement is twelve (12) years with automatic three (3) year renewals. Either party may terminate the agreement on twelve (12) months prior written notice before the end of any term. The price of the product may increase based on increases in labor costs in Italy or raw materials. Payments under the agreement are made in Euros.



## Products

### *Progesterone Gel Products: CRINONE and PROCHIEVE*

Progesterone is a hormone manufactured by a woman's ovaries in the second half of the menstrual cycle. Progesterone is responsible for preparing the uterus for pregnancy and, if pregnancy occurs, maintaining it until birth, or, if pregnancy does not occur, inducing menstruation.

Our principal product is a sustained release gel that delivers natural progesterone vaginally. Our vaginal progesterone gel product is marketed under the two brand names CRINONE and PROCHIEVE, and is available in 8% and 4% formulations.

CRINONE 8% is principally marketed to reproductive endocrinologists who generally perform the more technical procedures to assist women who are infertile become pregnant. Our 2008 focus for CRINONE commercialization will be to seek to convert sales of pharmacy compounded intramuscular progesterone injections and progesterone suppositories to sales of CRINONE. Preparation of marketing materials showing our compilation of 16 clinical trials that have been conducted to compare CRINONE to other forms of progesterone, will provide us with a compelling case for the efficacy of CRINONE. These data show that CRINONE is as effective as, and in some cases, numerically more effective than all the other delivery systems for progesterone. In the six clinical trials that included an arm evaluating patient preference, patients preferred CRINONE over the competing product in all six clinical trials. We believe that if we are able to communicate the information that we have compiled on CRINONE, through direct marketing to physicians and presentations by key opinion leaders in the reproductive endocrinology field, we should be able to convince physicians to prescribe CRINONE over the competing injections and suppositories. Our sales force is now focused on promoting our CRINONE 8% to the infertility specialty market. We plan to execute on the foundation we laid in 2007 for CRINONE 8% and expect that CRINONE will be a key revenue driver in 2008.

PROCHIEVE 8% is principally marketed to obstetricians and gynecologists who may use progesterone in conjunction with clomiphene citrate to assist women who are infertile become pregnant. We expect that in 2008 we will invest significant resources in the development program for PROCHIEVE 8% to reduce the risk of preterm birth in women with a short cervix as measured by transvaginal ultrasound at mid-pregnancy. This program includes a clinical trial in pregnant women which we have named the PREGNANT study. In 2007, we reported data from our completed clinical trial of PROCHIEVE 8% in pregnant women with a history of prior pre-term birth. In that clinical trial, the study endpoints were not met, and the trial demonstrated that there was no benefit of administering vaginal progesterone to that patient population. However, secondary analyses of the data from this earlier study demonstrated a statistically significant improvement in the rate of preterm birth and infant outcomes in trial participants who had a short cervix at mid-pregnancy. This secondary analyses was conducted on a subset of patients with a short cervix at mid-pregnancy from the previous trial and the PREGNANT clinical trial is designed to confirm these data in a larger trial. The PREGNANT study was designed based in part on the data set forth in the White Journal and discussions with the FDA. This randomized, double-blind, placebo-controlled Phase III clinical trial is designed to evaluate the ability of PROCHIEVE 8% to reduce the risk of preterm birth in women with a short cervix of between 1.0 and 2.0 centimeters as measured by transvaginal ultrasound at mid-pregnancy. The primary endpoint of this clinical trial is a reduction in preterm births at less than or equal to 32 weeks versus placebo. If the results of the PREGNANT trial confirm the results seen in the earlier clinical trial, we expect to file a NDA supplement seeking approval of PROCHIEVE 8% for this indication and utilize the name PROCHIEVE solely related to the preterm birth indication.

PROCHIEVE 4% is indicated for treatment of secondary amenorrhea. It is marketed only in the United States. Merck Serono suspended any promotional support for the 4% progesterone vaginal gel outside the United States but maintains the marketing rights. In September 2007, the Company and Ascend Therapeutics, Inc. ("Ascend"), entered into a five year license and supply agreement under which Ascend is responsible for marketing and sales of PROCHIEVE® 4% in the United States.

The Company sells CRINONE and PROCHIEVE brand progesterone gels in the United States. The Company promotes these products to reproductive endocrinologists, obstetricians, and gynecologists. CRINONE brand progesterone gel is sold outside the U. S. by Merck Serono under a worldwide (excluding the U.S.) license from the Company.

CRINONE/ PROCHIEVE utilizes the Company's patented BDS, which enables the progesterone to achieve a preferential uptake of drug from the vagina to the uterus, or a "First Uterine Pass Effect<sup>TM</sup>". The product is available in two strengths, an 8% progesterone gel and a 4% progesterone gel. It is the first product designed to deliver progesterone directly to the uterus, thereby providing a therapeutic benefit and avoiding high blood levels of metabolites seen with orally-delivered synthetic progestins.

CRINONE /PROCHIEVE in the 8% progesterone gel is approved in the U.S. for progesterone supplementation or replacement as part of an Assisted Reproductive Technology ("ART") treatment for infertile women with progesterone deficiency. CRINONE®/PROCHIEVE® in both the 8% and 4% progesterone gels is approved in the U.S. for the treatment of secondary amenorrhea (loss of menstrual period). CRINONE was first marketed in the U.S. in 1997. In 2002, Merck Serono discontinued marketing CRINONE 4% worldwide. PROCHIEVE 8% and PROCHIEVE 4% were first marketed in the U.S. in September 2002 and March 2003, respectively. In September 2007, we licensed PROCHIEVE 4% to Ascend to market this product in the U.S. effective January 1, 2008.

Outside the U.S., CRINONE has been approved for marketing for one or more medical indications in 60 countries. The medical indications include: progesterone supplementation or replacement as part of an ART treatment for infertile women; the treatment of secondary amenorrhea; the prevention of hyperplasia in post-menopausal women receiving hormone replacement therapy ("HRT"); the reduction of symptoms of premenstrual syndrome ("PMS"); menstrual irregularities; dysmenorrhea; and, dysfunctional uterine bleeding. PROCHIEVE is not marketed outside the U.S.

The most common side effects of CRINONE/PROCHIEVE 8% are breast enlargement, constipation, somnolence, nausea, headache, and perineal pain. The most common side effects of PROCHIEVE 4% when used in combination with estrogen include cramps, fatigue, depression, emotional lability, sleep disorder, and headache. CRINONE/PROCHIEVE is contraindicated in the U.S. in patients with active thrombophlebitis or thromboembolic disorders, or a history of hormone-associated thrombophlebitis or thromboembolic disorders, missed abortion, undiagnosed vaginal bleeding, liver dysfunction or disease, and known or suspected malignancy of the breast or genital organs.

#### *Other Vaginal Gel Women's Products*

**Replens® Vaginal Moisturizer.** Our BDS vaginal gel, without an active pharmaceutical ingredient, is sold as Replens Vaginal Moisturizer. Replens is indicated for replenishment of vaginal moisture on a sustained basis and to relieve the discomfort associated with vaginal dryness. Replens was the first product developed utilizing the BDS. In May 2000, the Company sold the U.S. rights for Replens to Lil' Drug Store Products, Inc. ("Lil' Drug Store"), pursuant to an agreement under which the Company received royalties of 10% of sales of Replens in the U.S until October 2005. On June 29, 2004, the Company sold the remaining worldwide marketing rights for Replens to Lil' Drug Store and executed two related agreements with Lil' Drug Store: a five year supply agreement for Lil' Drug Store's requirements for Replens in non-U.S. markets that expires October 31, 2009 and a promotion agreement that expired at the end of 2006. See "Licensing and Development Agreements."

**RepHresh® Vaginal Gel.** RepHresh Vaginal Gel is a feminine hygiene product that can eliminate vaginal odor. RepHresh works by maintaining vaginal pH in the normal physiologic range of 4.5 or below. Using the BDS, RepHresh adheres to the epithelial cells of the vaginal lining for three or more days. It is available in convenient, pre-filled, disposable applicators. On June 29, 2004, the Company sold the worldwide marketing rights to the product to Lil' Drug Store and executed two related agreements with Lil' Drug Store: a five year supply agreement that expires October 31, 2009 and a promotion agreement that expired at the end of 2006. Columbia sells product on a worldwide basis to Lil' Drug Store. See "Licensing and Development Agreements."

**Advantage-S® Bioadhesive Contraceptive Gel.** The Company marketed one additional product, Advantage-S® a female contraceptive gel, until June 2004. On June 29, 2004, the Company sold worldwide marketing rights to Advantage-S to Lil' Drug Store. The production and sale of Advantage-S was discontinued during 2006. See "Licensing and Development Agreements."

### *Products Outside of the Women's Reproductive Healthcare Market*

**STRIANT® (testosterone buccal system).** STRIANT is approved in the U.S., the U.K., Germany, France, Spain, Italy and 10 other European countries for treatment of hypogonadism in men. Hypogonadism is characterized by a deficiency or absence of endogenous testosterone production. Signs and symptoms of hypogonadism can include decreased libido (sexual desire), erectile dysfunction (ED), fatigue, depression, reduced muscle mass, and osteoporosis. The purpose of testosterone replacement therapy is to provide and maintain normal levels of testosterone. It is estimated that hypogonadism affects 38.7% of men aged 45 years or older in the United States, approximately one million of whom currently receive treatment. The treatment for hypogonadism is to replace testosterone through one of many available delivery systems including transdermal patches, topical gels, injectable formulations of testosterone and the STRIANT buccal system.

STRIANT utilizes the BDS to achieve controlled and sustained delivery of testosterone via the buccal cavity — the small depression in the mouth where the gum meets the upper lip above the incisor teeth. The product, which has the appearance of a small monoconvex tablet, rapidly adheres to the buccal mucosa. STRIANT is absorbed into the bloodstream and delivered directly into the superior vena cava (major blood vessel), bypassing the gastrointestinal system and liver. In clinical trials, STRIANT produced circulating testosterone concentrations in hypogonadal males approximating physiologic levels seen in healthy young men.

The clinical data supporting the approval of STRIANT by the U.S. Food and Drug Administration (“FDA”) were generated from a 12-week U.S. multi-center, open-label, single arm trial that evaluated the efficacy, safety and tolerability of STRIANT in 98 men with hypogonadism. The most frequent adverse events that occurred with STRIANT in that trial at an incidence of 1% or greater which were possibly, probably or definitely related to the use of STRIANT were: gum or mouth irritation (9.2%), bitter taste (4.1%), gum pain (3.1%), gum tenderness (3.1%), headache (3.1%), gum edema (2.0%), and taste perversion (2.0%). A total of 16 patients reported 19 gum-related adverse events. Of these, ten patients (10.2%) reported 12 events of mild intensity, four patients (4.1%) reported five events of moderate intensity, and two patients (2.0%) reported two events of severe intensity. Four patients (4.1%) discontinued treatment with STRIANT® due to gum- or mouth-related adverse events, including two with severe gum irritation, one with mouth irritation and one with “bad taste in mouth.” The majority of the gum-related adverse events were transient and resolved within one to 14 days. Patients on STRIANT should be advised to regularly inspect the gum region where they apply STRIANT and report any abnormality to their health care professional.

STRIANT is not indicated for women and must not be used in women. Testosterone supplements may cause fetal harm. STRIANT should not be used in patients with known hypersensitivity to any of its ingredients, including testosterone USP that is chemically synthesized from soy. Androgens are contraindicated in men with carcinoma of the breast or known carcinoma of the prostate. Edema with or without congestive heart failure may be a serious complication in patients with preexisting cardiac, renal or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required. Gynecomastia frequently develops and occasionally persists in patients being treated with androgens for hypogonadism. The treatment of hypogonadal men with testosterone esters may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung diseases. Geriatric patients treated with androgens may be at an increased risk for the development of prostatic hyperplasia and prostatic carcinoma. In diabetic patients, the metabolic effects of androgens may decrease blood glucose and, therefore, insulin requirements.

We market and sell STRIANT in the United States. STRIANT sales comprise less than 1% of the market for testosterone replacement products in 2007. Due to our focus on increasing prescriptions for our progesterone gel products and increasing our overall business in products for women's reproductive health, our marketing and sales organization is not undertaking activities beyond those that we believe are required to maintain current U.S. sales of STRIANT.

In October 2002, the Company and Ardana plc (then Ardana Biosciences, Ltd., “Ardana”) entered into a license and supply agreement under which Ardana has licensed and, after obtaining necessary governmental product and pricing approvals, will sell STRIANT in 18 European countries (excluding Italy). See “Licensing and Development Agreements”. Ardana is currently marketing and selling STRIANT in the U.K., Ireland, Germany, Sweden, Finland, Norway, Denmark and the Netherlands.

In May 2003, the Company and Mipharm entered into a license and supply agreement under which Mipharm will market, distribute and sell STRIANT in Italy. See “Licensing and Development Agreements”. Mipharm launched STRIANT into the Italian market in November, 2007.

**Advance Formula Legatrin PM.** In May 2000, the Company licensed Advanced Formula Legatrin PM<sup>®</sup>, a product for the relief of occasional pain and sleeplessness associated with minor muscle aches to Lil’ Drug Store. Lil’ Drug Store pays the Company a royalty of 20% of the net sales of the product. The license agreement had an initial five-year term with provisions for automatic renewal. The license for Advanced Formula Legatrin PM was renewed to May 2010. See “Licensing and Development Agreements.”

## Research and Development

The Company spent \$5.8 million in 2007, \$6.6 million in 2006 and \$5.8 million in 2005 on research and development activities. The expenditures in 2007, 2006 and 2005 were primarily costs associated with the Company’s clinical study of PROCHIEVE<sup>®</sup> 8% (progesterone gel) for the prevention of recurrent preterm birth, discussed below. The expenditures in 2007 also included costs associated with the development of its vaginally-administered lidocaine candidate to prevent and relieve dysmenorrhea. The Company cannot predict whether it will be successful in the development of the products listed below or any other product candidates.

Generally the Company’s drug development activities take the following steps in the U.S. (and comparable steps in foreign countries): After the Company formulates an active drug ingredient into the BDS, it files an Investigational New Drug Application (“IND”) with the FDA to begin to test the product in humans. The IND becomes effective and the studies may begin if the FDA does not disapprove the IND within 30 days of its submission. The IND describes how, where, and by whom the studies will be conducted; information about the safety of the active drug ingredient; how it is thought to work in the body; any toxic effects it may have; and how it is manufactured. All clinical studies must also be reviewed and approved by an Institutional Review Board (“IRB”) that is responsible for the study site. Progress reports on clinical studies must be submitted at least annually to the FDA and the IRB.

Clinical studies are divided into three phases. Phase I studies typically involve small numbers of normal, healthy volunteers. Phase I studies are intended to assess a drug’s safety profile, including the safe dosage range. Phase I studies also determine how the drug is absorbed, distributed, metabolized, and excreted, as well as the duration of its action. Columbia has historically developed products using already approved active ingredients and developed them in our BDS technology. This has typically meant that Phase I studies are not required. Phase II studies involve volunteer patients (people with the disease intended to be treated) to assess the drug’s effectiveness. Phase III studies usually involve larger numbers of patients in clinics and hospitals to confirm the product’s efficacy and identify possible adverse events. Phase III studies are the “pivotal” studies that regulatory agencies require to show both safety and efficacy on a statistically representative population of people intended to be treated.

Following the completion of all three phases of clinical trials, the Company analyzes all of the data and files a New Drug Application (“NDA”) with the FDA if the data successfully demonstrate both safety and effectiveness. The NDA contains all of the scientific information that the Company has gathered. NDAs typically run thousands of pages. If the FDA approves the NDA, the new product becomes available for physicians to prescribe. The Company must continue to submit periodic reports to the FDA, including any cases of adverse reactions and appropriate quality-control records. For some medicines, the FDA requires additional studies after approval (Phase IV studies) to evaluate long-term effects of the drug. The development, clinical testing and filing of an application to the respective regulatory agencies of those countries where the drug is intended to be approved for marketing and sales can cost millions of dollars.

**PROCHIEVE 8% in Preventing Preterm Birth.** On February 5, 2007, the Company reported the results of its Phase III multi-center, randomized, double-blind, placebo-controlled, clinical trial designed to assess the efficacy, safety and tolerability of PROCHIEVE 8% in preventing preterm birth in pregnant women with a previous preterm birth before 35 weeks gestation. The study did not achieve a statistically significant reduction in the incidence of preterm birth at week 32, the primary endpoint in the study population. The incidence and profile of adverse events in patients receiving PROCHIEVE 8% was similar to placebo.



On April 26, 2007, the Company reported that evaluation of a secondary endpoint of the study revealed a possible effect of PROCHIEVE 8% in delaying cervical shortening. Although an effect on cervical length was not the primary focus of this trial, pursuant to the study protocol, cervical length measurements were performed on all women at baseline (approximately at 20 weeks gestation) and at 28 weeks gestation. Data from the study show a statistically significant delay in cervical shortening in patients treated with PROCHIEVE 8%, and suggest a correlation between the cervical length data, PROCHIEVE 8% administration, and both a reduction in the likelihood of preterm birth and an improvement in infant outcomes.

Evaluation of treatment by cervical length at baseline revealed that the “responders” to progesterone were patients with a short cervix at baseline. Further evaluation of all randomized patients, including patients randomized with a short cervix only, show that patients with a cervical length less than 3.0 cm had a significant treatment effect to reduce the incidence of preterm birth less than 37 weeks. A further evaluation of the patients with baseline short cervical length revealed that in women with a baseline cervical length less than 2.8 cm, there was a statistically significant reduction in preterm birth less than or equal to 32 weeks gestation. These delays in delivery were associated with significant improvements in infant outcome.

We believe that these data may provide an explanation for previous studies conducted by others showing an effect of progesterone administration in preventing preterm delivery. While previous clinical trials have been conducted in a study population of women who have experienced prior pre-term deliveries, those trials did not measure cervical length. We believe that it is possible that the group of women who responded to progesterone in earlier trials may correspond to the women in our clinical trial whose cervixes were shorter at baseline. Due to the fact that our study measured cervical length at baseline, certain women with a short cervix who were treated at clinics where a cervical cerclage is standard of care, were not randomized into our trial. Our trial therefore eliminated some of the population of patients that the secondary analysis indicates should benefit from progesterone treatment. On the basis of this analysis and discussions with the FDA, we designed the PREGNANT study which is underway. This randomized, double-blind, placebo-controlled Phase III clinical trial is designed to evaluate the ability of PROCHIEVE 8% to reduce the risk of preterm birth in women with a short cervix of between 1.0 and 2.0 centimeters as measured by transvaginal ultrasound at mid-pregnancy. The primary endpoint of the PREGNANT clinical trial is a reduction in preterm births at less than or equal to 32 weeks versus placebo.

In the fourth quarter of 2007 we recruited 19 study sites, filed the protocol with each site’s IRB and trained their staff on the study protocol. We expect to begin enrollment in the PREGNANT study in the first quarter of 2008. We plan to enroll and complete this study in 2008 with all the babies delivered in time to report results in the first half of 2009.

**Vaginally Administered Lidocaine.** The Company is conducting clinical development activities for vaginally-administered lidocaine to prevent and treat dysmenorrhea, a common gynecologic disorder characterized by recurrent uterine cramping and pain before and during menses. Dysmenorrhea affects approximately 50% of menstruating women, 10% of whom have cramps severe enough to incapacitate them from one to three days each month. Current treatments address the pain but not the underlying problem. Our hypothesis is that administration of lidocaine vaginally using our BDS technology can minimize or prevent the severe cramping that results in the debilitating pain of dysmenorrhea. A European clinical trial conducted by the Company in 2003 demonstrated that vaginally-administered lidocaine reduced the frequency of uterine contractions, as well as the intensity and frequency of uterine pain. Subjects were evaluated following vasopressin-induced cramping in the late luteal phase of the menstrual cycle, near menses.

On September 8, 2005, we announced the successful completion of a pharmacokinetics study for our vaginally administered lidocaine. The study evaluated both the blood levels obtained by, as well as the relative safety from, three doses of lidocaine formulated with the Company’s BDS. On June 27, 2007, we announced the successful completion of a multi-dose pharmacokinetic study of vaginally-administered lidocaine. The 43-subject study was designed to measure blood levels associated with the Company’s bioadhesive vaginal lidocaine formulation at three dose strengths over multiple doses. For each of the dose levels studied, use of our bioadhesive formulation over four consecutive days was associated with blood levels that are well within an accepted range. Based on those results, the Company initiated a Phase II study in the second quarter of



2007. This study is a 75-patient Phase II cross-over study in patients with dysmenorrhea. We expect to conclude enrollment in April 2008, and announce results from this clinical trial in the third quarter of 2008.

Once we have Phase II data on our lidocaine candidate, assuming positive results, we believe we will be in a position to explore potential partnership opportunities for this product candidate, ideally to co-develop and co-market it. A partnership makes sense because many young women affected by dysmenorrhea are seen by pediatricians and family practice physicians, not OB/GYNs, and the pediatric and family practice markets fall outside our strategic focus. We plan to have an end of Phase II meeting with FDA and begin designing the Phase III program for lidocaine in 2008, again assuming positive data. This will keep us on track to meet our ultimate goal of an NDA filing with FDA and potential approval in 2010.

**PROCHIEVE 4% for the Prevention of Endometrial Hyperplasia.** In 2004 a third party, five-year study was initiated to evaluate the long-term effects of Hormone Replacement Therapy in menopausal women. The study investigators selected PROCHIEVE 4% as the active progesterone to be administered to all menopausal women with an intact uterus who receive estrogen to prevent them from developing endometrial hyperplasia. We are supplying Prochieve 4% for this trial, therefore, our costs are minimal, but we will have access to the data and could possibly utilize the data for publication purposes in a peer reviewed medical journal.

**Terbutaline Vaginal Gel.** In December 2002, the Company entered into a development and license agreement with Ardana to develop the Company's terbutaline vaginal gel product candidate for the treatment of infertility, dysmenorrhea and endometriosis. The Company received a payment of \$0.3 million upon signing of the agreement and will receive an additional \$0.3 million upon completion of a successful Phase II clinical trial by Ardana. Under the terms of the agreement, if the Phase II trial is successful the Company can elect to continue to work with Ardana to progress the product through further clinical trials and subsequent applications for regulatory approvals. In that case, the Company would have the right to market the product in North America and Ardana would have rights focused in Europe. The parties would share equally in proceeds from licensing and distribution of the product in the rest of the world. If the Company elects not to continue working on the product at the end of the Phase II trial, Ardana can continue to develop the product. In 2007, Ardana elected to suspend development of the product as a result of slow recruitment in a proof of concept clinical trial.

**Testosterone Progressive Hydration Vaginal Tablet.** In October 2000, the Company completed a Phase I trial of its testosterone progressive hydration vaginal tablet for women. The study demonstrated that testosterone could be delivered vaginally over a period of days. A preliminary clinical plan, with a focus on reducing the size of systemic uterine fibroids is under review. We are not currently investing further in this drug candidate due to our investment in the PREGNANT and vaginal lidocaine clinical trials. We may consider further investment, if resources allow, at a later date.

**Vaginally Administered Carbamide Peroxide.** The Company is conducting pre-clinical development activities for a vaginally-administered carbamide peroxide product for treating or preventing vaginal infections. The product candidate is being investigated to determine the benefit of releasing and maintaining a very low concentration of peroxide over an extended period of time, in order to provide the benefits of oxygen release without adversely affecting normally-desired local vaginal flora. We do not plan to invest fully in development of this drug candidate at this time, but may consider further investment as resources become available at a later date.

**Peptide Delivery System.** The Company has completed a program that demonstrates that the BDS can deliver therapeutic doses of small chain peptides for extended periods of time using the Company's progressive hydration buccal technology. Based on these positive results, the Company has initiated partnering discussions related to peptide buccal tablets.

## **Licensing and Development Agreements**

### ***Merck Serono S.A.***

In May 1995, the Company entered into a license and supply agreement with American Home Products Corporation, now Wyeth, ("Wyeth") for its Wyeth-Ayerst Laboratories division to market CRINONE® worldwide. The Company agreed to supply CRINONE at a price equal to 30% of Wyeth's net selling price. In

July 1999, Wyeth assigned the license and supply agreement to Serono (now “Merck Serono”). In June 2002, the license and supply agreement was amended and restated and a marketing sublicense was granted to the Company. Under the terms of the license and sublicense, Merck Serono marketed CRINONE® in the U.S. to a defined list of fertility specialists and the Company was free to market PROCHIEVE® to all other physicians in the U.S., including obstetricians, gynecologists and primary care physicians.

Under the marketing sublicense, the Company paid Merck Serono a royalty equal to 30% of net sales on all PROCHIEVE sales and an additional 40% royalty on all PROCHIEVE sales dispensed to patients of physicians on Serono’s target list of fertility specialists. Conversely, Merck Serono paid the Company an additional royalty of 40% of CRINONE net sales on all CRINONE sales dispensed to patients of physicians outside its target list of fertility specialists in the U.S. In December 2006, the Company and Merck Serono agreed to terminate Merck Serono’s U.S. marketing rights for CRINONE and terminate the Company’s marketing sublicense to PROCHIEVE. As a result, the Company holds the U.S. marketing rights to both CRINONE and PROCHIEVE brand progesterone vaginal gel, and Merck Serono retains the marketing rights to CRINONE for the rest of the world.

#### ***Mipharm S.p.A.***

In March 1999, the Company entered into a license and supply agreement with Mipharm under which Mipharm is the exclusive marketer of the Company’s women’s healthcare products (other than CRINONE) in Italy, Portugal, Greece and Ireland with a right of first refusal for Spain. Mipharm currently sells Replens® in Italy and sells RepHresh® in Italy under the name MipHil.

In May 2003, the Company and Mipharm entered into an agreement under which Mipharm will market, distribute and sell STRIANT® in Italy. In exchange for these rights, Mipharm is obligated to pay the Company an aggregate of \$1.4 million upon achievement of certain milestone events, including \$0.4 million that was paid in 2003. We received a payment of \$0.1 million, less VAT withholding, in 2004 on account of the UK approval of STRIANT and a payment of \$0.2 million, less VAT withholding, in 2007 on marketing authorization received by Mipharm in Italy in late 2006. Mipharm will provide additional performance payments upon the achievement of certain levels of sales in Italy, and the Company will receive a percentage markup on the cost of goods for each unit sold. Mipharm is a manufacturer of STRIANT under a May 2002 agreement. In 2007, Mipharm launched sales of STRIANT® in Italy.

#### ***Ardana plc***

In October 2002, the Company and Ardana entered into a license and supply agreement under which Ardana will market, distribute and sell STRIANT in 18 European countries (excluding Italy) as necessary governmental product and pricing approvals are obtained. In exchange for the license, the Company may receive total potential payments of \$8 million. To date the Company has received \$6.0 million under this agreement, including \$4 million in signature and milestone fees received in 2002, \$0.8 million received in 2004 upon marketing approval in the U.K and \$0.4 million received in 2005 upon marketing approval in Germany. Additional milestone payments totaling \$0.8 million were received in 2006 for approval in France and Spain. In addition, a performance payment of \$2 million is due upon achievement of a certain level of sales. Ardana will purchase its requirements of product from the Company during the term of the agreement. The agreement will continue in each country in the territory until the date of expiration or lapse of the last patent covering the product in such country.

In December 2002, the Company and Ardana executed a development and license agreement (described above) to develop the Company’s terbutaline vaginal gel product. In 2007, Ardana elected to suspend development of the product as a result of slow recruitment in a proof of concept clinical trial.

#### ***Lil’ Drug Store Products, Inc.***

In June 2004, the Company and Lil’ Drug Store entered into an asset purchase agreement, a five year supply agreement, and a 2½ year professional services agreement. Under the agreements, Lil’ Drug Store acquired the Company’s over-the-counter women’s healthcare products, RepHresh® Vaginal Gel and Advantage-S® Bioadhesive Contraceptive Gel, and foreign marketing rights for Replens® Vaginal Moisturizer. The Company sold the U.S. marketing rights for Replens to Lil’ Drug Store in May 2000. Under the terms of

the asset purchase agreement, Lil' Drug Store also purchased the U.S. inventory of RepHresh and Advantage-S from the Company. The production and sale of Advantage-S was discontinued during 2006. The Company supplies RepHresh and ex-U.S. requirements for Replens under the supply agreement. The professional services agreement expired at the end of 2006.

In May 2000, the Company licensed Advanced Formula Legatrin PM®, a product for the relief of occasional pain and sleeplessness associated with minor muscle aches, to Lil' Drug Store. Lil' Drug Store pays the Company a royalty of 20% of the net sales of the product. The license agreement had an initial five-year term with provisions for automatic renewal. The license for Advanced Formula Legatrin PM was renewed to May 2010.

#### ***Ascend Therapeutics, Inc.***

In September 2007, the Company and Ascend, entered into a five year license and supply agreement for the Company's PROCHIEVE® 4% progesterone gel, pursuant to which, effective January 1, 2008, Ascend is responsible for marketing and sales of PROCHIEVE® 4% in the United States. Ascend will purchase product from the Company at a transfer price equal to 35% of Ascend's net selling price with minimum annual purchase obligations that increase over the life of the agreement.

#### **Financing Agreements**

On July 31, 2002, PharmaBio Development ("PharmaBio"), an affiliate of Quintiles Transnational Corp. agreed to pay \$4.5 million in four equal quarterly installments commencing third quarter 2002 for the right to receive a 5% royalty on net sales of the Company's women's healthcare products in the United States for five years, beginning in the first quarter of 2003. The royalty payments are subject to aggregate minimum (\$8 million) and maximum (\$12 million) amounts. Because the minimum amount exceeds \$4.5 million, the Company has recorded the amounts received as liabilities. The excess of the minimum (\$8 million) to be paid by the Company over the \$4.5 million received by the Company is being recognized as interest expense over the five-year term of the agreement, assuming an interest rate of 17%. As of December 31 2007, the Company has paid \$4.4 million in royalties to PharmaBio under this agreement. The final payment under this agreement of \$3.6 million was paid February 29, 2008. During 2007, the Company recognized that its method of calculating interest on this financing agreement was incorrect and has restated results for 2004, 2005 and 2006. See Note 2 in the Company's Consolidated Financial Statements that shows the effect of the restatement.

On March 5, 2003, the Company and PharmaBio entered into a second agreement under which PharmaBio paid \$15 million to the Company over a 15-month period that commenced with the signing of the agreement. In return, PharmaBio will receive a 9% royalty on net sales of STRIANT® in the United States up to agreed annual sales levels, and a 4.5% royalty of net sales above those levels. The royalty term is seven years. Royalty payments commenced in the third quarter of 2003 and are subject to the aggregate minimum (\$30 million) and maximum (\$55 million) amounts. A true-up payment under the STRIANT agreement due in November of 2006 was prepaid by the Company in April 2006 in the amount of \$11.6 million, representing the present value of the true up payment at a discount value of 6%. Because the minimum amount exceeds \$15 million, the Company has recorded the amounts received as liabilities. The excess of the minimum (\$30 million) to be paid by the Company over the \$15 million received by the Company is being recognized as interest expense over the seven-year term of the agreement, assuming an interest rate of 15%. As of December 31, 2007, the Company has paid \$13.1 million in royalties (including the true-up payment) to PharmaBio under this agreement. In 2007, the Company recognized that its method of calculating interest on this financing agreement was incorrect and has restated results for 2004, 2005 and 2006. See Note 2 in the Company's Consolidated Financial Statements that shows the effect of the restatement.

## Patents, Trademarks and Proprietary Information

We actively seek protection for our products and technology by means of United States and foreign patents, trademarks, and copyrights, as appropriate. The following table sets forth United States patents granted to the Company since 2002.

Year Granted	Nature of Patent
2006	Bioadhesive progressive hydration tablets using desmopressin or prostaglandin E2 as the active
2004	Compositions and methods for safely preventing or treating premature labor using a beta-adrenergic agonist, such as terbutaline.
2004	Methods of safely treating endometriosis or infertility, and for improving fertility, using a beta-adrenergic agonist.
2003	Use of progestin therapy for maintaining amenorrhea.
2003	Bioadhesive progressive hydration tablet.
2002	Use of certain polycarboxylic acid polymers for vaginal pH buffering to prevent miscarriage and premature labor associated with bacterial vaginosis.

The Company continues to develop the core BDS and has filed additional patent applications in the United States and other countries around the world. We believe our patents are important to our business and we intend to continue to protect them, including through legal action, when appropriate. While patent applications do not ensure the ultimate issuance of a patent, and having patent protection cannot ensure that competitors will not emerge, this is a fundamental step in protecting the Company's technologies.

The following table sets forth the expiration dates of the principal United States patents for the Company's marketed products and current development projects.

Subject of Patent	Year of Expiration	Product or Project
Progressive hydration tablets	2019	STRIANT® — testosterone progressive hydration vaginal tablet — peptide delivery system
First Uterine Pass Effect™	2018	vaginally administered lidocaine — terbutaline vaginal gel — testosterone vaginal gel
Progesterone delivery	2013	CRINONE®/PROCHIEVE®

The Company owns or is seeking registration of "CRINONE", "PROCHIEVE" "STRIANT", and "STRIANT SR®" as trademarks in countries throughout the world. Applications for the registration of trademarks do not ensure the ultimate registration of these marks; however, the Company believes marks with pending applications will be registered. In addition, there can be no assurance that such trademarks will afford the Company adequate protection or that the Company will have the financial resources to enforce its rights under such trademarks. In 2004, the Company sold the trademarks "Replens®", "Advantage 24®", "Advantage-S®", "Advantage-LA®", "RepHresh®", and "RepHresh Vaginal Gel®" to Lil' Drug Store. See "Licensing and Development Agreements."

The Company also relies on confidentiality and nondisclosure agreements to protect its intellectual property. There can be no assurance that other companies will not acquire information that the Company considers

to be proprietary. Moreover, there can be no assurance that other companies will not independently develop know-how comparable, or superior, to that of the Company.

### **Sales of Products**

We receive revenues from our “Progesterone Products” that we promote through our own sales force to reproductive endocrinologists and obstetricians and gynecologists and sell to wholesalers and specialty pharmacies and from sales to licensors. We supplement our Progesterone Products revenues by selling other products that use our BDS which we refer to as “Other Products”. Most of the Other Product revenue is based on sales of products to licensees. As of December 31, 2007:

Progesterone Products are:

- CRINONE® 8% progesterone gel marketed by us in the U.S.
- CRINONE® 8% sold to Merck Serono for sale outside the U.S.
- PROCHIEVE® 8% progesterone gel marketed by us in the U.S.
- PROCHIEVE® 4% progesterone gel sold to Ascend for sale in the U.S. from January 1, 2008

Other Products are:

- STRIANT® testosterone buccal system marketed by us in the U.S.
- STRIANT® sold to our marketing partners outside the U.S.;
- Replens® Vaginal Moisturizer sold to Lil’ Drug Store outside the U.S.
- RepHresh® Vaginal Gel sold to Lil’ Drug Store on a worldwide basis; and
- Royalty and licensing revenues.

Prior to establishing our own sales force in 2002, we generally out-licensed marketing rights to our products. In October 2002, our sales force began to call on obstetricians and gynecologists to encourage prescriptions for PROCHIEVE 8%. The sales force began sales efforts for PROCHIEVE 4% in April 2003, and in September 2003 began to call on endocrinologists, urologists and certain primary healthcare doctors to encourage prescriptions for STRIANT.

On December 22, 2006, the Company acquired the U.S. marketing rights to CRINONE® and added reproductive endocrinologists to its infertility physician targets. In addition to these specialists, who typically handle the more sophisticated infertility treatments, the Company’s sales force calls on obstetricians and gynecologists, general endocrinologists, urologists and certain primary healthcare physicians. The sales force is predominantly focused on women’s reproductive healthcare providers with the aim of building the Company’s existing infertility business. In July of 2007, in order to better align territories and revenue potential with our targeted reproductive endocrinologists and obstetricians, we expanded the sales force to 35 sales representatives and sales management.

### **Success of Marketing Efforts**

Our business is dependent on market acceptance of our products by physicians, healthcare payors, patients, and the medical community. Medical doctors’ willingness to prescribe our products depends on many factors, including:

- Perceived efficacy of our products;
- Convenience and ease of administration;
- Prevalence and severity of adverse side effects in both clinical trials and commercial use;
- Availability of alternative treatments;
- Cost effectiveness;
- The pricing of our products; and
- Our ability to obtain third party coverage or reimbursement for our products.



Even though we have received regulatory approval for CRINONE®, PROCHIEVE® and STRIANT®, and even if we receive regulatory approval and satisfy the above criteria for any of our other investigational indications and product candidates, physicians may not prescribe our products. We promote CRINONE, PROCHIEVE and STRIANT on our own behalf in the U.S. We have entered into agreements with other companies for the distribution and marketing of PROCHIEVE 4% in the U.S., RepHresh® in the U.S. and foreign countries, and of Replens®, CRINONE, and STRIANT in foreign countries. Factors that could affect our success in marketing our products include:

- The effectiveness of our production, distribution and marketing capabilities;
- The successful marketing of our products by our distribution and marketing partners;
- The success of competing products; and,
- The availability and extent of reimbursement from third party payors.

If any of our products or product candidates fail to achieve market acceptance, we or our marketing partners may be unable to sell the products successfully, which would limit our ability to generate revenue and could harm our business.

As previously disclosed, in July 2002 and March 2003 we entered into agreements with PharmaBio, under which we received upfront money in exchange for royalty payments on our women's healthcare products and STRIANT, respectively. We owe royalty payments to PharmaBio for a fixed period of time. These royalty payments are subject to minimum and maximum amounts, and the minimum amounts are in excess of the amounts we received from PharmaBio. Our failure to successfully market our products could have a material adverse effect on our ability to pay the minimum amounts to PharmaBio. The final payment under the 2002 agreement was made on February 29, 2008.

## **Competition**

We and our marketing partners compete against established pharmaceutical and consumer product companies which market products addressing similar needs. Further, numerous companies are developing, or may develop, enhanced delivery systems and products that compete with our present and proposed products. It is possible that we may not have the resources to withstand these and other competitive forces. Some of these competitors possess greater financial, research and technical resources than our Company or our partners. Moreover, these companies may possess greater marketing capabilities than our Company or our partners, including the resources to implement extensive advertising campaigns.

The pharmaceutical industry is subject to change as new delivery technologies are developed, new products enter the market, generic versions of available drugs become available and treatment paradigms evolve to reflect these and other medical research discoveries. We face significant competition in all areas of our business. The rapid pace of change in the pharmaceutical industry continually creates new opportunities for existing competitors and start-ups and can quickly render existing products less valuable. Customer requirements and physician and patient preferences continually change as new treatment options emerge, are more or less heavily promoted and become less expensive. As a result, we may not gain, and may lose, market share.

CRINONE/PROCHIEVE, a natural progesterone product, competes in markets with other progestins, both synthetic and natural, that may be delivered by pharmacy-compounded injections, by pharmacy-compounded vaginal suppositories, with Prometrium® (oral micronized progesterone) marketed by Solvay Pharmaceuticals, Inc. ("Solvay"), and Endometrin® (progesterone vaginal insert) marketed by Ferring Pharmaceuticals, Inc. ("Ferring"). CRINONE/PROCHIEVE and Endometrin are the only progestin products approved by FDA for use in infertility or for use in pregnant women. Endometrin was approved by the FDA in June of 2007.

STRIANT competes against other testosterone products that can be delivered by injection, transdermal patch and transdermal gel. Some of the more successful testosterone products include AndroGel® (testosterone gel) marketed by Unimed Pharmaceuticals, Inc. ("Unimed"), Testim® (testosterone gel) marketed by Auxilium Pharmaceuticals Inc. ("Auxilium"), and Androderm® (testosterone transdermal system) marketed by Watson Pharma, Inc. ("Watson") Competition is based primarily on delivery method. Transdermal testosterone gels currently have the largest market share and transdermal testosterone patches have the next largest market share, followed by injectable products. STRIANT is priced comparably to the gels and patches.

## Customers

Our customers include trade customers, such as drug wholesalers, specialty pharmacies, and chain drug stores, and our marketing partners. We make calls on the Company's trade customers and doctors to promote CRINONE®, PROCHIEVE® and STRIANT®. Our practice, in the case of our trade customers, is to ship our products promptly upon receipt of purchase orders from customers; consequently, backlog orders are not significant. In the case of our marketing partners, firm purchase orders are received by the Company ninety to one hundred twenty days in advance of the expected shipping date.

## Revenue by Product

The following table sets forth the percentage of the Company's consolidated net revenues, consisting of sales, licensing fees, sales force promotional fees, and royalty revenues, by revenue source for each product accounting for 3% or more of consolidated revenues in any of the four years ended December 31:

	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>
CRINONE® . . . . .	64%	39%	37%	40%
RepHresh® . . . . .	11%	4%	12%	4%
PROCHIEVE® . . . . .	5%	16%	15%	10%
Replens® . . . . .	8%	16%	11%	15%
STRIANT® . . . . .	7%	5%	6%	18%
Royalty income . . . . .	2%	12%	11%	6%
Sales force promotional fees . . . . .	0%	4%	3%	3%
Licensing fees . . . . .	3%	4%	3%	3%
Other products . . . . .	0%	0%	2%	1%
	<u>100%</u>	<u>100%</u>	<u>100%</u>	<u>100%</u>

The following table presents information about Columbia's net revenues, including royalty and license revenue, by customer for each of the four years ended December 31:

	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>
	In Millions			
Merck-Serono (formerly Serono) . . . . .	\$ 8.2	\$ 8.2	\$ 9.7	\$ 8.5
Cardinal Healthcare . . . . .	6.0	2.1	1.8	1.4
Lil' Drug Store Products, Inc. . . . .	6.0	4.6	6.9	3.6
McKesson . . . . .	3.9	1.9	1.6	1.2
AmerisourceBergen . . . . .	2.8	—	—	—
All others (none over 5%) . . . . .	2.7	0.6	2.0	3.1
	<u>\$29.6</u>	<u>\$17.4</u>	<u>\$22.0</u>	<u>\$17.8</u>

## Sales by Geographic Area

The following table sets forth the Company's consolidated net revenues, based on sales by geographic area, for each area accounting for 5% or more of consolidated revenues in any of the three years ended December 31:

	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>
	In Millions			
United States . . . . .	\$15.2	\$ 8.0	\$10.9	\$11.2
Switzerland . . . . .	8.1	5.7	5.4	3.3
Other European Countries . . . . .	6.3	3.7	5.7	3.3
Subtotal International . . . . .	<u>14.4</u>	<u>9.4</u>	<u>11.1</u>	<u>6.6</u>
	<u>\$29.6</u>	<u>\$17.4</u>	<u>\$22.0</u>	<u>\$17.8</u>

## **Employees**

As of March 5, 2008, the Company had 56 employees: 3 in management, 4 in production, 36 in sales and marketing, and 13 in support functions. Our success is highly dependent on our ability to attract and retain qualified employees. Competition for employees is intense in the pharmaceutical industry. We believe we have been successful in our efforts to recruit qualified employees, but we cannot guarantee that we will continue to be as successful in the future. None of the Company's employees are represented by a labor union or are subject to collective bargaining agreements. We believe that our relationship with our employees is good.

The Company has employment agreements with three employees, Mr. Mills, president and chief executive officer, Mr. McGrane, senior vice president, general counsel and secretary, and Mr. Meer, senior vice president, chief financial officer and treasurer. The Board of Directors of the Company has adopted an Indemnification Agreement for Officers and Directors and an Executive Change of Control Severance Agreement for Officers.

## **Available Information**

The Company's Internet address is [www.columbialabs.com](http://www.columbialabs.com). Through a link on the "Investor" section of this website, which is also accessible at [www.cbrxir.com](http://www.cbrxir.com), we make available, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with or furnish it to the SEC. In addition, we will provide electronic or paper copies of our filings free of charge upon request. Information contained on our corporate website or any other website is not incorporated into this Annual Report and does not constitute a part of this Annual Report.

In addition, the public may read and copy any materials filed by the Company with the SEC at the SEC's Reference Room, which is located at 100 F Street NE, Washington, D.C., 20549. Interested parties may call (800) SEC-0330 for further information on the Reference Room. The SEC also maintains a website containing reports, proxy materials and information statements, among other information, at <http://www.sec.gov>.

## **Corporate Information**

Columbia was incorporated as a Delaware corporation in 1986. Our principal executive offices are located at 354 Eisenhower Parkway, Livingston, New Jersey 07039, and our telephone number is (973) 994-3999. The Company's wholly-owned subsidiaries are Columbia Laboratories (Bermuda) Ltd. ("Columbia Bermuda"), Columbia Laboratories (France) SA ("Columbia France") and Columbia Laboratories (UK) Limited ("Columbia UK").

## **Item 1A. Risk Factors**

***We have a history of losses and we may continue to incur losses.***

We have had a history of losses since our founding. For the fiscal year ended December 31, 2007, we had a net loss of \$14.3 million. If we and our partners are unable to successfully market our products, and otherwise increase sales of our products, and contain our operating expenses, we may not have sufficient funds to continue operations unless we are able to raise additional funds from sales of securities or otherwise. Additional financing may not be available to us on acceptable terms, if at all.

***Our business is heavily dependent on the continued sale of CRINONE® 8%, PROCHIEVE® 4%, Replens®, and RepHresh® by our marketing partners. If revenues from these partnered products fail to increase as anticipated, or materially decline, our financial condition and results of operations will be materially harmed.***

Our operating results are heavily dependent on the revenues and royalties derived from the sale of CRINONE 8% to Merck Serono for sale outside the U.S., the sale of PROCHIEVE 4% to Ascend for sale in the U.S., the sale of STRIANT to Ardana and Mipharm for sale in Europe, and the sale of Replens and RepHresh to Lil' Drug Store. Revenues from sales of these partnered products in 2007, comprised approximately 49% of our total revenues. We do not control the amount and timing of marketing resources that our partners devote to our products. If Merck Serono fails to effectively market CRINONE 8% in its ex-U.S. territories, Ascend fails to effectively market PROCHIEVE 4% in the U.S., Ardana and Mipharm fail to effectively market STRIANT in their respective territories, or Lil' Drug Store fails to effectively market Replens and RepHresh, this could have a material adverse effect on our business, financial condition and results of operations.

***We acquired marketing rights to CRINONE in the United States in December 2006, and we may never realize the anticipated benefits of the acquisition.***

On December 22, 2006, we purchased the marketing rights in the United States to CRINONE from Merck Serono, and we began in 2007 to call for the first time on reproductive endocrinologists, a medical specialty in infertility. Our goal is to grow CRINONE® prescribing practices with these specialists. We believe the reproductive endocrinologists are particularly important because of their influence on prescribing practices of obstetricians and gynecologists who also treat infertility. Our efforts to grow the CRINONE business may not be successful and we may fail to realize the anticipated benefits of the acquisition.

***Healthcare insurers and other payors may not pay for our products or may impose limits on reimbursement.***

Our ability to commercialize our prescription products will depend, in part, on the extent to which reimbursement for our products is available from third-party payors, such as health maintenance organizations, health insurers and other public and private payors. If we succeed in bringing new prescription products to market, we cannot be assured that third-party payors will pay for such products, or establish and maintain price levels sufficient for realization of an appropriate return on our investment in product development.

Many health maintenance organizations and other third-party payors use formularies, or lists of drugs for which coverage is provided under a healthcare benefit plan, to control the costs of prescription drugs. Each payor that maintains a drug formulary makes its own determination as to whether a new drug will be added to the formulary and whether particular drugs in a therapeutic class will have preferred status over other drugs in the same class. This determination often involves an assessment of the clinical appropriateness of the drug and, in some cases, the cost of the drug in comparison to alternative products. Our current or our future products may not be added to payors' formularies, our products may not have preferred status to alternative therapies, and formulary decisions may not be conducted in a timely manner. Once reimbursement at an agreed level is approved by a third-party payor, we may lose that reimbursement entirely or we may lose the similar or better reimbursement we receive compared to competitive products. As reimbursement is often approved for a period of time, this risk is greater at the end of the time period, if any, for which the reimbursement was approved. We may also decide to enter into discount or formulary fee arrangements with payors, which could result in us receiving lower or discounted prices for CRINONE®, PROCHIEVE® and STRIANT® or future products.

***We face significant competition from pharmaceutical and consumer product companies, which may adversely impact our market share.***

We and our marketing partners compete against established pharmaceutical and consumer product companies that market products addressing similar needs. Further, numerous companies are developing, or may develop, enhanced delivery systems and products that compete with our present and proposed products. It is possible that we may not have the resources to withstand these and other competitive forces. Some of these competitors may possess greater financial, research and technical resources than our company or our partners. Moreover, these companies may possess greater marketing capabilities than our company or our partners, including the resources to implement extensive advertising campaigns.

The pharmaceutical industry is subject to change as new delivery technologies are developed, new products enter the market, generic versions of available drugs become available, and treatment paradigms evolve to reflect these and other medical research discoveries. We face significant competition in all areas of our business. The rapid pace of change in the pharmaceutical industry continually creates new opportunities for existing competitors and start-ups, and can quickly render existing products less valuable. Customer requirements and physician and patient preferences continually change as new treatment options emerge, are more or less heavily promoted, and become less expensive. As a result, we may not gain, and may lose, market share.

CRINONE/PROCHIEVE, a natural progesterone product, competes in markets with other progestins, both synthetic and natural, including Endometrin<sup>®</sup> (progesterone vaginal insert) marketed by Ferring, Prometrium<sup>®</sup> (oral micronized progesterone) marketed by Solvay, pharmacy-compounded injections and pharmacy-compounded vaginal suppositories. In June, 2007, Ferring obtained FDA approval for, and launched, Endometrin<sup>®</sup> (progesterone vaginal insert) a competing product for use in infertility. Ferring is one of the leading companies in the infertility market and, in addition to Endometrin, offers gonadotropin hormones generally used for the treatment of infertility. Ferring may have greater awareness among key reproductive endocrinology opinion leaders than Columbia.

STRIANT<sup>®</sup> competes against other testosterone products that can be delivered by injection, transdermal patch and transdermal gel. Some of the more successful testosterone products include AndroGel<sup>®</sup> (testosterone gel) marketed by Unimed, Testim<sup>®</sup> (testosterone gel) marketed by Auxilium, and Androderm<sup>®</sup> (testosterone transdermal system) marketed by Watson. Competition is based primarily on delivery method. Transdermal testosterone gels currently have the largest market share and transdermal testosterone patches have the next largest market share, followed by injectable products. STRIANT is priced comparably to the gels and patches.

***Our products could demonstrate hormone replacement risks.***

In the past, certain studies of female hormone replacement therapy products, such as estrogen, have reported an increase in health risks. Progesterone is a natural female hormone, present at normal levels in most women through their lifetimes. However, some women require progesterone supplementation due to a natural or chemical-related progesterone deficiency. It is possible that data suggesting risks or problems may come to light in the future which could demonstrate a health risk associated with progesterone or progestin supplementation or our 8% and 4% progesterone gels. It is also possible that future study results for hormone replacement therapy could be negative and could result in negative publicity about the risks and benefits of hormone replacement therapy. As a result, physicians and patients may not wish to prescribe or use progestins, including our progesterone gels.

Similarly, while testosterone is a natural male hormone, present at normal levels in most men through their lifetimes, some men require testosterone replacement therapy, or TRT, to normalize their testosterone levels. It is possible that data suggesting risks or problems may come to light in the future that could demonstrate a health risk associated with TRT or STRIANT<sup>®</sup>. It is also possible that future study results for hormone replacement therapy could be negative and could result in negative publicity about the risks and benefits of TRT. As a result, physicians and patients may not wish to prescribe or use TRT products, including STRIANT.

In addition investors may become concerned about these issues and decide to sell our Common Stock. These factors could adversely affect our business and the price of our Common Stock.



***We may be exposed to product liability claims.***

We could be exposed to future product liability claims by consumers. Although we presently maintain product liability insurance coverage at what we believe is a commercially reasonable level, such insurance may not be sufficient to cover all possible liabilities. An award against us in an amount greater than our insurance coverage could have a material adverse effect on our operations. Some customers require us to have a minimum level of product liability insurance coverage before they will purchase or accept our products for distribution. If we fail to satisfy insurance requirements, our ability to achieve broad distribution of our products could be limited. This could have a material adverse effect upon our business and financial condition.

***Steps taken by us to protect our proprietary rights might not be adequate, in which case competitors may infringe on our rights or develop similar products. The United States and foreign patents upon which our original Bioadhesive Delivery System was based have expired.***

Our success and competitive position are partially dependent on our ability to protect our proprietary position for our technology, products and product candidates. We rely primarily on a combination of patents, trademarks, copyrights, trade secret laws, third-party confidentiality and nondisclosure agreements, and other methods to protect our proprietary rights. The steps we take to protect our proprietary rights, however, may not be adequate. Third parties may infringe or misappropriate our patents, copyrights, trademarks, and similar proprietary rights. Moreover, we may not be able or willing, for financial, legal or other reasons, to enforce our rights. To date, we have never been a party to a proprietary rights action.

Bio-Mimetics, Inc. held the patent upon which our original Bioadhesive Delivery System, or BDS, was based and granted us a license under that patent. Bio-Mimetics' patent contained broad claims covering controlled release products that include a bioadhesive. However, this United States patent and its corresponding foreign patents expired in November 2003. Based upon the expiration of the original Bio-Mimetics patent, other parties will be permitted to make, use or sell products covered by the claims of the Bio-Mimetics patent, subject to other patents, including those which we hold. We have obtained numerous patents with claims covering improved methods of formulating and delivering therapeutic compounds using the BDS. We cannot assure you that any of these patents will enable us to prevent infringement, or that our competitors will not develop alternative methods of delivering compounds, potentially resulting in competitive products outside the protection that may be afforded by our patents. Other companies may independently develop or obtain patent or similar rights to equivalent or superior technologies or processes. Additionally, although we believe that our patented technology has been independently developed and does not infringe on the proprietary rights of others, we cannot assure you that our products do not and will not infringe on the proprietary rights of others. In the event of infringement, we may be required to modify our technology or products, obtain licenses or pay license fees. We may not be able to do so in a timely manner or upon acceptable terms and conditions. This may have a material adverse effect on our operations.

The standards that the U.S. Patent and Trademark Office and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. Limitations on patent protection in some countries outside the U.S., and the differences in what constitutes patentable subject matter in these countries, may limit the protection we seek outside of the U.S. For example, methods of treating humans are not patentable subject matter in many countries outside of the U.S. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws of the U.S. In determining whether or not to seek a patent or to license any patent in a particular foreign country, we weigh the relevant costs and benefits, and consider, among other things, the market potential of our product candidates in the jurisdiction and the scope and enforceability of patent protection afforded by the law of the jurisdiction.

We own or are seeking registration of the following as trademarks in countries throughout the world: CRINONE®, PROCHIEVE®, STRIANT®, and STRIANT SR®. These trademarks, however, may not afford us adequate protection or we may not have the financial resources to enforce our rights under these trademarks.

***We are subject to government regulation, which could affect our ability to sell products.***

Nearly every aspect of the development, manufacture and commercialization of our pharmaceutical products is subject to time-consuming and costly regulation by various governmental entities, including the Food and Drug Administration, or FDA, the Drug Enforcement Administration and state agencies, as well as

regulatory agencies in those foreign countries in which our products are manufactured or distributed. The FDA has the power to seize adulterated or misbranded products and unapproved new drugs, to require their recall from the market, to enjoin further manufacture or sale, and to publicize certain facts concerning a product.

We employ various quality control measures in our efforts to ensure that our products conform to their intended specifications and meet the standards proscribed by applicable governmental regulations, including FDA's current Good Manufacturing Practices regulations. Notwithstanding our efforts, our products or the ingredients we purchase from our suppliers for inclusion in our products may contain undetected defects or non-conformities with specifications. Such defects or non-conformities could compel us to recall the affected product, make changes to or restrict distribution of the product, or take other remedial actions. The occurrence of such events may harm our relations with or result in the loss of customers, injure our reputation, impair market acceptance of our products, harm our financial results, and, in certain circumstances, expose us to product liability or other claims.

***The development of our pharmaceutical products is uncertain and subject to a number of significant risks.***

Some of our pharmaceutical products are in various stages of development. In the United States and most foreign countries, we must complete extensive human clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product.

The process of developing product candidates involves a degree of risk and may take several years. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- Clinical trials may show our product candidates to be ineffective for the indications studied or to have harmful side effects;
- Product candidates may fail to receive regulatory approvals required to bring the products to market;
- Manufacturing costs or other factors may make our product candidates uneconomical; and
- The proprietary rights of others and their competing products and technologies may prevent our product candidates from being effectively commercialized.

Success in early clinical trials does not ensure that large-scale clinical trials will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals.

The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and may be difficult to predict. The speed with which we can complete clinical trials and applications for marketing approval will depend on several factors, including the following:

- The rate of patient enrollment, which is a function of factors including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, and the nature of the study protocol;
- Institutional review board, or IRB, approval of the study protocol and the informed consent form;
- Prior regulatory agency review and approval;
- Analysis of data obtained from clinical activities, which are susceptible to varying interpretations and which interpretations could delay, limit or prevent regulatory approval;
- Changes in the policies of regulatory authorities for drug approval during the period of product development; and
- The availability of skilled and experienced staff to conduct and monitor clinical studies and to prepare the appropriate regulatory applications.

In addition, developing product candidates is very expensive and will continue to have a significant impact on our ability to generate profits. Factors affecting our product development expenses include:

- Our ability to raise any additional funds that we need to complete our trials;
- The number and outcome of clinical trials conducted by us and/or our collaborators;
- The number of products we may have in clinical development;
- In licensing or other partnership activities, including the timing and amount of related development funding, license fees or milestone payments; and
- Future levels of our revenue.

Clinical trials are expensive and can take years to complete, and there is no guarantee that the clinical trials will demonstrate sufficient safety and/or efficacy of the products to meet FDA requirements, or those of foreign regulatory authorities.

***We may experience adverse events in clinical trials, which could delay or halt our product development.***

Our product candidates may produce serious adverse events. These adverse events could interrupt, delay or halt clinical trials of our product candidates and could result in FDA or other regulatory authorities denying approval of our product candidates for any or all targeted indications. An IRB or independent data safety monitoring board, the FDA, other regulatory authorities, or we ourselves may suspend or terminate clinical trials at any time. Our product candidates may prove not to be safe for human use.

***Delays or failures in obtaining regulatory approvals may delay or prevent marketing of the products that we are developing.***

Other than PROCHIEVE® 8% (progesterone gel) which is being evaluated for the prevention of preterm birth in women with a short cervix at mid-pregnancy, and PROCHIEVE® 4% (progesterone gel), which is being evaluated for the prevention of endometrial hyperplasia in women with an intact uterus undergoing estrogen replacement therapy, none of our product candidates have received regulatory approval from the FDA or any foreign regulatory authority. The regulatory approval process typically is extremely expensive, takes many years, and the timing or likelihood of any approval cannot be accurately predicted. Delays in obtaining regulatory approval can be extremely costly in terms of lost sales opportunities and increased clinical trial costs. If we fail to obtain regulatory approval for our current or future product candidates or expanded indications for currently marketed products, we will be unable to market and sell such products and indications and therefore may never be profitable.

As part of the regulatory approval process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy. The number of clinical trials that will be required varies depending on the product candidate, the indication being evaluated, the trial results, and the regulations applicable to any particular product candidate.

The results of initial clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials. The data collected from the clinical trials of our product candidates may not be sufficient to support FDA or other regulatory approval. In addition, the continuation of a particular study after review by an IRB or independent data safety monitoring board does not necessarily indicate that our product candidate will achieve the clinical endpoint.

The FDA and other regulatory agencies can delay, limit or deny approval for many reasons, including:

- A product candidate may not be deemed to be safe or effective;
- The manufacturing processes or facilities we have selected may not meet the applicable requirements; and
- Changes in their approval policies or adoption of new regulations may require additional clinical trials or other data.

Any delay in, or failure to receive, approval for any of our product candidates could prevent us from growing our revenues or achieving profitability.

***We are dependent on third-party suppliers of raw materials for our products, the loss of whom could impair our ability to manufacture and sell our products.***

Medical grade, cross-linked polycarbophil, the polymer used in our BDS-based products is currently available from only one supplier, Noveon, Inc., or Noveon. We believe that Noveon will supply as much of the material as we require because our products rank among the highest value-added uses of the polymer. In the event that Noveon cannot or will not supply enough of the product to satisfy our needs, we will be required to seek alternative sources of polycarbophil. An alternative source of polycarbophil may not be available on satisfactory terms or at all, which would impair our ability to manufacture and sell our products.

We currently purchase progesterone and testosterone for our products from only one supplier. If that supplier is unable or unwilling to satisfy our needs, we will be required to seek alternative sources of supply. While several alternative sources of progesterone and testosterone exist, the time needed to obtain regulatory approvals for new suppliers may impair our ability to manufacture and sell our products.

***We are dependent upon third-party developers and manufacturers, the loss of which could result in a loss of revenues.***

We rely on third parties to develop and manufacture our products, including Fleet, which manufactures our vaginal gel products in bulk, Maropack, which fills our vaginal gel products into applicators and Mipharm which manufactures STRIANT®. These third parties may not be able to satisfy our needs in the future, and we may not be able to find or obtain FDA approval of alternate developers and manufacturers. Delays in the development and manufacture of our products could have a material adverse effect on our business. This reliance on third parties could have an adverse effect on our profit margins. Any interruption in the manufacture of our products would impair our ability to deliver our products to customers on a timely and competitive basis, and could result in the loss of revenues.

***The loss of our key executives could have a significant impact on our company.***

Our success depends in large part upon the abilities and continued service of our executive officers and other key employees. Our employment agreements with our executive officers are terminable by them on short notice. The loss of key employees may result in a significant loss in the knowledge and experience that we, as an organization, possess, and could cause significant delays in, or outright failure of, the development and commercialization of our products and product candidates. If we are unable to attract and retain qualified and talented senior management personnel, our business may suffer.

***We may be limited in our use of our net operating loss carryforwards.***

As of December 31, 2007, we had certain net operating loss carryforwards of approximately \$157.3 million that may be used to reduce our future U.S. federal income tax liabilities. Our ability to use these loss carryforwards to reduce our future U.S. federal income tax liabilities could be lost if we were to experience more than a 50% change in ownership within the meaning of Section 382(g) of the Internal Revenue Code. If we were to lose the benefits of these loss carryforwards, our future earnings and cash resources would be materially and adversely affected.

***The price of our Common Stock has been and may continue to be volatile.***

Historically, the market price of our Common Stock has fluctuated over a wide range. In fiscal year 2006, our Common Stock traded in a range from \$2.53 to \$5.98 per share. In fiscal year 2007, our Common Stock traded in a range from \$1.04 to \$5.25 per share. It is likely that the price of our Common Stock will fluctuate in the future. The market prices of securities of small specialty pharmaceutical companies, including ours, from time to time experience significant price and volume fluctuations. In particular, the market price of our Common Stock may fluctuate significantly due to a variety of factors, including: the results of clinical trials for our product candidates; FDA's determination with respect to new drug applications for new products and new indications; and our ability to develop additional products. In addition, the occurrence of any of the risks described in these "Risk Factors" could have a material and adverse impact on the market price of our Common Stock.

***Sales of large amounts of Common Stock may adversely affect our market price. The issuance of preferred stock or convertible debt may adversely affect rights of common stockholders.***

As of March 3, 2008, we had 51,961,789 shares of Common Stock outstanding, of which 51,482,724 shares were freely tradable by non-affiliates. As of that date, approximately 479,065 shares of Common Stock were restricted or held by affiliates. We also have the following securities outstanding: series B convertible preferred stock, series C convertible preferred stock, series E convertible preferred stock, convertible subordinated notes, warrants, and options. If all of these securities are exercised or converted, an additional 21,098,776 shares of Common Stock will be outstanding, all of which will have been registered for resale under the Securities Act. The exercise and conversion of these securities is likely to dilute the book value per share of our Common Stock. In addition, the existence of these securities may adversely affect the terms on which we can obtain additional equity financing.

In March 2002, our Board of Directors authorized shares of series D junior participating preferred stock in connection with its adoption of a stockholder rights plan, under which we issued rights to purchase series D convertible preferred stock to holders of our Common Stock. Upon certain triggering events, such rights become exercisable to purchase shares of Common Stock (or, in the discretion of our Board of Directors, series D convertible preferred stock) at a price substantially discounted from the then current market price of our Common Stock.

Under our certificate of incorporation, our Board of Directors has the authority to issue up to 1.0 million shares of preferred stock and to determine the price, rights, preferences and privileges of those shares without any further vote or action by our stockholders. In addition, we may issue convertible debt without shareholder approval. The rights of the holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of any shares of preferred stock or convertible debt that may be issued in the future. While we have no present intention to authorize or issue any additional series of preferred stock or convertible debt, such preferred stock or convertible debt, if authorized and issued, may have other rights, including economic rights senior to the Common Stock, and, as a result, their issuance could have a material adverse effect on the market value of our Common Stock.

***We have a substantial amount of debt.***

As of December 31, 2007, we had outstanding approximately \$40 million principal amount of our convertible debt due December 31, 2011. In addition, as of December 31, 2007 we had remaining future minimum payments due to PharmaBio pursuant to certain financing agreements of approximately \$20.5 million. On February 29, 2008, the Company paid \$3.6 million of this obligation. Our annual interest expense is more than \$8 million of which approximately \$3.2 million is the annual cash portion of the expense relating to the convertible debt, for the next four years. Unless we generate substantial additional sales from our products or raise substantial additional capital, we may not be able to pay the interest on our debt or repay our debt at maturity.

***Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable regulations.***

We are a relatively small company and we rely heavily on third parties to conduct many important functions. As a pharmaceutical company, we are subject to a large body of legal and regulatory requirements. In addition, as a publicly traded company we are subject to significant regulations, including the Sarbanes-Oxley Act of 2002, some of which have either only recently been adopted or are currently proposals subject to change. We cannot assure you that we are or will be in compliance with all potentially applicable laws and regulations. Failure to comply with all potentially applicable laws and regulations could lead to the imposition of fines, cause the value of our common stock to decline, impede our ability to raise capital or lead to the de-listing of our stock.

***We could be negatively impacted by future interpretation or implementation of federal and state fraud and abuse laws, including anti-kickback laws, false claims laws and federal and state anti-referral laws.***

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws, false claims laws and physician self-referral laws. Violations of these laws are punishable



by criminal and/or civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs, including Medicare, Medicaid, and veterans' health programs. We have not been challenged by a governmental authority under any of these laws and believe that our operations are in compliance with such laws.

However, because of the far-reaching nature of these laws, we may be required to alter one or more of our practices to be in compliance with these laws. Health care fraud and abuse regulations are complex, and even minor, inadvertent irregularities can potentially give rise to claims that the law has been violated. Any violations of these laws could result in a material adverse effect on our business, financial condition and results of operations. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations.

We could become subject to false claims litigation under federal or state statutes, which can lead to civil money penalties, criminal fines and imprisonment, and/or exclusion from participation in federal health care programs. These false claims statutes include the federal False Claims Act, which allows any person to bring suit alleging the false or fraudulent submission of claims for payment under federal programs or other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in recent years and have increased the risk that companies like us may have to defend a false claim action. We could also become subject to similar false claims litigation under state statutes. If we are unsuccessful in defending any such action, such action may have a material adverse effect on our business, financial condition and results of operations.

***Anti-takeover provisions could impede or discourage a third-party acquisition of our company. This could prevent stockholders from receiving a premium over market price for their stock.***

We are a Delaware corporation. Anti-takeover provisions of Delaware law impose various obstacles to the ability of a third party to acquire control of our company, even if a change in control would be beneficial to our existing stockholders. In addition, our Board of Directors has adopted a stockholder rights plan and has designated a series of preferred stock that could be used defensively if a takeover is threatened. Our incorporation under Delaware law, our stockholder rights plan, and our ability to issue additional series of preferred stock, could impede a merger, takeover or other business combination involving our company or discourage a potential acquiror from making a tender offer for our Common Stock. This could reduce the market value of our Common Stock if investors view these factors as preventing stockholders from receiving a premium for their shares.

***We are exposed to market risk from foreign currency exchange rates.***

With two operating subsidiaries and third party manufacturers in Europe, economic and political developments in the European Union can have a significant impact on our business. All of our products are currently manufactured in Europe. We are exposed to currency fluctuations related to payment for the manufacture of our products in Euros and other currencies and selling them in U.S. dollars and other currencies.

## Item 1B. Unresolved Staff Comments

None.

## Item 2. Properties

As of December 31, 2007, the Company leased the following properties:

Location	Use	Square Feet	Expiration	Annual Rent
Livingston, NJ	Corporate office	9,450	October, 2013	\$212,625
Paris, France	European logistics office	150	3 months notice	\$ 18,811

## Item 3. Legal Proceedings

Claims and lawsuits have been filed against the Company and its subsidiaries from time to time. Although the results of pending claims are always uncertain, the Company does not believe the results of any such actions, individually or in the aggregate, will have a material adverse effect on our financial position or results of operation. Additionally, the Company believes that it has reserves or insurance coverage in respect of these claims, but no assurance can be given as to the sufficiency of such reserves or insurance in the event of any unfavorable outcome resulting from these actions.

In connection with the 1989 purchase of the assets of Bio-Mimetics, Inc., which assets consisted of the patents underlying the Company's BDS, other patent applications, and related technology, the Company agreed to pay Bio-Mimetics a royalty equal to two percent of the net sales of products based on the assets up to an aggregate of \$7.5 million or until the last of the relevant patents expired. The Company determined that the obligation to pay royalties on STRIANT®, PROCHIEVE®, and CRINONE® terminated in September of 2006, with the expiration of a certain Canadian patent, but continues on Replens® and RepHresh®. On December 28, 2007, Bio-Mimetics filed a complaint in the United States District Court for Massachusetts (*Bio-Mimetics, Inc. v. Columbia Laboratories, Inc.*) alleging breach of contract, violation of the covenant of good faith and fair dealing, and unjust enrichment for the Company's failure to continue royalty payments on STRIANT®, PROCHIEVE®, and CRINONE®. The Company intends to defend this action vigorously.

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

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2007.

### Executive Officers and Directors of the Registrant

Our executive officers and Directors as of March 3, 2008, were as follows:

Name	Age	Position with the Company
Robert S. Mills	55	President and Chief Executive Officer, Director
Michael McGrane	58	Senior Vice President, General Counsel and Secretary
James A. Meer	62	Senior Vice President, Chief Financial Officer and Treasurer
Stephen G. Kasnet	61	Chairman of the Board
Edward A. Blechschmidt	55	Vice Chairman of the Board
Valerie L. Andrews	48	Director
James S. Crofton	55	Director
Denis M. O'Donnell, M.D.	54	Director
Selwyn P. Oskowitz, M.D.	62	Director

Officers serve at the discretion of the Board of Directors. There is no family relationship between any of the executive officers or between any of the executive officers and the Company's directors. There is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected, except with respect to Messrs. Mills', McGrane's and Meer's employment agreements.

**Mr. Mills** was promoted to President and Chief Executive Officer on March 6, 2006. On January 5, 2006, Mr. Mills was elected President and Chief Operating Officer and was elected to the Company's Board of Directors. Mr. Mills joined Columbia in May 2001 as Senior Vice President, Operations and was named Chief Operating Officer in September 2003. Prior to joining the Company, Mr. Mills served five years as Senior Vice President, Manufacturing Operations, at Watson Pharmaceuticals, Inc. from 1996 to 2001. During his 33-year career in the pharmaceutical industry he also served as Vice President, Operations, at Alpharma, Inc. from 1993 to 1996 and held various positions with Aventis SA, including Director-Plant Operations. Mr. Mills holds a B.S. degree from Grove City College.

**Mr. McGrane** has served as Senior Vice President, since January 2006, and our General Counsel and Secretary since January 2002. He joined the Company from The Liposome Company, Inc., a biotechnology company, where he served as Vice President, General Counsel and Secretary from 1999 to 2001, prior to which he was Vice President, General Counsel and Secretary to Novartis Consumer Health, Inc. from 1997 to 1998. Previously, Mr. McGrane held various positions, including Associate General Counsel, with Novartis Pharmaceuticals Corporation from 1984 to 1996, and was Regulatory Counsel to the U.S. Food and Drug Administration from 1975 to 1984. Mr. McGrane received his J.D. degree from Georgetown University and his B.A. degree from Cornell College. He is a member of the New Jersey bar.

**Mr. Meer** has served as Senior Vice President, Chief Financial Officer and Treasurer since December 2006. He has over 35 years of financial experience in both privately-held and publicly-traded companies, of which 15 years are in the life sciences industry. He most recently served from 2004 to 2006 as Senior Vice President, Chief Financial Officer, Secretary and Treasurer of Pharmos Corporation, a biotechnology company, prior to which he was a consultant from 2001 to 2004 to pharmaceutical and biotech companies providing strategic and financial advice. Mr. Meer previously served eight years as Vice President and Treasurer of Schein Pharmaceutical, Inc., where he was responsible for capital formation, including a successful IPO, strategic planning and investor relations. He also held senior financial positions with public companies including EnviroSource, Inc., John Labatt Ltd. and General Host Corporation. Mr. Meer holds an M.B.A. degree from Pace University and a B.A. degree on economics from Rutgers College.

**Mr. Kasnet** has been a director of the Company since August 2004 and Chairman of the Board since November 2004. He is the Chairman of Dartmouth Street Capital LLC, which he joined in 2007. He was President and Chief Executive Officer of Harbor Global Company, Ltd., from June 2000 through 2006. He previously held senior management positions with various financial organizations, including Pioneer Group, Inc.; First Winthrop Corporation and Winthrop Financial Associates; and Cabot and Forbes. He serves as Chairman of the Board of Rubicon Ltd. (forestry) and is a director of Tenon Ltd. (wood products). He was Chairman of Warren Bank from 1990 to 2003. He is also a trustee and vice president of the board of The Governor's Academy, Byfield, MA.

**Mr. Blechschmidt** has been a director of Columbia since August 2004 and Vice Chairman of the Board since November 2004. He was Chairman, Chief Executive Officer and President of Gentiva Health Services (home healthcare) from March 2000 until his retirement in July 2002. He previously served as Chief Executive Officer of Olsten Corporation ("Olsten") (staffing services), the conglomerate from which Gentiva Health Services was split off and taken public. Before joining Olsten, Mr. Blechschmidt was President and Chief Executive Officer of both Siemens' Nixdorf Americas (information technology) and Siemens' Pyramid Technology (information technology), prior to which he served more than 20 years with Unisys Corporation (information technology), ultimately as Chief Financial Officer. He is currently a director of Health South Corp. (healthcare) and Lionbridge Technologies, Inc. (business services).

**Ms. Andrews** has been a director of Columbia since October 2005 and is Vice President and Deputy General Counsel of Vertex Pharmaceuticals Inc. Before joining Vertex in 2002, Ms. Andrews was Executive Director of Licensing for Massachusetts General and The Brigham and Women's Hospitals, and prior to that a partner in the law firm of Hill & Barlow. She served as a law clerk to Chief Judge Levin H. Campbell of the United States Court of Appeals for the First Circuit from 1988 to 1989, and earlier rose to the rank of Captain in the United States Air Force.

**Mr. Crofton** has been a director of Columbia since October 2005. He has been Senior Vice President and Chief Financial Officer of Sarnoff Corporation (technology) since 1999. Previously, Mr. Crofton was Chief Financial Officer of EA Industries, Inc. (electronics manufacturing), and prior to that served in various positions, including Vice President of Finance, with Unisys Corporation ((information technology)). He is currently a Director of American Mold Guard, Inc (construction materials).

**Dr. O'Donnell** has been a director of the Company since January 1999, and is Managing Director of Seaside Capital, LLC. From 2004 to 2005, he also served as Chief Executive Officer of Molecular Diagnostics, Inc. (medical diagnostics and screening). Dr. O'Donnell served as Chairman of the Board of Directors of Novavax, Inc. (pharmaceuticals) from 2000 to 2005, President from 1995 to 1997, and Vice President from 1991 to 1995. He remains a Director of Novavax, Inc. and serves on both the Board of Directors and audit committee of ELXSI, Inc. (restaurant and water inspection services).

**Dr. Oskowitz** has been a director of the Company since January 1999. Dr. Oskowitz has been an assistant professor of obstetrics, gynecology and reproductive biology at Harvard Medical School since 1993. He is a reproductive endocrinologist at, and Director of, Boston IVF, a fertility clinic with which he has been associated since 1986. Dr. Oskowitz is a past President of the Boston Fertility Society.

### **Code of Ethics**

The Board of Directors of the Company has adopted a Code of Business Conduct and Ethics applicable to all Board members, executive officers and all employees. The Code of Business Conduct and Ethics is available on the Company's website, under the investor relations tab. We will provide an electronic or paper copy of this document free of charge upon request. If substantial amendments to the Code of Business Conduct and Ethics are executed, or if waivers are granted, the Company will post and disclose the nature of such amendments or waivers on the Company's website or in a report on Form 8-K.

## PART II

### Item 5. Market for the Registrant's Common Equity and Related Stockholder Matters and Issuer Purchases of Equity Securities

The Company's Common Stock, par value \$.01 per share ("Common Stock"), is traded on the NASDAQ Global Market under the symbol CBRX. The following table sets forth for the periods indicated the high and low sales prices of the Common Stock on the NASDAQ Global Market.

	High	Low
<i>Fiscal Year Ended December 31, 2006</i>		
First Quarter . . . . .	\$5.20	\$4.01
Second Quarter . . . . .	5.26	2.90
Third Quarter . . . . .	4.03	2.53
Fourth Quarter . . . . .	5.98	3.21
<i>Fiscal Year Ended December 31, 2007</i>		
First Quarter . . . . .	\$5.25	\$1.04
Second Quarter . . . . .	3.20	1.29
Third Quarter . . . . .	2.72	2.00
Fourth Quarter . . . . .	2.96	2.03

At March 3, 2008, there were approximately 300 shareholders of record of the Company's Common Stock, one shareholder of record of the Company's Series B convertible preferred stock ("Series B Preferred Stock"), 5 shareholders of record of the Company's contingently redeemable Series C Convertible Preferred Stock ("Series C Preferred Stock") and 7 shareholders of record of the Company's Series E convertible preferred stock ("Series E Preferred Stock"). The Company estimates that there were approximately 7,000 beneficial owners of its Common Stock on such date.

The Series C Preferred Stock was issued and sold by the Company in January 1999 to 24 accredited investors, through which the Company raised approximately \$6.4 million, net of expenses. The Series C Preferred Stock has a stated value of \$1,000 per share, and is convertible into Common Stock at the lower of: (i) \$3.50 per share of Common Stock, and (ii) 100% of the average of the closing prices during the three trading days immediately preceding the conversion notice (not to exceed 2,705,236 shares at December 31, 2007). The Series C Preferred Stock pays a 5% dividend, payable quarterly in arrears on the last day of the quarter. The security holders of Series C Preferred Stock have certain redemption rights due to events beyond the control of the Company such as delisting, dividend defaults and certain other defaults. The terms of the Series C Preferred Stock have remained the same since inception.

During 2005, the Company raised \$6.9 million from the issuance and sale of 69,000 shares of Series E Preferred Stock. The Series E Preferred Stock has a stated value of \$100 per share. Each share of the Series E Preferred Stock may be converted by the holder into 50 shares of Common Stock, subject to adjustment, and will automatically be converted into Common Stock at that rate upon the date that the average of the daily market prices of the Company's Common Stock for the 20 consecutive trading days preceding such date exceeds \$6.00 per share. The Series E Preferred Stock pays no dividends and contains voting rights equal to the number of shares of Common Stock into which each share of Series E Preferred Stock is convertible. Upon liquidation of the Company, the holders of the Series E Preferred Stock are entitled to \$100 per share.

On March 10, 2006, the Company raised \$30 million in gross proceeds to the Company from the issuance and sale of 7,428,220 shares of its Common Stock at a price of \$4.04 per share and warrants to purchase 1,857,041 shares of Common Stock with an exercise price of \$5.39 per share. The warrants became exercisable on September 9, 2006, and expire on March 13, 2011, unless earlier exercised or terminated. Proceeds were used for general corporate purposes.

On December 22, 2006, the Company raised approximately \$40 million in gross proceeds to the Company from the issuance and sale of convertible subordinated notes. The notes bear interest at a rate of 8% per annum and mature on December 31, 2011. They are convertible into shares of Common Stock at a conversion price of \$5.25. Investors also received warrants to purchase 2,285,714 shares of Common Stock at an



exercise price of \$5.50 per share. The warrants became exercisable on June 20, 2007, and expire on December 22, 2011, unless earlier exercised or terminated. The Company used the proceeds of this offering to acquire from Merck Serono the U.S. marketing rights to CRINONE® for \$33 million, purchase Serono's current inventory of that product, and pay other costs related to the transaction. On April 1, 2007, the Company recorded a liability from the contract with Merck Serono for certain sales returns associated with sales made by Merck Serono. The Company recorded the estimated liability of \$1,000,000 as an increase in the purchase price that is being amortized over the remaining term of the license. The balance of approximately \$3.7 million was used for general corporate purposes.

All of such securities were issued in unregistered offerings pursuant to Section 4(2) of the Securities Act of 1933, as amended or Regulation D thereunder.

During 2007, outstanding options were exercised resulting in the issuance of 43,050 shares of Common Stock and the receipt of \$0.1 million by the Company. Proceeds were used for general corporate purposes. In addition, 2,075 shares of Series C Preferred Stock were converted into 1,564,548 shares of Common Stock, and 5,453 shares of Series E Preferred Stock were converted into 272,650 shares of Common Stock.

### Equity Compensation Plan Information

The following table sets forth aggregate information for the fiscal year ended December 31, 2007, regarding the Company's compensation plans, including individual compensation agreements, under which equity securities of the Company are authorized for issuance:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance
	(a)	(b)	(c)
Equity compensation plans approved by security holders . . . . .	4,936,335	\$4.64	1,862,026
Equity compensation plans not approved by security holders . . . . .	625,000	\$7.28	0
Total . . . . .	5,561,335	\$4.94	1,862,026

The Company has one shareholder-approved equity compensation plan, the 1996 Long-term Performance Plan (the "1996 Plan"), adopted in October 1996, which provides for the grant of stock options, stock appreciation rights and restricted stock to certain designated employees of the Company, non-employee directors of the Company and certain other persons performing significant services for the Company as designated by the Compensation Committee of the Board of Directors.

### Stockholder Rights Plan

On March 12, 2002, the Company adopted a Stockholder Rights Plan (the "Rights Plan") designed to protect company stockholders in the event of takeover activity that would deny them the full value of their investment. The Rights Plan was not adopted in response to any specific takeover threat. In adopting the Rights Plan, the Board declared a dividend distribution of one preferred stock purchase right for each outstanding share of Common Stock of the Company, payable to stockholders of record at the close of business on March 22, 2002. The rights will become exercisable only in the event, with certain exceptions, a person or group of affiliated or associated persons acquires 15% or more of the Company's voting stock, or a person or group of affiliated or associated persons commences a tender or exchange offer which, if successfully consummated, would result in such person or group owning 15% or more of the Company's voting stock. The rights will expire on March 12, 2012. Each right, once exercisable, will entitle the holder (other than rights owned by an acquiring person or group) to buy one one-thousandth of a share of a series of the Company's Series D Junior Participating Preferred Stock at a price of \$30 per one-thousandth of a share, subject to adjustments. In addition, upon the occurrence of certain events, holders of the rights (other than rights owned by an acquiring person or group) would be entitled to purchase either the Company's preferred stock or shares in an "acquiring entity" at approximately half of market value. Further, at any time after a person or group acquires 15%

or more (but less than 50%) of the Company's outstanding voting stock, subject to certain exceptions, the Board of Directors may, at its option, exchange part or all of the rights (other than rights held by an acquiring person or group) for shares of the Company's Common Stock having a fair market value on the date of such acquisition equal to the excess of (i) the fair market value of preferred stock issuable upon exercise of the rights over (ii) the exercise price of the rights. The Company generally will be entitled to redeem the rights at \$0.01 per right at any time prior to the close of business on the tenth day after there has been a public announcement of the beneficial ownership by any person or group of 15% or more of the Company's voting stock, subject to certain exceptions.

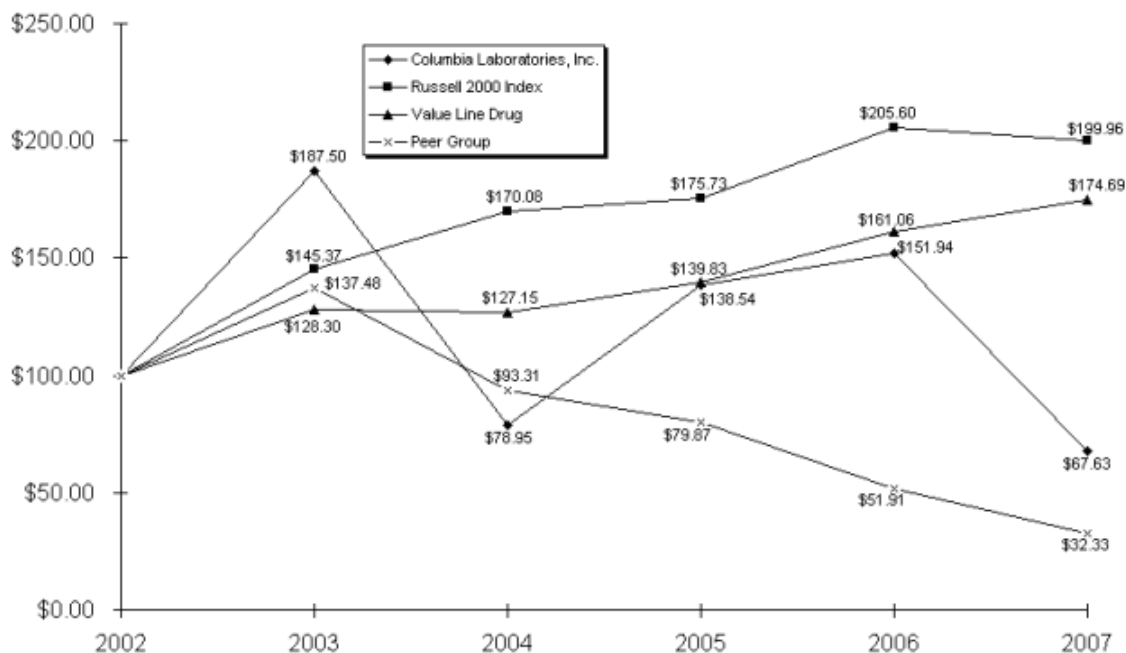
### Dividend Policy

The Company has never paid a cash dividend on its Common Stock and does not anticipate the payment of cash dividends in the foreseeable future. The Company intends to retain any earnings for use in the development and expansion of its business. The Company is required to pay a 5% dividend on its Series C Preferred Stock on the last day of each quarter.

Applicable provisions of the Delaware General Corporation Law may affect the ability of the Company to declare and pay dividends on its Common Stock as well as on its Series C Preferred Stock. In particular, pursuant to the Delaware General Corporation Law, a company may pay dividends out of its surplus, as defined, or out of its net profits, for the fiscal year in which the dividend is declared and/or the preceding year. Surplus is defined in the Delaware General Corporation Law to be the excess of net assets of the company over capital. Capital is defined to be the aggregate par value of shares issued unless otherwise established by the Board of Directors.

### Performance Graph

**Comparison of Five-Year Cumulative Total Return\***  
**Columbia Laboratories, Inc., Russell 2000 Index, Value Line Drug, And Peer Group**  
 (Performance Results Through 12/31/07)



Assumes \$100 invested at the close of trading 12/02 in Columbia Laboratories, Inc. common stock, Russell 2000 Index, Value Line Drug, and Peer Group.

Source: Value Line, Inc.

Factual material is obtained from sources believed to be reliable, but the publisher is not responsible for any errors or omissions contained herein.

Peer Group Companies are Adolor Corp., Anesiva, Inc., Antares Pharma, Inc., Barrier Therapeutics, Inc., Cell Therapeutics, Inc., Collagenex Pharmaceuticals, Inc., Cyclacel Pharmaceuticals, Inc., Depomed, Inc., Entremed, Inc., ISTA Pharmaceuticals, Inc., NPS Pharmaceuticals, Inc., Penwest Pharmaceuticals Co., Renovis, Inc., and Sciclone Pharmaceuticals, Inc.

## Item 6. Selected Financial Data

The following selected financial data (not covered by the auditors' reports) are derived from the Company's audited financial statements and are qualified in their entirety by reference to, and should be read in conjunction with, such consolidated financial statements and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report. The historical results are not necessarily indicative of the results we expect for future periods. As discussed in Note 2 to the consolidated financial statements, the financial statements for the years ended December 31, 2006, 2005, and 2004 have been restated to correct previously reported interest expense for financing arrangements and to correct the classification of contingently redeemable Series C Preferred stock. The interest expense and net loss have been adjusted for the year 2003.

	<b>Financial Highlights</b>				
	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>	<u>2003</u>
		(Restated)	(Restated)	(Restated)	(Restated)
<b>Statement of Operations Data:</b>					
(000's except per share data)					
Net Revenues . . . . .	\$ 29,627	\$ 17,393	\$ 22,041	\$ 17,860	\$ 22,415
Gross Profit . . . . .	20,613	9,573	13,929	10,072	12,632
Operating Expenses . . . . .	28,721	20,733	21,160	32,044	32,214
Interest Expense . . . . .	7,946	2,670	3,491	3,928	2,285
Net Loss . . . . .	(14,292)	(12,485)	(10,104)	(26,067)	(21,590)
Loss per common share . . . . .	(0.28)	(0.26)	(0.25)	(0.64)	(0.58)
Weighted average number of common shares outstanding-basic and diluted . . . . .	51,124	48,089	41,752	40,984	37,440
<b>Balance Sheet Data at December 31 (000's)</b>					
Working capital (deficiency) . . . . .	\$ 14,461	\$ 23,410	(\$ 3,471)	\$ 9,303	\$ 33,690
Total Assets . . . . .	56,589	65,839	14,732	29,268	42,755
Notes payable . . . . .	27,536	25,299	—	—	10,000
Long-term portion of financing agreements . . . . .	11,426	13,277	10,921	20,299	16,186
Contingently Redeemable Series C Preferred Stock . . . . .	1,125	3,200	3,250	3,250	3,250
Shareholders' equity (deficiency) . . .	2,015	12,616	(20,573)	(17,157)	2,398

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

### Overview

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to help the reader understand the Company's financial condition and results of operations. The MD&A is provided as a supplement to, and should be read in conjunction with, our financial statements and the accompanying notes ("Notes").

We are in the business of developing, manufacturing and selling pharmaceutical products that utilize our proprietary bioadhesive drug delivery technologies. We are focused predominantly on the women's reproductive healthcare market but our product development projects address the broader women's healthcare market. Our bioadhesive vaginal gel products provide patient-friendly solutions for infertility, pregnancy support, amenorrhea, and other obstetric, gynecologic and medical conditions.

We have a 35 person sales organization that promotes our two natural progesterone gel products, CRINONE® 8% and PROCHIEVE® 8% in the United States. We acquired the U.S. marketing rights to CRINONE in December 2006, and can now promote these products to a full range of reproductive endocrinologists, obstetricians and gynecologists who treat infertility. We also promote STRIANT® testosterone buccal system for the treatment of hypogonadism in men, however, our focus in fiscal 2008 is to increase prescriptions of our infertility products.

We derive additional revenues from our established marketing partnerships, through which certain of our products are commercialized in global territories outside the U.S. and U.S. markets on which we are not currently focused.

Through our development organization, we seek opportunities to develop new products using our drug delivery technology and obtain new label indications for our existing products. We expect that we will retain proprietary rights to certain of these products and label indications, particularly where they are complementary to our existing sales and marketing capabilities. We also expect to seek strategic partners for, or to divest, products that fall outside our core women's healthcare focus.

Our net loss for 2007 was \$ 14.3 million, or \$0.28 per basic and diluted common share. We expect to continue to incur operating losses in the near future because of the significant non-cash items related to the CRINONE® acquisition that our future financial statements will reflect. Our sales and distribution expenses will be higher in 2008 to fund market research and medical education programs for our progesterone products. In 2008, we expect that our research and development expenses will be higher than those in 2007, primarily as a result of our investment in our PREGNANT clinical trial of Prochieve 8% for the prevention of preterm birth in women with a short cervix at mid-pregnancy, and in clinical trials related to development of our drug candidate, vaginally-administered lidocaine for treatment of dysmenorrhea, or painful menstruation.

Our 2007 revenues reflect the first full year of our marketing efforts for both brands of 8% progesterone gel in the US, and in particular our attention to CRINONE 8%. In 2007, we undertook significant activities to frame the marketing materials and activities for CRINONE 8%. Our CRINONE 8% sales and marketing activities in 2007 included:

- Expansion of our sales force from 25 to 35 sales representatives and sales management personnel to focus on the infertility specialty market, particularly on the west coast of the U.S.
- Establishment of a strong presence at the annual meeting of the American Society of Reproductive Medicine in October 2007, which we believe effectively emphasized our objective of becoming a major player in the market for infertility treatments
- Preparation of marketing materials showing our compilation of 16 clinical trials that have been conducted to compare CRINONE to other forms of progesterone, which provided us with a compelling case for the efficacy of CRINONE. We believe that these data show that CRINONE is as effective as, and in some cases numerically more effective than the other delivery systems for progesterone. In the six clinical trials that included an arm evaluating patient preference, patients preferred CRINONE over the competing product in all six clinical trials;
- Formulation of our Infertility Advisory Committee of respected reproductive endocrinologists from around the United States who provide us with insight on how to best communicate to physicians and patients all the clinical information that is available for CRINONE
- Outreach to key opinion leaders and a number of reproductive endocrinologists who have agreed to speak on behalf of CRINONE

Our partner Merck Serono has exclusive rights to market CRINONE in all countries outside of the United States. Increased sales of CRINONE in non-U.S. markets by Merck Serono, who pays us a transfer price on CRINONE sales, contributed to revenue growth in 2007. Worldwide progesterone sales were up 84% over 2006. We expect that CRINONE sales will continue to increase in markets outside the U.S., and that it may enter new markets, including China, if approved.

We expect that our 2008 focus for CRINONE commercialization will be to seek to convert sales of pharmacy compounded intramuscular progesterone injections and progesterone suppositories to sales of CRINONE. We believe that these products share 75% of the total U.S. progesterone market. We believe that if we are able to communicate the information that we have compiled on CRINONE, through direct marketing to physicians and presentations by key opinion leaders in the reproductive endocrinology field, we should be able to convince physicians to prescribe CRINONE over the competing injections and suppositories.

Our sales force is now focused on promoting our CRINONE 8% to the infertility specialty market. We plan to execute on the foundation we laid in 2007 for CRINONE 8% and expect that CRINONE will be a key revenue driver in 2008.

#### **Clinical Development of PROCHIEVE 8% for Prevention of Preterm Birth in Women with Mid-pregnancy Short Cervix.**

We expect that in 2008 we will invest significant resources in the development program for PROCHIEVE 8% to reduce the risk of preterm birth in women with a short cervix as measured by transvaginal ultrasound at mid-pregnancy. This program includes a clinical trial in pregnant women which we have named the PREGNANT study. In 2007, we reported data from our completed clinical trial of PROCHIEVE 8% in pregnant women with a history of prior pre-term birth. In that clinical trial, the study endpoints were not met, and the trial demonstrated that there was no benefit of administering vaginal progesterone to this patient population. However, secondary analyses of the data from this earlier study demonstrated a statistically significant improvement in the rate of preterm birth and infant outcomes in trial participants who had a short cervix in mid-pregnancy. The PREGNANT clinical trial is designed to confirm these data in a larger trial. If the results of the PREGNANT trial confirm the results seen in the earlier clinical trial, we expect to file a NDA supplement seeking approval of PROCHIEVE 8% for this indication.

The clinical trial data were published in October 2007 in the peer-reviewed journal *Ultrasound in Obstetrics & Gynecology* (also known as the “White Journal”), which, was followed by the publication of an abstract entitled “*Progesterone Reduces the Rate of Cervical Shortening in Women at Risk for Preterm Birth*” in the December 2007 supplement of the *American Journal of Obstetrics and Gynecology*. Because we were able to publish data in advance of the 2008 Annual Meeting of the Society for Maternal-Fetal Medicine in late January 2008, the data underlying this abstract were discussed in an oral presentation at that meeting.

The PREGNANT study was designed based in part on the data set forth in the White Journal and discussions with the FDA. This randomized, double-blind, placebo-controlled Phase III clinical trial is designed to evaluate the ability of PROCHIEVE 8% to reduce the risk of preterm birth in women with a short cervix of between 1.0 and 2.0 centimeters as measured by transvaginal ultrasound at mid-pregnancy. The primary endpoint of this clinical trial is a reduction in preterm births at less than or equal to 32 weeks versus placebo.

In the fourth quarter of 2007 we recruited 19 study sites, filed the protocol with each site’s Institutional Review Board (“IRB”) and trained their staff on the study protocol. We expect to begin the recruiting efforts in the PREGNANT study in the first quarter of 2008. If we are able to meet our enrollment timeline for this trial, we expect to enroll and complete this clinical trial in 2008, with all the babies delivered in time to report results in the first half of 2009.

#### **Clinical Development of Vaginally-Administered Lidocaine for the Treatment of Dysmenorrhea.**

Throughout 2007 we continued to invest in our vaginal lidocaine drug candidate, which we are evaluating to prevent and treat the severe uterine cramps that result in the debilitating pain of dysmenorrhea. In the U.S. alone, this common, painful condition seriously affects about 5.6 million women in the age range of 20 to 45 to the point where they frequently miss work. This figure exclude very young women between the onset of menstruation and age 20 who can suffer dysmenorrhea at a higher percentage than the more mature female population between the ages of 20 and 45.



In mid 2007 we completed a multi-dose pharmacokinetic study of the lidocaine candidate and reported positive results demonstrating safe blood levels from our delivery system. We subsequently initiated a 75-patient Phase II cross-over study in patients with dysmenorrhea. We expect to conclude enrollment in April 2008, at the current rate of enrollment. We expect to announce data and results from this clinical trial in the third quarter of 2008.

We expect that the data from the Phase II clinical trial of our lidocaine candidate, if positive, will significantly reduce the risk of further investment in this drug candidate, allowing us to explore potential collaborative arrangements for further development and commercialization of this product candidate. The potential market for a vaginal lidocaine product includes pediatricians and family practice physicians, who fall outside our strategic focus. If the Phase II clinical trial data support further development of the drug candidate, we plan to have an end of Phase II meeting with FDA and begin designing the Phase III program for lidocaine in 2008.

## Results of Operations

### Summary

We restated our historical audited financial statements for the fiscal years ended December 31, 2006, 2005, and 2004, and our unaudited financial information for the quarters ended March 31, 2007, June 30, 2007, September 30, 2007, and March 31, 2006, June 30, 2006 and September 30, 2006. These restatements and revisions primarily reflect adjustments to:

- Correct previously reported interest expense for financing agreements for understatement in 2004 and 2005 and overstatement in 2006, along with the respective increase or decrease in net loss and the impact on outstanding loan balances and to increase or decrease the accumulated deficit.
- Correct the classification of the contingently redeemable Series C Convertible Preferred Stock from Shareholders Equity to temporary equity.

We receive revenues from our Progesterone Products that we either promote through our own sales force to reproductive endocrinologists, obstetricians, and gynecologists, and sell to wholesalers and specialty pharmacies or have partnered with other companies. We supplement our Progesterone Product revenue by selling other products that use our BDS which we refer to as “Other Products”. Most of the Other Product revenue is based on sales of products to licensees.

#### Fiscal 2007

Progesterone Products	<ul style="list-style-type: none"> <li>• CRINONE® 8% (progesterone gel) marketed by the Company in the U.S.</li> <li>• CRINONE® 8% sold to Merck Serono for foreign markets:</li> <li>• PROCHIEVE® 8% (progesterone gel):</li> <li>• PROCHIEVE® 4% (licensed to Ascend Therapeutics, Inc., effective January 1, 2008)</li> </ul>
Other Products	<ul style="list-style-type: none"> <li>• STRIANT® (testosterone buccal system) marketed by the Company in the US</li> <li>• STRIANT® sold to our partners for foreign markets:</li> <li>• Replens® Vaginal Moisturizer sold to Lil’ Drug Store Products, Inc (“Lil’ Drug Store”) for foreign markets</li> <li>• RepHresh® Vaginal Gel sold to Lil’ Drug Store on a worldwide basis</li> <li>• Royalty and licensing revenues</li> </ul>

All of our products are manufactured in Europe by third parties on behalf of our foreign subsidiaries who sell the products to our worldwide licensees, and to the Company in the case of the products we commercialize ourselves in the United States. Because our European revenues reflect these sales and are reduced only by our product manufacturing costs, we have historically shown a profit from our European operations.

Revenues from our United States operations principally relate to the Company’s products that we promote to physicians through our sales representatives, as well as royalty income from products that we have

licensed. The Company charges our United States operations all Selling and Distribution expenses that support our marketing, sales and distribution efforts. Research and Development expenses are charged to our United States operations for product development which principally supports new products and new label indications for products to be sold in this country. In addition, the majority of our General and Administrative expenses represent the Company's management activities as a public company and are charged to our United States operations. The amortization of the repurchase of the U.S. rights to CRINONE® is also charged to our United States operations. As a result, we have historically shown a loss from our United States operations that has been significantly greater than, and offsets, the profits from our European operations.

## Net Revenues

	2007	Percentage Inc./(dec.) from Prior Year	2006	Percentage Inc./(dec.) from Prior Year	2005	Percentage Inc./(dec.) from Prior Year	2004
	(In Thousands, Except Percentages)						
Revenues . . . . .	\$29,628	70%	\$17,393	-21%	\$22,041	23%	\$17,860

Net revenues increased 70% in 2007 to \$29.6 million as compared to \$17.4 million in 2006, \$22.0 million in 2005 and \$17.9 million in 2004. Net revenues from Progesterone Products increased 83% to \$20.5 million from \$11.2 million in 2006, \$13.0 in 2005 and \$9.0 million in 2004. The increase in 2007 over 2006 was primarily as a result of the addition of the U.S. CRINONE® sales generated by the Company under the marketing rights purchased from Merck Serono in December 2006. The decline in 2006 from 2005 was primarily driven by the cancellation of the sale of a semi-annual batch of CRINONE® to Merck Serono in anticipation of the U.S. rights acquisition. In the fourth quarter of 2004, primarily two customers returned \$1.4 million of PROCHIEVE 8% that was to expire in 2005. The Company re-evaluated its estimate for product returns, taking into consideration such factors as historical trends, distributor inventory levels and product prescription data and recorded additional provisions of \$1 million in 2004 and \$0.5 million in 2005.

Net revenues from Other Products increased 48% to \$9.2 million from \$6.2 million in 2006, decreased 29% from \$9.0 million in 2005 and increased 1% from \$8.9 million in 2004. The principal drivers of the increase in 2007 net revenues are from additional RepHresh® orders from Lil' Drug Stores and increased STRIANT® sales. The decrease of sales in 2006 from 2005 was principally due to lower RepHresh® orders and lower STRIANT® sales. Revenues in 2005 reflect an additional provision for STRIANT sales returns of \$1.8 million. Worldwide rights to RepHresh were sold in 2004 to Lil' Drug Store, who placed orders in 2005.

Gross profit as a percentage of net revenues was 70% in 2007 as compared to 55% in 2006, 63% in 2005 and 56% in 2004. The 15 percentage point increase in gross profit percentage from 2006 to 2007 was the result of the change in product mix to higher margin U.S. CRINONE® sales including the elimination of royalty income and expense formerly recognized under the license agreement with Merck Serono. For 2007, gross profit percentage for Progesterone Products improved 26% based on the shift from the previous Merck Serono license arrangement to the current full U.S. ownership of CRINONE. Gross profit percentage on Other Products decreased to 63% in 2007 from 73% in 2006 principally due to the loss of promotion fee income from Lil' Drug Store.

The decrease in 2006 gross profit as a percentage of net revenues from 63% in 2005 to 55% was caused by reduced sales of CRINONE® in the U.S. by Merck Serono in anticipation of the Company's acquisition of U.S. marketing rights to this product in December 2006, which caused a shift in the mix of product sales to lower margin OTC products and the purchase of CRINONE® inventory from Merck Serono.

The increase in the 2005 gross profit percentage was caused by an overall reduction in the provision for product returns and a reduction in the royalty paid to Merck Serono as a result of product returned in 2005.

The net loss for 2007 was \$14.3 million or \$.28 per share as compared to a net loss of \$12.5 million (restated), or \$.26 per share, in 2006, a net loss of \$10.1 million (restated) or \$.25 per share in 2005 and \$26.1 million (restated) or \$.54 per share in 2004 as a result of the foregoing as well as the following components.

## Selling and Distribution

	2007	Percentage Inc./ (dec.) from Prior Year	2006	Percentage Inc./ (dec.) from Prior Year	2005	Percentage Inc./ (dec.) from Prior year	2004
(In Thousands, Except Percentages)							
Selling and distribution . . . . .	\$10,112	53%	\$6,600	(23.1)%	\$8,578	-55%	\$19,007
As a percentage of revenue . . . . .	34%	(4)pp	38%	(1)pp	39%	(67.5)pp	106 %

Note: PP — percentage points

Selling and distribution expenses include payroll, employee benefits, equity compensation and other personnel-related costs associated with sales and marketing personnel, and advertising, promotions, trade-shows, seminars, and other marketing-related programs. Selling and distribution expenses were approximately \$10.1 million, \$6.6 million, \$8.6 million and \$19.0 million in 2007, 2006, 2005, and 2004 respectively. Selling and distribution expenses increased by approximately 53% in 2007 compared to 2006 and decreased by approximately 23% and 55% in 2006 compared to 2005 and 2005 compared to 2004, respectively. The primary reason for the 2007 increase was market research and marketing expenses to aid the Company in marketing CRINONE®. The decrease in 2006 from 2005 reflects a restructured sales force as well as reduced overall expenses. The decrease in 2005 from 2004 reflects the restructuring of the sales force in February 2005.

Included in the 2007 expenses were sales force costs of approximately \$5.2 million, product marketing expenses of approximately \$3.7 million and \$1.0 million in sales information and distribution costs. Expenses in 2006 included approximately \$4.0 million in sales force costs, approximately \$2.2 million in product marketing expenses and approximately \$0.5 million in distribution costs. Expenses in 2005 included approximately \$5.6 million in sales force costs, approximately \$2.2 million in product marketing expenses and approximately \$0.7 million in distribution costs. Expenses in 2004 included approximately \$10.9 million in sales force costs, approximately \$4.8 million in product marketing expenses and approximately \$1.2 million in salary costs.

## General and Administrative

	2007	Percentage Inc./ (dec.) from Prior Year	2006	Percentage Inc./ (dec.) from Prior Year	2005	Percentage Inc./ (dec.) from Prior Year	2004
(In Thousands, Except Percentages)							
General and administrative . . . . .	\$7,825	6%	\$7,402	9%	\$6,825	-10%	\$7,588
As a percentage of revenue . . . . .	26%	(17)pp	43%	12pp	31%	-11.5pp	19.1%

General and administrative costs include payroll, employee benefits, equity compensation, and other personnel-related costs associated with finance, legal, regulatory affairs, information technology, facilities and certain human resources, and other administrative personnel, as well as legal costs and other administrative fees. General and Administrative expenses increased by approximately \$0.4 million, or 6%, to approximately \$7.8 million in 2007 from approximately \$7.4 million in 2006 which was an increase of \$0.6 million from \$6.8 million in 2005. The increase from Statement 123R stock compensation expense over 2006 was \$0.3 million and the balance was an increase in professional expenses. The increase in 2006 over 2005 of \$0.6 million resulted primarily from the impact of 123R recognition and severance expenses. General and administrative expenses decreased by approximately \$0.8 million, or 10%, to approximately \$6.8 million in 2005 from approximately \$7.6 million in 2004. The decrease resulted primarily from lower insurance costs (\$0.7 million).

## Research and Development

	2007	Percentage Inc./ (dec.) from Prior Year	2006	Percentage Inc./ (dec.) from Prior Year	2005	Percentage Inc./ (dec.) from Prior Year	2004
(In Thousands, Except Percentages)							
Research and development . . . . .	\$5,779	(12)%	\$6,596	15%	\$5,757	6%	\$5,449
As a percentage of revenue . . . . .	20%	(19)pp	38%	(12)pp	26%	-4.4pp	30.5%

Research and development expenses include payroll, employee benefits, equity compensation and other personnel -related costs associated with product development, as well as the cost of conducting and administering clinical studies and the cost of regulatory filings for our products. Research and Development expenses decreased \$0.8 million in 2007 from 2006. The decrease is primarily related to the completion in early 2007 of the Company's Phase III trial for PROHIEVE® 8% for the prevention of recurrent preterm birth which is partially offset by expenses associated with the 2007 Phase II lidocaine trial for women with severe dysmenorrhea and the start up expenses for the Phase III PREGNANT study. Research and development expenses increased to approximately \$6.6 million in 2006 from approximately \$5.8 million in 2005. This increase primarily reflects costs associated with the Company's Phase III clinical trial of PROCHIEVE® 8% in preventing recurrent preterm birth. Study-related costs increased by approximately \$1.2 million in 2006 over 2005 levels. 2006 costs also included development costs related to the Company's vaginally-administered lidocaine drug candidate. The 2005 increase was partially offset by the reduction in payments related to the Mutual Recognition Process ("MRP") for obtaining regulatory approval of STRIANT® in European countries, a one-time event which culminated in October 2004 with the approval of STRIANT in 14 European countries (\$0.4 million) and a reduction of costs associated with the continuation studies associated with STRIANT (\$0.4 million). Research and development expenses increased to approximately \$5.4 million in 2004 from approximately \$3.3 million in 2003. This increase primarily reflects costs associated with the Company's Phase III clinical trial of PROCHIEVE® 8% in preventing recurrent preterm birth. 2004 costs also included payments related to the MRP, a one-time event as previously discussed.

### Amortization of Crinone® Acquisition

The Company purchased the marketing rights for U.S. sales of CRINONE® 8% from Merck Serono in December 2006 for \$33 million. In the second quarter of 2007, the Company recognized a \$1 million adjustment to the purchase price to reflect contingent liabilities for Merck Serono sales returns. The \$33 million charge is being amortized over 6.75 years, and the \$1 million charge is being amortized over 6.5 years. Amortization expense of the acquisition cost for CRINONE® U.S. marketing rights for 2007 was \$5.0 million. The 2006 charge was \$0.1 million.

### Other Income (Expense)

Interest expense was \$7.9 million, \$2.7 million as restated, \$3.5 million as restated and \$3.9 million as restated in 2007, 2006 2005, and 2004 respectively. In December of 2006, the Company issued \$40 million in convertible subordinated notes. Interest expense of 2007 includes cash interest of \$3.2 million and \$2.5 million in charges associated with amortization of beneficial conversion feature, amortization of the warrant costs and issuance costs. The balance of \$2.2 million was for the remainder of the PharmaBio obligations. The restatement of interest expense lowers interest for PharmaBio by \$0.1 million in 2006 and raises previously reported interest expense in 2005 by \$0.8 million, and in 2004 by \$0.9 million.

2007, 2006, 2005, and 2004 interest expense included approximately \$2.3 million, \$2.5 million as restated, \$3.3 million as restated, and \$3.2 million as restated, respectively, as a result of amortizing interest expense over the term of the agreements, the difference between the minimum amounts to be paid to PharmaBio and the amounts received. Additionally, interest expense related to a \$10 million convertible subordinated note totaled \$0.2 million in 2005. This note was paid in full on March 15, 2005.





## Recent Accounting Pronouncements

In December 2006, the Financial Accounting Standards Board (“FASB”) issued a FASB Staff Position (“FSP”) EITF 00-19-2 “*Accounting for Registration Payment Arrangements*” (“FSP 00-19-2”). FSP 00-19-2 defines a registration payment arrangement as an arrangement where the issuer (i) will endeavor to file a registration statement for the resale of financial instruments, have the registration statement declared effective, or maintain its effectiveness and (ii) transfer consideration to the counterparty if the registration statement is not declared effective or its effectiveness is not maintained. We entered into certain registration payment arrangements in connection with the sale of our Common Stock in March 2006 and the issuance of our convertible notes in December 2006. This FSP specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5 “*Accounting for Contingencies*.” The guidance in this FSP amends FASB Statements No. 133, “*Accounting for Derivative Instruments and Hedging Activities*,” and No. 150, “*Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*,” as well as FASB Interpretation No. 45, “*Guarantor’s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*” to include scope exceptions for registration payment arrangements. This FSP was effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issuance of this FSP. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of this FSP, this is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. FSP 00-19-2 did not have a material impact on our consolidated results of operations and financial position in 2007.

In September 2006, the FASB issued SFAS No. 157, “*Fair Value Measurements*” (“SFAS 157”), which clarifies the definition of fair value, establishes guidelines for measuring fair value, and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements and eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS No. 157 and FSP 157 (b) are effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. As proposed the effective date of SFAS No. 157 would be deferred to Fiscal years beginning after November 15, 2008 and for interim periods within those years for certain non financial assets and liabilities. The Company is currently evaluating the impact that adopting SFAS 157 will have on our financial position, cash flows or results of operations.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, “*The Fair Value Option for Financial Assets and Financial Liabilities*” (“SFAS 159”). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between entities that choose different measurement attributes for similar assets and liabilities. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company has not yet determined the impact, if any, that the implementation of SFAS.159 will have on its results of operations or financial position.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), “*Business Combinations*” (“SFAS 141(R)”). SFAS 141(R) will change the accounting for business combinations. Under SFAS 141(R), an acquiring entity will be required to recognize all the assets acquired and liabilities assumed in a transaction at the acquisition-date fair value with limited exceptions. SFAS 141(R) will change the accounting treatment and disclosure for certain specific items in a business combination. SFAS 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. SFAS 141(R) will impact the Company in the event of any future acquisition.

In December 2007, the FASB also issued SFAS No. 160, “*Non-controlling Interests in Consolidated Financial Statements — an Amendment of Accounting Research Bulletin No. 51*” (“SFAS 160”). SFAS 160 establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the

deconsolidation of a subsidiary. SFAS No. 160 is effective for fiscal years beginning on or after December 15, 2008. The Company does not believe that SFAS 160 will have a material impact on its consolidated financial statements.

The Company does not believe that any other recently issued, but not yet effective, accounting standards would have a material effect on the Company's consolidated financial position, results of operations or cash flows.

### Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

### Impact of Inflation

Sales revenues, manufacturing costs, selling and distribution expenses, general and administrative expenses, and research and development costs tend to reflect the general inflationary trends.

### Liquidity and Capital Resources

Cash and cash equivalents were \$17 million, \$25 million, and \$7 million, at December 31, 2007, December 31, 2006, and December 31, 2005, respectively.

The Company believes the approximately \$17 million of cash on hand at December 31, 2007 will allow it to sustain its operations.

Cash provided by (used in) operating, investing, and financing activities is summarized as follows:

	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>
		(Restated)	(Restated)	(Restated)
Cash flows:				
Operating activities . . . . .	\$(7,914,299)	\$(13,080,977)	\$(8,283,473)	\$(20,399,171)
Investing activities . . . . .	(102,021)	(33,015,757)	(83,367)	(282,367)
Financing activities . . . . .	(40,803)	64,208,356	(4,213,299)	9,447,186

#### Operating Activities:

The net loss in 2007 of \$14.3 million is reduced by non cash items totaling \$10.4 million leaving cash operating losses of \$3.9 million. Changes to assets and liabilities increased by \$5.4 million leaving cash flow from operations as a use of funds at \$7.9 million. Changes to assets and liabilities reflect the effects of the increased revenues of CRINONE®, STRIANT® and RepHresh®. Accounts receivable grew by \$1.5 million. Inventory grew by \$1.0 million. Accounts payable and accrued expenses decreased by \$1.4 million and \$0.2 million respectively. The reduction in accrued expenses related to: sales returns of \$1.3 million, miscellaneous expenses and interest.

The restated net loss in 2006 of \$12.5 million is reduced by non-cash items totaling \$4.2 million leaving cash operating losses of \$8.3 million. Working capital decreased by \$0.8 million less the increase in other assets of \$1.4 million for deferred financing charges plus deferred revenues of \$0.1 million leaving cash flow from operating activities as a use of funds at \$13.1 million. Working capital changes reflect a reduction in the sales return levels from 2005 levels by both a reduction in receivables \$1.3 million and heavy sales returns in the fourth quarters. Inventories increased \$0.9 million. The increase in other assets, (\$1.4 million) represents the capitalization of the \$40 million subordinated debt issue expenses. Similarly, the increase in accounts payable of \$1.7 million represents the sum of the issue expenses (\$1.3 million) and clinical trial expenses (\$0.3 million). Accrued expenses grew by \$1.0 million half of which is due to the increase in sales returns by \$0.5 million and professional fees for \$0.3 million.

The restated net loss in 2005 was \$10.1 million which included \$3.9 million in non cash charges leaving cash operating losses of \$6.2 million. Working capital grew by \$3.8 million, a decrease in accrued expenses of approximately \$3.2 million (principally related to customer usage of sales return credits), and a decrease in

accounts payable of \$0.9 million during the year amounting to most of the increase in working capital. These were partially offset by a reduction in prepaid expenses and other current assets of approximately \$0.5 million, as a result of paying insurance payments in installments instead of in one up-front payment.

The restated net loss in 2004 of \$26.1 million included \$4.8 million of non cash charges leaving net cash operating losses of \$21.3 million. Working capital decreased by \$2.3 million. Accrued expenses decreased by approximately \$3.2 million (principally related to customer usage of approximately \$1.5 million in sales return credits, and approximately \$1.4 million decrease in the accrual for costs associated with the sales and marketing of STRIANT®). Inventory increased approximately \$1.3 million (primarily related to STRIANT). These were partially offset by a decrease in prepaid expenses and other current assets of approximately \$1.1 million (primarily as a result of a significant reduction in insurance premiums), a decrease in the 2004 year-end balance in accounts receivable of approximately \$0.7 million caused by a difference in the timing of sales within the fourth quarters of 2004 and 2003, and the receipt of \$0.8 million in milestone fees from one of the Company's licensees in 2004.

#### *Investing Activities:*

In 2007, the Company purchased office equipment at a cost of \$0.1 million.

In December of 2006, the Company purchased the U.S. rights to CRINONE® for the US market at a cost of \$33 million. In the second quarter of 2007, the Company recognized an additional \$1 million adjustment to the purchase price to reflect contingent liabilities for Merck Serono sales returns.

Net cash used in investing activities in 2005 was primarily attributable to the purchase of office equipment.

Net cash used in investing activities in 2004 was primarily attributable to the purchase of manufacturing equipment associated with STRIANT® and the purchase of office equipment. Additionally, in 2004, the Company received \$0.3 million from the sale of intangible assets associated with the sale of our over-the-counter products to Lil' Drug Store Products, Inc

#### *Financing Activities:*

Net cash used in financing activities in 2007 of \$0.04 million represents Series C Preferred Stock dividends, purchase of treasury stock and the proceeds from the exercise of options.

Financing activities in 2006 produced net funds to the Company of \$64.2 million. The Company had two major fund raises, one in March and the other in December. The March capital raise of \$28.8 million was through the sale of 7,428,220 shares of common stock and the issue of 1,857,041 warrants. In December, the Company raised \$40 million through the sale of subordinated convertible notes discussed below. Stock option exercises generated \$1.0 million of proceeds. Offsetting these receipts were the payment of \$5.4 million to PharmaBio and \$0.2 million in dividends to the holders of the Company's Series C Preferred Stock.

On December 22, 2006, the Company raised approximately \$40 million in gross proceeds to the Company from the sale of convertible subordinated notes to a group of existing institutional investors. The notes bear interest at a rate of 8% per annum and mature on December 31, 2011. They are convertible into shares of Common Stock at a conversion price of \$5.25. Investors also received warrants to purchase 2,285,714 shares of Common Stock at an exercise price of \$5.50 per share. The warrants become exercisable on June 20, 2007, and expire on December 22, 2011, unless earlier exercised or terminated. The Company used the proceeds of this offering to acquire from Merck Serono the U.S. marketing rights to CRINONE® (\$33 million), purchase Merck Serono's current inventory of that product, and pay other costs related to the transaction. In the second quarter of 2007, the Company recognized an additional \$1 million adjustment to the purchase price to reflect contingent liabilities for Merck Serono sales returns. The balance of the proceeds will be used for general corporate purposes.

We recorded original issue discounts of \$6.3 million to the notes based upon the fair value of warrants granted. In addition, beneficial conversion features totaling \$8.5 million have been recorded as a discount to the notes. These discounts are being amortized over the five year term of the related notes. For the year ended December 31, 2006, \$0.1 million of amortization related to these discounts is classified as interest expense in

our consolidated statements of operations. Unamortized discounts of \$14.8 million have been reflected as a reduction to the face value of convertible notes in our consolidated balance sheet as of December 31, 2006.

Net cash used in 2005 was attributable to the payoff of a \$10 million subordinated convertible note on March 15, 2005, \$1.0 million paid to PharmaBio Development under the Company's two product financing agreements (including a \$1.9 million true-up payment under the women's healthcare products financing agreement), and \$0.2 million in dividends paid to the owners of the Company's Series C Preferred Stock. Offsetting these payments was the receipt of \$6.9 million by the Company from the issuance of Series E Convertible Preferred Stock and \$8,253 received from the exercise of options and warrants.

Net cash provided by financing activities in 2004 resulted from the receipt of \$6.4 million from the issuance of Common Stock, \$3 million pursuant to the Striant financing agreement, and \$0.2 million from the exercise of options and warrants. Offsetting these receipts was \$0.2 million in dividends paid to the owners of the contingently redeemable Company's Series C Convertible Preferred Stock.

As previously discussed, on July 31, 2002, we entered into an investment and royalty agreement with PharmaBio under which we received \$4.5 million in return for a 5% royalty to PharmaBio on net sales of the Company's women's healthcare products in the United States for five years, beginning in the first quarter of 2003. The royalty payments are subject to aggregate minimum (\$8 million) and maximum (\$12 million) amounts, including a true-up payment paid on February 28, 2005 for the difference between royalties paid to that date and \$2.75 million. We made the required true-up payment of approximately \$1.9 million on February 28, 2005, and have paid \$4.4 million to December 31, 2007. The final payment under this agreement of \$3.6 million was paid to PharmaBio on February 29, 2008.

Also, as previously discussed, on March 5, 2003, we entered into a second investment and royalty agreement with PharmaBio under which we received \$15 million in return for a 9% royalty to PharmaBio on net sales of STRIANT® in the United States up to agreed annual sales revenues, and a 4.5% royalty of net sales above those levels. The royalty term is seven years. Royalty payments commenced in the 2003 third quarter and are subject to aggregate minimum (\$30 million) and maximum (\$55 million) amounts, including a true-up payment due on November 14, 2006 for the difference between royalties paid to that period and \$13 million. On April 14, 2006, the Company made an advance payment of \$11.6 million on the contractually required true-up payment. This amount represented the present value of a \$12 million true-up payment due November 14, 2006, calculated using a six percent annual discount factor. Additionally, the Company made a follow-up \$0.2 Million true-up payment at the end of the year. The Company has paid \$13.1 million to December 31, 2007.

The Company has an effective registration statement that we filed with the Securities and Exchange Commission (the "SEC") using a shelf registration process. Under the shelf registration process, we may offer from time to time shares of our Common Stock up to an aggregate amount of \$75 million. To date the Company has sold approximately \$56.4 million in Common Stock under the registration statement. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the marketing of one or more of our products and the development and/or commercialization of one or more of our product candidates.

As of December 31, 2007, the Company had outstanding exercisable options and warrants that, if exercised, would result in approximately \$50.0 million of additional capital and would cause the number of shares of Common Stock outstanding to increase. However, there can be no assurance that any such options or warrants will be exercised.

In connection with the 1989 purchase of the assets of Bio-Mimetics, which assets consisted of the patents underlying the Company's BDS, other patent applications and related technology, the Company pays Bio-Mimetics a royalty equal to two percent of the net sales of products based on the BDS up to an aggregate of \$7.5 million or until the last of the relevant patents expires. The Company is required to prepay 25% of the remaining royalty obligation, in cash or stock at the option of the Company, if the closing price of the

Company's Common Stock is \$20 or more on March 2, or within 30 days after that date, of any year. To date, the Company has paid approximately \$3.3 million in royalty payments. Royalty payments on STRIANT, PROCHIEVE®, and CRINONE® expired in September of 2006, but continue on Replens® and RepHresh®. On December 28, 2007, Bio-Mimetics filed a complaint in the United States District Court for Massachusetts (*Bio-Mimetics, Inc. v Columbia Laboratories, Inc.*) alleging breach of contract, violation of the covenant of good faith and fair dealing, and unjust enrichment for the Company's failure to continue royalty payments on STRIANT®, PROCHIEVE®, and CRINONE®. The Company intends to defend this action vigorously.

The Company anticipates it will spend approximately \$0.4 million on equipment in 2008.

As of December 31, 2007, the Company had available net operating loss carryforwards of approximately \$157.3 million to offset its potential future U.S. taxable income. There can be no assurance that the Company will have sufficient income to utilize the net operating loss carryforwards or that the net operating loss carryforwards will be available at that time.

In accordance with Statement of Financial Accounting Standards No. 109, as of December 31, 2007, 2006, and 2005 other assets in the accompanying consolidated balance sheet include deferred tax assets of approximately \$60.5 million, \$53.2 million, and \$50.8 million respectively, (comprised primarily of a net operating loss carryforward) for which a valuation allowance has been recorded because the probability of realizing the deferred tax assets are not determinable. With respect to the Company's net operating loss carryforwards, it has not undertaken an analysis to determine whether the utilization of this tax asset would be limited by Section 382 of the Internal Revenue Code.

### **Critical Accounting Policies and Estimates**

Our financial statements and accompanying notes are prepared in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). The preparation of financial statements requires management to make estimates and assumptions that affect the reported amount of assets and liabilities, and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. There can be no assurance that actual results will not differ from those estimates. These estimates and assumptions are affected by management's application of accounting policies. Critical accounting policies for us include revenue recognition, impairment of intangible assets, and accounting for the agreements with PharmaBio. For a detailed discussion on the application of these and other accounting policies, see Note 1 of the consolidated financial statements included in Item 15 of this Annual Report on Form 10-K.

*Revenue recognition.* The Company's revenue recognition is significant because revenue is a key component of our results of operations. In addition, revenue recognition determines the timing of certain expenses, such as commissions and royalties. Revenue results are difficult to predict, and any shortfall in revenue or delay in recognizing revenue could cause operating results to vary significantly from quarter to quarter. Revenues on sales of products by Columbia are discussed in detail below. Royalties and additional monies owed to the Company based on sales by our licensees are recorded as revenue as those sales are made by the licensees. License fees not based on sales are recognized as revenues over the term of the license.

*Sales Returns.* Revenues from the sale of products are recorded at the time goods are shipped to customers. The Company believes that it has not made any shipments in excess of its customers' ordinary course of business inventory levels. Our return policy allows product to be returned for a period beginning three months prior to the product expiration date and ending twelve months after the product expiration date. Provisions for returns on sales to wholesalers, distributors and retail chain stores are estimated based on a percentage of sales, using such factors as historical sales information, distributor inventory levels and product prescription data, and are recorded as a reduction to sales in the same period as the related sales are recognized. We also continually analyze the reserve for future sales returns and increase such reserve if deemed appropriate. The Company purchases prescription data on all its products from IMS Health, a leading provider of market intelligence to the pharmaceutical and healthcare industries. The Company also purchases certain information regarding inventory levels from its largest wholesale customer. This information includes for each of the Company' products, the quantity on hand, the number of days of inventory on hand, and a 28 day forecast of sales by units. Using this information and historical information, the Company estimates potential returns by taking the number of product units sold by the Company by expiration date and then subtracting



actual units and potential units that may be sold to end users (consumers) based on prescription data up to five months prior to the product's expiration date. The Company assumes that our customers are using the first-in, first-out method in filling orders so that the oldest salable product is used first. The Company also assumes that our customers will not ship product that has expiration dating less than six months to a retail pharmacy, but that retail pharmacies will continue to dispense product they have on hand until two months prior to the product's expiration date. The Company's products are used by the consumer immediately so no shelf life is needed. Retail pharmacies tend not to maintain a large supply of our products in their inventory, so they order on an 'as needed' basis. The Company also subtracts units that have already been returned or, based on notifications received from customers, will be returned. The Company then records a provision for returns on a quarterly basis using an estimated rate and adjusts the provision if the above analysis indicates that the potential for product non-salability exists.

*Accounting For PharmaBio Agreements.* In July 2002 and March 2003, the Company entered into agreements with PharmaBio under which the Company received upfront money paid in quarterly installments in exchange for royalty payments on certain of the Company's products to be paid to PharmaBio for a fixed period of time. The royalty payments are subject to minimum and maximum amounts. Because the minimum amounts exceed the amount received by the Company, the Company has recorded the monies received as liabilities. We are recording the excess of the minimum to be paid by the Company over the amount received by the Company as interest expense over the terms of the agreements. In 2007, the Company revalued the financing agreements to reflect the cash flow component of the arrangement which resulted in a restatement of earnings for 2006, 2005, and 2004. The impact of this change was to increase interest expense for 2004 and 2005 by \$0.9 million and \$0.8 million respectively, and to lower interest expense for 2006 by \$0.1 million.

*Adjustments for Stock-Based Compensation on Prior Year Financial Statements.* As of January 1, 2006, the Company adopted FAS 123R, using the modified prospective transition method. FAS 123R requires the measurement and recognition of compensation expense for all stock-based awards made to the Company's employees and directors including stock options and other stock-based awards based on estimated fair values. Prior to January 1, 2006, the Company accounted for share-based compensation granted under its stock option plans using the recognition and measurement provisions of APB 25. Under APB 25, a company was not required to recognize compensation expense for stock options issued to employees if the exercise price of the stock options was at least equal to the quoted market price of the Company's common stock on the "measurement date." APB 25 defined the measurement date as the first date on which both the number of shares that an individual employee was entitled to receive and the option price, if any, were known.

As previously disclosed, a review of the Company's stock option granting practices from October 1996 through 2006, resulted in the recording for the year ended December 31, 2006, of \$998,000 to reflect additional stock-based compensation expense under APB 25, the accounting method in effect at the time, relating to the company's historical stock option practices. The majority of such amount was attributable to options granted in 1997, with related compensation expense allocable to the years ended December 31, 1997, and 1998. In accordance with the transition provisions of Staff Accounting Bulletin (SAB) No. 108, "*Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*," the Company recorded a reclassification within the equity section of the consolidated balance sheet as an increase in additional paid-in capital and an increase in accumulated deficit for the year ended December 31, 2006, of \$998,000, excluding any related tax effect. Because the Company substantially reported losses during this period, the impact to income taxes was not considered material. This reclassification represents the effect of the adjustment resulting from the non-cash charges discussed above, all of which relate to prior fiscal years.

### **Forward-Looking Statements**

This Annual Report on Form 10-K contains statements that are forward-looking. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements include, without limitation, the Company's expectations regarding sales, earnings or other future financial performance and liquidity, completion or outcome of clinical studies, product introductions, entry into new geographic regions, and general optimism about future operations or operating results. Some of these statements can be identified by the use of forward-looking terminology such as "prospects," "outlook,"

“believes,” “estimates,” “intends,” “may,” “will,” “should,” “anticipates,” “expects, or “plans,” or the negative or other variation of these or similar words, or by discussion of trends and conditions, strategy or risks and uncertainties.

These forward looking expectations are based on current assumptions within the bounds of management’s knowledge of our business and operations and which management believes are reasonable. These assumptions are subject to risks and uncertainties, and actual results could differ materially from expectations because of issues and uncertainties such as those listed in “Risk Factors” and elsewhere in this Annual Report, which, among others, should be considered in evaluating our future financial performance. All subsequent written and oral forward-looking statements attributable to the Company or persons acting on behalf of the Company are expressly qualified in their entirety by the cautionary statements in this Annual Report. Readers are advised to consult any further disclosures the Company may make on related subjects in subsequent reports filed with the SEC.

#### **Item 7A. Quantitative and Qualitative Disclosures About Market Risks**

The Company does not believe that it has material exposure to market rate risk. The Company may, however, require additional financing to fund future obligations and no assurance can be given that the terms of future sources of financing will not expose the Company to material market risk. Expenditures primarily related to manufacturing in 2007 were approximately \$0.7 million more than they would have been if the average 2006 exchange rates had been in effect in 2007.

#### **Item 8. Financial Statements and Supplementary Data**

The financial statements and supplementary data required by this item are set forth at the pages indicated in Item 15, set forth in this annual report.

#### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None

#### **Item 9A. Controls and Procedures**

##### **Evaluation of Disclosure Controls and Procedures**

The Company maintains disclosure controls and procedures designed to ensure that the information the Company must disclose in its filings with the SEC is recorded, processed, summarized and reported on a timely basis. The Company’s management, under the supervision and with the participation of the Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of the Company’s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2007. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2007, the Company’s disclosure controls and procedures were not effective due to the material weakness noted below.

##### **Management’s Annual Report on Internal Control over Financial Reporting**

The Company’s management is responsible for establishing and maintaining an adequate system of internal control over financial reporting. Internal control over financial reporting is a process designed 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. A company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Further, because of changes in conditions, effectiveness of internal control over financial reporting may vary over time.

Management of the Company conducted an evaluation of the effectiveness, as of December 31, 2007, of the Company's internal control over financial reporting based on the Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO Framework"). Based on its evaluation under the COSO Framework, management has concluded that the Company's internal control over financial reporting was not effective as of December 31, 2007.

#### **Identification of a Material Weakness**

A material weakness is a significant deficiency, or a combination of significant deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

During the audit of the 2007 financial statements, it was determined that the Company's method for calculating interest on its financing agreements and the classification of its contingently redeemable Series C Convertible Preferred stock were not correct, and the Company's management has elected to restate the financial statements for 2004, 2005 and 2006.

#### **Remediation of a Material Weakness**

The Company will engage an external consultant to review its current accounting for financial transactions and report to management its findings.

McGladrey and Pullen LLP, an independent registered public accounting firm, has issued an attestation report on the Company's internal control over financial reporting (see Report of Independent Registered Public Accounting Firm).

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders  
of Columbia Laboratories, Inc.

We have audited Columbia Laboratories, Inc. and Subsidiaries internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Columbia Laboratories, Inc. and Subsidiaries' management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. As of December 31, 2007, the Company did not maintain effective internal control over (i) accounting for contingently redeemable preferred stock and (ii) accounting for interest expense in relation to financing agreements with indeterminate payments. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2007 financial statements, and this report does not affect our report dated March 25, 2008, on those financial statements.

In our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, Columbia Laboratories, Inc. and Subsidiaries has not maintained effective internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the December 31, 2007 consolidated financial statements of Columbia Laboratories, Inc. and our report dated March 25, 2008 expressed an unqualified opinion on those financial statements.

/s/ McGladrey & Pullen, LLP  
McGLADREY & PULLEN, LLP  
New York, NY  
March 25, 2008

### Item 9 B. Other Information

In the fourth quarter of 2007 the Company reported all required disclosures on Form 8-K.

## **PART III**

### **Item 10. Directors and Executive Officers of the Company**

The information concerning directors and all audit committee financial experts required by Item 10 is incorporated herein by reference to Columbia's Proxy Statement for its 2008 Annual Meeting of Shareholders. The information concerning compliance with Section 16(a) of the Exchange Act is incorporated herein by reference to Columbia's Proxy Statement for its 2008 Annual Meeting of Shareholders. The information concerning executive officers required by Item 10 is contained in the discussion entitled Executive Officers of the Registrant in Part I hereof.

### **Item 11. Executive Compensation**

The information required by Item 11 is incorporated herein by reference to Columbia's Proxy Statement for its 2008 Annual Meeting of Shareholders under the heading "Executive Compensation".

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by Item 12 is incorporated herein by reference to Columbia's Proxy Statement for its 2008 Annual Meeting of Shareholders under the heading "Ownership of the Company".

### **Item 13. Certain Relationships and Related Transactions**

The information required by Item 13 is incorporated herein by reference to Columbia's Proxy Statement for its 2008 Annual Meeting of Shareholders under the heading "Certain Relationships and Related Transactions".

### **Item 14. Principal Accountant Fees and Services**

The information required by Item 14 is incorporated herein by reference to Columbia's Proxy Statement for its 2008 Annual Meeting of Shareholders under the heading "Relationship with Independent Auditors".



## PART IV

### Item 15. Exhibits and Financial Statement Schedules

#### (a)(1)(2) Financial Statements and Financial Statement Schedules

Indexes to financial statements and financial statement schedules appear on F-1 and F-26, respectively.

#### (b) Exhibits

Exhibit No	Description
3.1	Restated Certificate of Incorporation of the Company, as amended <sup>(14)</sup>
3.2	Amended and Restated By-laws of Company <sup>(3)</sup>
4.1	Certificate of Designations, Preferences and Rights of Series C Convertible Preferred Stock of the Company, dated as of January 7, 1999 <sup>(3)</sup>
4.2	Securities Purchase Agreement, dated as of January 7, 1999, between the Company and each of the purchasers named on the signature pages thereto <sup>(3)</sup>
4.3	Securities Purchase Agreement, dated as of January 19, 1999, among the Company, David M. Knott and Knott Partners, L.P. <sup>(3)</sup>
4.4	Form of Warrant to Purchase Common Stock <sup>(3)</sup>
4.5	Warrant to Purchase Common Stock granted to James J. Apostolakis on September 23, 1999
4.6	Certificate of Designations of Series E Convertible Preferred Stock, filed May 10, 2005 with the Delaware Secretary of State <sup>(13)</sup>
4.7	Preferred Stock Purchase Agreement, dated as of May 10, 2005, among Columbia Laboratories, Inc., Perry Partners L.P. and Perry Partners International, Inc. <sup>(13)</sup>
4.8	Securities Purchase Agreement, dated March 10, 2006, by and between Columbia Laboratories, Inc. and the Purchasers listed on Exhibit A thereto <sup>(15)</sup>
4.9	Form of Restricted Stock Agreement <sup>(18)</sup>
4.10	Form of Option Agreement <sup>(18)</sup>
4.11	Securities Purchase Agreement, dated December 21, 2006, by and between Columbia Laboratories, Inc. and the Purchasers listed on Exhibit A thereto <sup>(21)</sup>
10.1	1996 Long-term Performance Plan, as amended, of the Company <sup>(2)</sup>
10.2	Asset Purchase, License and Option Agreement between Bio-Mimetics, Inc. and Columbia Laboratories, Inc., dated November 22, 1989 <sup>(1)</sup>
10.3	License and Supply Agreement by and between the Company and Mipharm S.p.A. dated March 5, 1999 <sup>(4)</sup>
10.4	Settlement Agreement and Release dated as of March 16, 2000 between Columbia Laboratories (Bermuda) Ltd. and Lake Consumer Products, Inc. <sup>(5)</sup>
10.5	License Agreement dated April 18, 2000, between the Company and Lil' Drug Store Products, Inc. <sup>(6)</sup>
10.6	Rights Agreement dated as of March 13, 2002, by and between Columbia Laboratories, Inc. and First Union National Bank, as Rights Agent <sup>(7)</sup>
10.7†	Semi-Exclusive Supply Agreement dated May 7, 2002 between the Company and Mipharm S.p.A. <sup>(8)</sup>
10.8†	Amended and Restated License and Supply Agreement dated June 4, 2002 between the Company and Ares Trading S.A. <sup>(8)</sup>
10.9†	Marketing License Agreement dated June 4, 2002 between the Company and Ares Trading S.A. and Serono, Inc. <sup>(8)</sup>

Exhibit No	Description
10.10†	Investment and Royalty Agreement dated July 31, 2002 between the Company and PharmaBio Development Inc. <sup>(8)</sup>
10.11†	License and Supply Agreement dated October 16, 2002 between the Company and Ardana Bioscience Limited <sup>(9)</sup>
10.12†	Development and License Agreement dated December 26, 2002 between the Company and Ardana Bioscience Limited <sup>(9)</sup>
10.13†	Investment and Royalty Agreement dated March 5, 2003 between the Company and PharmaBio Development Inc. <sup>(9)</sup>
10.14†	License and Supply Agreement Dated May 27, 2003 between the Company and Mipharm S.p.A. <sup>(10)</sup>
10.15	Form of Indemnification Agreement for Officers and Directors <sup>(11)</sup>
10.16	Form of Executive Change of Control Severance Agreement <sup>(11)</sup>
10.17†	Asset Purchase Agreement Dated June 29, 2004, between the Company and Lil' Drug Store Products, Inc. <sup>(12)</sup>
10.18†	Supply Agreement dated June 29, 2004, between the Company and Lil' Drug Store Products, Inc. <sup>(12)</sup>
10.19†	Professional Promotion Agreement dated June 29, 2004, between the Company and Lil' Drug Store Products, Inc. <sup>(12)</sup>
10.20	Employment Agreement by and between Columbia Laboratories, Inc. and Robert S. Mills dated March 30, 2006 <sup>(16)</sup>
10.21	Employment Agreement by and between Columbia Laboratories, Inc. and Michael McGrane dated March 30, 2006 <sup>(16)</sup>
10.22	Letter Agreement Supplement to STRIANT® Investment and Royalty Agreement dated April 14, 2006 <sup>(17)</sup>
10.23	Employment Agreement by and between Columbia Laboratories, Inc. and James Meer dated December 6, 2006 <sup>(19)</sup>
10.24	Separation Agreement by and between Columbia Laboratories, Inc. and David L. Weinberg effective as of December 12, 2006 <sup>(20)</sup>
10.25†	Agreement, dated December 21, 2006, by and among Ares Trading S.A., Serono, Inc., the Company and its wholly-owned subsidiary, Columbia Laboratories (Bermuda), Ltd <sup>(21)</sup>
10.26	Amendment No. 1 to the Amended and Restated License and Supply Agreement, entered into December 21, 2006, by and between Ares Trading S.A and Columbia Laboratories (Bermuda), Ltd. <sup>(21)</sup>
10.27	Description of the Registrant's Compensation and Reimbursement Practices for Non-employee Directors. <sup>(22)</sup>
10.28	Columbia Laboratories, Inc., Incentive Plan <sup>(22)</sup>
10.29	Lease Agreement between Allwood Associates I and Columbia Laboratories, Inc., dated July 6, 2007 <sup>(22)</sup>
10.30†	License and Supply Agreement between Columbia Laboratories, Inc. and Ascend Therapeutics, Inc., dated September 27, 2007 <sup>(23)</sup>
10.31	Supply Agreement between Columbia Laboratories (Bermuda) Limited and Fleet Laboratories Limited, dated July 12, 1996 <sup>(24)</sup>
10.32	Packaging Agreement between Columbia Laboratories (Ireland) Ltd. and Maropack AG, dated October 28, 1993 <sup>(24)</sup>
14	Code of Ethics of the Company <sup>(11)</sup>

Exhibit No	Description
21	Subsidiaries of the Company <sup>(24)</sup>
23.1	Consent of Goldstein Golub Kessler LLP <sup>(24)</sup>
23.2	Consent of McGladrey & Pullen, LLP <sup>(24)</sup>
31(i).1	Certification of Chief Executive Officer of the Company <sup>(24)</sup>
31(i).2	Certification of Chief Financial Officer of the Company <sup>(24)</sup>
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 <sup>(24)</sup>
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. <sup>(24)</sup>

† Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

- (1) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 33-31962) declared effective on May 14, 1990
- (2) Incorporated by reference to the Registrant's Proxy Statement dated May 10, 2000
- (3) Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998
- (4) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1999
- (5) Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999
- (6) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000
- (7) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated March 12, 2002
- (8) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q dated August 14, 2002
- (9) Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002
- (10) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q dated August 14, 2003
- (11) Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003
- (12) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q dated August 4, 2004
- (13) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated May 12, 2005
- (14) Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005
- (15) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated March 16, 2006
- (16) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated April 3, 2006
- (17) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated April 17, 2006
- (18) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated May 17, 2006
- (19) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated December 7, 2006
- (20) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated December 15, 2006
- (21) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated December 26, 2006
- (22) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, dated August 8, 2007
- (23) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, dated November 8, 2007
- (24) Filed herewith

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

### COLUMBIA LABORATORIES, INC.

Date: March 25, 2008

By: /s/ James A. Meer

\_\_\_\_\_  
James A. Meer  
Senior Vice President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Robert Mills</u> Robert Mills	President and Chief Executive Officer (Principal Executive Officer)	March 25, 2008
<u>/s/ James A. Meer</u> James A. Meer	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 25, 2008
<u>/s/ Valerie Andrews</u> Valerie Andrews	Director	March 25, 2008
<u>/s/ Edward A. Blechschmidt</u> Edward A. Blechschmidt	Vice Chairman of the Board of Directors	March 25, 2008
<u>/s/ James S. Crofton</u> James S. Crofton	Director	March 25, 2008
<u>/s/ Stephen G. Kasnet</u> Stephen G. Kasnet	Chairman of the Board of Directors	March 25, 2008
<u>/s/ Denis M. O'Donnell</u> Denis M. O'Donnell	Director	March 25, 2008
<u>/s/ Selwyn P. Oskowitz</u> Selwyn P. Oskowitz	Director	March 25, 2008

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders  
of Columbia Laboratories, Inc.:

We have audited the consolidated balance sheet of Columbia Laboratories, Inc. and Subsidiaries as of December 31, 2007, and the related consolidated statements of operations, comprehensive operations, shareholders' equity (deficiency) and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Columbia Laboratories, Inc. and Subsidiaries as of December 31, 2007 and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

As disclosed in Note 1 to the consolidated financial statements, effective January 1, 2007, the Company adopted FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes — an Interpretation of FASB Statement No. 109".

We also have audited the adjustments described in Note 2 that were applied to restate the 2006 and 2005 consolidated balance sheets and the 2006, 2005 and 2004 consolidated statements of operations, shareholders' equity (deficiency) and cash flows to correct errors. In our opinion, such adjustments are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to the 2006, 2005 and 2004 consolidated financial statements of the Company other than with respect to the adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2006, 2005 and 2004 consolidated financial statements taken as a whole.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Columbia Laboratories, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Our report dated March 25, 2008 expressed an opinion that Columbia Laboratories, Inc. and Subsidiaries had not maintained effective internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

/s/ McGladrey & Pullen, LLP  
McGLADREY & PULLEN, LLP

New York, New York  
March 25, 2008

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders  
of Columbia Laboratories, Inc.:

We have audited, before the effects of the adjustments for the correction of the errors described in Note 2, the accompanying consolidated balance sheets of Columbia Laboratories, Inc. (a Delaware corporation) and Subsidiaries as of December 31, 2006 and 2005, and the related consolidated statements of operations, comprehensive operations, shareholders' equity (deficiency) and cash flows for each of the three years in the period ended December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

We were not engaged to audit, review or apply any procedures to the adjustments for the correction of the errors described in Note 2 and, accordingly, we do not express an opinion or any other form of assurance about whether any adjustments are appropriate and have been properly applied. Those adjustments were audited by McGladrey and Pullen, LLP.

In our opinion, except for the errors described in Note 2, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Columbia Laboratories, Inc. and Subsidiaries as of December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006 in conformity with United States generally accepted accounting principles.

As disclosed in Note 7, the Company changed its method of accounting for stock-based compensation effective January 1, 2006.

/s/ Goldstein Golub Kessler LLP  
GOLDSTEIN GOLUB KESSLER LLP

New York, New York  
March 15, 2007

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**CONSOLIDATED BALANCE SHEETS  
As of December 31, 2007, 2006 and 2005**

	<u>2007</u>	<u>2006</u> (Restated)	<u>2005</u> (Restated)
<b>ASSETS</b>			
Current Assets			
Cash and cash equivalents of which \$16,982,742 is interest bearing as of December 31, 2007 . . . . .	\$ 17,221,811	\$ 25,270,377	\$ 7,136,854
Accounts receivable, net of allowances for doubtful accounts of \$95,733, \$100,000 and \$50,000 in 2007, 2006 and 2005 respectively. . . . .	3,810,993	2,305,056	3,897,068
Inventories . . . . .	3,047,129	2,105,038	1,821,433
Prepaid expenses and other current assets . . . . .	1,287,300	993,766	748,859
Total current assets . . . . .	<u>25,367,233</u>	<u>30,674,237</u>	<u>13,604,214</u>
Property and Equipment			
Machinery and equipment. . . . .	2,252,222	2,653,285	2,680,099
Computer software . . . . .	444,332	444,332	442,785
Office Equipment and furniture and fixtures . . . . .	643,390	645,039	660,437
	<u>3,339,944</u>	<u>3,742,656</u>	<u>3,783,321</u>
Less-accumulated depreciation and amortization. . . . .	<u>(2,687,977)</u>	<u>(2,978,820)</u>	<u>(2,780,741)</u>
	651,967	763,836	1,002,580
Intangible Assets – Net . . . . .	28,859,788	32,865,556	—
Other Assets . . . . .	1,710,289	1,535,115	124,756
Total Assets . . . . .	<u>\$ 56,589,277</u>	<u>\$ 65,838,744</u>	<u>\$ 14,731,550</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>			
Current liabilities:			
Current portion of financing agreements . . . . .	\$ 3,786,538	\$ 553,947	\$ 12,840,161
Accounts payable . . . . .	2,215,942	3,586,770	1,905,381
Accrued expenses. . . . .	4,903,881	3,123,092	2,329,475
Total Current Liabilities . . . . .	<u>10,906,361</u>	<u>7,263,809</u>	<u>17,075,017</u>
Notes Payable – (Note 4) . . . . .	27,536,178	25,299,135	
Deferred revenue. . . . .	3,580,880	4,182,648	4,058,327
Long-term portion of financing agreements. . . . .	11,425,601	13,276,784	10,921,092
Total liabilities . . . . .	<u>53,449,020</u>	<u>50,022,376</u>	<u>32,054,436</u>
Commitments and Contingencies			
Contingently Redeemable Series C Convertible Preferred Stock; 1,125, 3,200, and 3,250 shares issued and outstanding in 2007, 2006, and 2005, respectively (liquidation preference of \$1,250,000, \$3,200,000 and \$3,250,000 in 2007, 2006 and 2005, respectively) . . . . .	<u>1,125,000</u>	<u>3,200,000</u>	<u>3,250,000</u>
Shareholders' equity:			
Preferred stock, \$.01 par value; 1,000,000 shares authorized			
Series B Convertible Preferred Stock, 130 shares issued and outstanding in 2007, 2006 and 2005 (liquidation preference of \$13,000 in 2007, 2006 and 2005) . . . . .	1	1	1
Series E Convertible Preferred Stock, 63,547, 69,000 and 69,000 shares issued and outstanding in 2007, 2006 and 2005, respectively (liquidation preference of \$6,354,700, \$6,900,000 and \$6,900,000 in 2007, 2006 and 2005, respectively) . . . . .	635	690	690
Common stock \$.01 par value; 100,000,000 shares authorized; 51,730,151, 49,694,213 and 41,754,784 shares issued in 2007, 2006 and 2005, respectively . . . . .	517,302	496,942	417,548
Capital in excess of par value . . . . .	222,376,941	218,687,977	172,090,055
Less cost of 18,000 and 6,000 treasury shares in 2007 and 2006, respectively. . . . .	(54,030)	(26,880)	
Accumulated deficit . . . . .	(221,033,196)	(206,741,406)	(193,258,323)
Accumulated other comprehensive income . . . . .	207,604	199,044	177,143
Shareholders' equity . . . . .	<u>2,015,257</u>	<u>12,616,368</u>	<u>(20,572,886)</u>
Total Liabilities and Shareholders' Equity . . . . .	<u>\$ 56,589,277</u>	<u>\$ 65,838,744</u>	<u>\$ 14,731,550</u>

*The accompanying notes to consolidated financial statements are an integral part of these statements*

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**For the Four Years Ended December 31, 2007**

	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>
		(Restated)	(Restated)	(Restated)
Net revenues . . . . .	\$ 29,627,638	\$ 17,393,081	\$ 22,040,842	\$ 17,860,404
Cost of revenues . . . . .	<u>9,014,540</u>	<u>7,819,843</u>	<u>8,111,497</u>	<u>7,788,601</u>
Gross profit . . . . .	<u>20,613,098</u>	<u>9,573,238</u>	<u>13,929,345</u>	<u>10,071,803</u>
Operating Expenses:				
Selling and distribution . . . . .	10,111,796	6,600,371	8,578,022	19,006,585
General and administrative . . . . .	7,824,741	7,402,188	6,825,148	7,588,437
Research and development . . . . .	5,778,641	6,596,339	5,756,856	5,448,685
Amortization of licensing right . . . . .	5,005,768	134,444	—	—
Total operating expenses . . . . .	<u>28,720,946</u>	<u>20,733,342</u>	<u>21,160,026</u>	<u>32,043,707</u>
Loss from operations . . . . .	<u>(8,107,848)</u>	<u>(11,160,104)</u>	<u>(7,230,681)</u>	<u>(21,971,904)</u>
Other income (expense):				
Interest income . . . . .	979,953	862,068	165,886	241,342
Interest expense . . . . .	(7,946,048)	(2,669,771)	(3,491,234)	(3,928,156)
Other, net . . . . .	782,153	482,428	451,700	(407,926)
	<u>(6,183,942)</u>	<u>(1,325,275)</u>	<u>(2,873,648)</u>	<u>(4,094,740)</u>
Net loss . . . . .	<u>\$(14,291,790)</u>	<u>\$(12,485,379)</u>	<u>\$(10,104,329)</u>	<u>\$(26,066,644)</u>
Loss per common share – basic and diluted . . . . .	<u>\$ (0.28)</u>	<u>\$ (0.26)</u>	<u>\$ (0.25)</u>	<u>\$ (0.64)</u>
Weighted-average number of common shares outstanding – basic and diluted . . . . .	<u>51,124,266</u>	<u>48,088,516</u>	<u>41,752,422</u>	<u>40,984,083</u>

*The accompanying notes to consolidated financial statements are an integral part of these statements*

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE OPERATIONS**  
**For the Four Years Ended December 31, 2007**

	2007	2006	2005	2004
Net loss. . . . .	\$(14,291,790)	\$(12,485,379)	\$(10,104,329)	\$(26,066,644)
Other comprehensive income (loss):		(Restated)	(Restated)	(Restated)
Foreign currency translation, net of tax. . . . .	8,560	21,901	(64,684)	50,458
Comprehensive loss . . . . .	\$(14,283,230)	\$(12,463,478)	\$(10,169,013)	\$(26,016,186)

*The accompanying notes to consolidated financial statements are an integral part of these statements*



COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES

**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIENCY)**  
**For the Four Years Ended December 31, 2007**  
**(Restated)**

	Series B Convertible Preferred Stock		Series E Convertible Preferred Stock		Common Stock		Capital in Excess of Par Value	Treasury Stock	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total	
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount						
<b>Balance, January 1, 2004</b> . . . . .	130	\$ 1	0	\$ —	39,679,381	\$396,794	\$158,896,593			\$(157,087,350)	\$ 191,369	\$ 2,397,407
Issuance of common stock					2,000,000	20,000	6,360,000					6,380,000
Warrants exercised					72,553	725	228,961					229,686
Fair market value of options granted to non-employees							14,514					14,514
Options exercised												—
Dividends on preferred stock							(162,500)					(162,500)
Translation adjustment										50,458		50,458
Net loss										(26,066,644)		(26,066,644)
<b>Balance, December 31, 2004</b> . . . . .	130	1	—	—	41,751,934	417,519	165,337,568	—		(183,153,994)	241,827	(17,157,079)
Issuance of preferred stock			69,000	690			6,899,310					6,900,000
Options exercised					2,850	29	8,224					8,253
Fair market value of options granted to non-employees							7,453					7,453
Dividends on preferred stock							(162,500)					(162,500)
Translation adjustment										(64,684)		(64,684)
Net loss										(10,104,329)		(10,104,329)
<b>Balance, December 31, 2005</b> . . . . .	130	\$ 1	69,000	\$690	41,754,784	\$417,548	\$172,090,055	\$—		\$(193,258,323)	\$177,143	\$(20,572,886)

*The accompanying notes to consolidated financial statements are an integral part of these statements*

COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES

**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIENCY) – (continued)**  
**For the Four Years Ended December 31, 2007**  
**(Restated)**

	Series B Convertible Preferred Stock		Series E Convertible Preferred Stock		Common Stock		Capital in Excess of Par Value	Treasury Stock	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount					
<b>Balance, January 1, 2004</b> . . . . .											
<b>Balance, December 31, 2005</b> . . . . .	<u>130</u>	<u>\$1</u>	<u>69,000</u>	<u>\$690</u>	<u>41,754,784</u>	<u>\$417,548</u>	<u>\$172,090,055</u>	<u>\$ —</u>	<u>\$(193,258,323)</u>	<u>\$177,143</u>	<u>\$(20,572,886)</u>
Cumulative effect adjustment on stock options . . . . .							997,705		(997,705)	—	—
Issuance of common stock . . . . .					7,428,220	74,282	28,691,844				28,766,126
Options exercised . . . . .					335,049	3,350	1,018,409				1,021,759
Share based compensation expense . . . . .					161,875	1,619	1,246,830				1,248,449
Beneficial conversion & warrant – value for convertible notes . . . . .							14,754,656				14,754,656
Conversion of Series C Preferred Stock . . . . .					14,285	143	49,857				50,000
Purchase of treasury stock . . . . .								(26,880)			(26,880)
Dividends on preferred stock . . . . .							(161,379)				(161,379)
Translation adjustment . . . . .										21,901	21,901
Net loss . . . . .									(12,485,378)		(12,485,378)
<b>Balance, December 31, 2006</b> . . . . .	<u>130</u>	<u>1</u>	<u>69,000</u>	<u>690</u>	<u>49,694,213</u>	<u>496,942</u>	<u>218,687,977</u>	<u>(26,880)</u>	<u>(206,741,406)</u>	<u>199,044</u>	<u>12,616,368</u>
Options exercised . . . . .					43,050	431	62,810				63,241
Share based compensation expense . . . . .					155,690	1,557	1,646,365				1,647,922
Conversion of Series C Preferred Stock . . . . .					1,564,548	15,645	2,059,355				2,075,000
Conversion of Series E Preferred Stock . . . . .			(5,453)	(55)	272,650	2,727	(2,672)				—
Purchase of treasury stock . . . . .								(27,150)			(27,150)
Dividends on preferred stock . . . . .							(76,894)				(76,894)
Translation adjustment . . . . .										8,560	8,560
Net loss . . . . .									(14,291,790)		(14,291,790)
<b>Balance, December 31, 2007</b> . . . . .	<u>130</u>	<u>\$1</u>	<u>63,547</u>	<u>\$635</u>	<u>51,730,151</u>	<u>\$517,302</u>	<u>\$222,376,941</u>	<u>\$(54,030)</u>	<u>\$(221,033,196)</u>	<u>\$207,604</u>	<u>\$ 2,015,257</u>

*The accompanying notes to consolidated financial statements are an integral part of these statements*

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**For the Four Years Ended December 31, 2007**

	<u>2007</u>	<u>2006</u> (Restated)	<u>2005</u> (Restated)	<u>2004</u> (Restated)
<b>Cash Flows from Operating Activities:</b>				
Net loss . . . . .	\$ (14,291,790)	\$ (12,485,379)	\$ (10,104,329)	\$ (26,066,644)
Adjustments to reconcile net loss to net cash used in operating activities –				
Depreciation and amortization . . . . .	5,462,888	395,003	287,741	379,855
Amortization of beneficial conversion features . . . . .	1,265,496	30,344	—	—
Amortization of warrants . . . . .	971,548	23,449	—	—
Provision for doubtful accounts . . . . .	15,000	105,855	187,962	48,917
Provision for sales returns . . . . .	992,502	1,802,868	2,431,823	3,336,339
Write-down of inventories . . . . .	80,961	612,094	1,036,136	1,018,677
Share based compensation . . . . .	1,647,922	1,248,448	—	—
Interest accrued on financing agreements net of payments made . . . . .	1,381,407	(4,539,253)	1,667,223	2,638,385
Loss on sale of intangible assets . . . . .	—	—	—	577,917
Issuance of options for services . . . . .	—	—	7,453	14,514
Changes in assets and liabilities –				
(Increase) decrease in:				
Accounts receivable . . . . .	(1,520,937)	1,345,895	27,457	725,519
Inventories . . . . .	(1,023,052)	(895,699)	(115,025)	(1,291,997)
Prepaid expenses and other current assets . . . . .	(293,534)	(104,645)	554,706	1,106,353
Other assets . . . . .	(418,405)	(1,416,416)	(3,615)	19,514
Increase (decrease) in:				
Accounts payable . . . . .	(1,370,828)	1,681,389	(866,726)	(34,129)
Accrued expenses . . . . .	(211,709)	(1,009,251)	(3,213,546)	(3,231,833)
Deferred revenue . . . . .	(601,768)	124,321	(180,733)	359,442
Net cash used in operating activities . . . . .	<u>(7,914,299)</u>	<u>(13,080,977)</u>	<u>(8,283,473)</u>	<u>(20,399,171)</u>
<b>Cash Flows from Investing Activities:</b>				
Purchase of property and equipment . . . . .	\$ (102,021)	\$ (15,757)	\$ (83,367)	\$ (582,367)
Acquisition of intangibles . . . . .	—	(33,000,000)	—	300,000
Net cash used in investing activities . . . . .	<u>(102,021)</u>	<u>(33,015,757)</u>	<u>(83,367)</u>	<u>(282,367)</u>
<b>Cash Flows from Financing Activities:</b>				
Net proceeds from issuance of preferred stock . . . . .	—	—	6,900,000	—
Net proceeds from issuance of common stock . . . . .	—	28,766,126	—	6,380,000
Proceeds from issuance of subordinated convertible notes . . . . .	—	39,999,998	—	—
Payment of note payable . . . . .	—	—	(10,000,000)	—
Proceeds from exercise of options . . . . .	63,241	1,021,759	8,253	229,686
Proceeds from financing agreements . . . . .	—	—	—	3,000,000
Payment for purchase of treasury stock . . . . .	(27,150)	(26,880)	—	—
Principal payment pursuant to financing agreements . . . . .	—	(5,391,268)	(959,052)	—
Dividends paid . . . . .	(76,894)	(161,379)	(162,500)	(162,500)
Net cash (used in) provided by financing activities . . . . .	<u>(40,803)</u>	<u>64,208,356</u>	<u>(4,213,299)</u>	<u>9,447,186</u>
Effect of Exchange Rate Changes on Cash . . . . .	8,557	21,900	(64,598)	50,426
Net (Decrease)/Increase in Cash and Cash Equivalents . . . . .	<u>(8,048,566)</u>	<u>18,133,522</u>	<u>(12,644,737)</u>	<u>(11,183,926)</u>
Cash and Cash Equivalents, Beginning of year . . . . .	25,270,377	7,136,854	19,781,591	30,965,517
Cash and Cash Equivalents, End of year . . . . .	<u>\$ 17,221,811</u>	<u>\$ 25,270,377</u>	<u>\$ 7,136,854</u>	<u>\$ 19,781,591</u>
<b>Supplemental Disclosure of Cash Flow Information</b>				
Interest paid . . . . .	\$ 2,488,889	\$ —	\$ 356,250	\$ 712,500
Taxes paid . . . . .	\$ 34,759	\$ 49,492	\$ 6,800	\$ 110,700
Accrual of financing costs . . . . .	\$ 25,000	\$ 1,275,000	\$ —	\$ —
Increase of US Crinone license right cost . . . . .	\$ 1,000,000	\$ —	\$ —	\$ —
Conversion of Series C preference shares to common stock . . . . .	\$ 2,075,000	\$ 50,000	\$ —	\$ —
Conversion of Series E preference shares to common stock . . . . .	\$ 545,300	\$ —	\$ —	\$ —

*The accompanying notes to consolidated financial statements are an integral part of these statements*

## COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### (1) Summary of Significant Accounting Policies

##### *Organization*

Columbia Laboratories, Inc. (the “Company”) was incorporated as a Delaware corporation in December 1986. The Company is primarily dedicated to research, development, and commercialization of women’s healthcare and endocrinology products, including those that treat or are intended to treat infertility, endometriosis, dysmenorrhea, preterm birth for women with a short cervix at mid-pregnancy and hormonal deficiencies. The Company has also developed a buccal delivery system for peptides. The Company’s products primarily utilize its patented Bioadhesive Delivery System technology.

##### *Principles of Consolidation*

The consolidated financial statements include the accounts of the Company and its subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. Prior year financial statements have been reclassified to conform to the 2007 presentation. The VAT refunds due for prior years have been reclassified from accounts receivable to prepaid assets. At December 31, 2005 and 2006 this amounted to \$24,941 and \$122,951, respectively.

##### *Liquidity*

As shown in the financial statements, the Company has had recurring losses from operations. Management believes the approximately \$17.2 million of cash on hand at December 31, 2007 will allow the Company to sustain its operations.

##### *Accounting Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates are used for, but are not limited to sales return reserves, license fees, payments to distributors, and share based compensation. Actual results could differ from those estimates in the near term.

##### *Foreign Currency*

The assets and liabilities of the Company’s foreign subsidiaries are translated into U.S. dollars at current exchange rates and revenue and expense items are translated at average rates of exchange prevailing during the period. Resulting translation adjustments are accumulated as a separate component of shareholders’ equity. Transaction gains and losses are reflected in the Statements of Operations.

##### *Accounts Receivable*

Accounts receivable are reported at their outstanding unpaid principal balances reduced by allowances for doubtful accounts. The Company estimates doubtful accounts based on historical bad debts, factors related to specific customers’ ability to pay and current economic trends. The Company writes off accounts receivable against the allowance when a balance is determined to be uncollectible.

##### *Fair Value of Financial Instruments*

The estimated fair value of the convertible subordinated notes payable, beneficial conversion feature, and detachable warrants amounted to \$52,463,820 and \$54,700,863 at December 31, 2007 and 2006, respectively. This value is the aggregate of the estimated future cash flows associated with the settlement of the notes payable, the application of the Black Scholes method to the warrants and the intrinsic value of the beneficial conversion feature. The fair value of the financing agreements described in Note 5 approximates their carrying amount.

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(1) Summary of Significant Accounting Policies – (continued)**

***Inventories***

Inventories are stated at the lower of cost (first-in, first-out) or market. Components of inventory cost include materials, labor and manufacturing overhead. Inventories consist of the following:

	<u>December 31,</u>		
	<u>2007</u>	<u>2006</u>	<u>2005</u>
Finished goods . . . . .	\$1,734,052	\$1,305,872	\$1,165,413
Raw materials . . . . .	1,313,077	799,166	656,020
	<u>\$3,047,129</u>	<u>\$2,105,038</u>	<u>\$1,821,433</u>

Shipping costs are included in selling and distribution expenses and amounted to approximately \$101,616, \$39,000, \$39,000 and \$63,000 in 2007, 2006, 2005, and 2004 respectively.

***Property and Equipment***

Property and equipment is stated at cost less accumulated depreciation. Leasehold improvements are amortized over the lesser of the useful life or the term of the respective leases. Depreciation is computed on the straight-line basis over the estimated useful lives of the respective assets, as follows:

	<u>Years</u>
Software . . . . .	3
Machinery and equipment . . . . .	5 – 10
Furniture and fixtures . . . . .	5

Costs of major additions and improvements are capitalized and expenditures for maintenance and repairs that do not extend the term of the assets are expensed. Upon sale or disposition of property and equipment, the cost and related accumulated depreciation are eliminated from the accounts and any resultant gain or loss is credited or charged to operations.

Depreciation expense amounted to approximately \$215,000, \$250,000, \$288,000 and \$337,000 in 2007, 2006, 2005, and 2004 respectively.

***Concentration of Risk***

The Company sells its products to customers worldwide. The Company performs ongoing credit evaluations of its customers and generally does not require collateral. See Note 10 for customer concentrations.

The Company depends on one supplier for a key excipient used in its products and one supplier for the active pharmaceutical ingredients.

***Intangible Assets***

On December 22, 2006, the Company acquired the US rights to CRINONE® (progesterone gel). The cost of the acquisition was \$33,000,000 in cash and is being amortized over a 6.75-year period. On April 1, 2007, the Company recorded a liability from the contract with Merck Serono for certain sales returns associated with

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(1) Summary of Significant Accounting Policies – (continued)**

sales made by Merck Serono. The Company recorded the estimated liability of \$1,000,000 as an increase in the purchase price that is being amortized over the remaining term of the license.

	<b>2007</b>	<b>2006</b>
Balance at January 1 . . . . .	\$33,000,000	
Acquisition of license . . . . .		\$33,000,000
Assumption of sales return liability . . . . .	1,000,000	—
	34,000,000	33,000,000
Accumulated amortization . . . . .	(5,140,212)	(134,444)
Balance at December 31 . . . . .	\$28,859,788	\$32,865,556

Amortization expense amounted to \$5,005,768 and \$134,444 in 2007 and 2006 respectively.

***Long-lived Assets***

Following the acquisition of any long-lived assets, the Company continually evaluates whether later events and circumstances have occurred that indicate the remaining estimated useful life of the long-lived asset may warrant revision or that the remaining balance of the long-lived asset may not be recoverable. When factors indicate that a long-lived asset may be impaired, the Company uses an estimate of the underlying product's future cash flows, including amounts to be received over the remaining life of the long-lived asset from license fees, royalty income, and related revenue, in measuring whether the long-lived asset is recoverable. Unrecoverable amounts are charged to operations.

***Accrued Expenses***

Accrued expenses consist of the following:

	<b>2007</b>	<b>2006</b>	<b>2005</b>
Sales returns . . . . .	\$1,923,765	\$1,240,234	\$ 745,882
Salaries . . . . .	757,587	752,022	684,286
Royalties . . . . .	17,390	216,411	369,303
Interest . . . . .	800,000	88,889	—
Professional fees . . . . .	441,525	594,166	284,914
Inventory management fees . . . . .	553,463	—	—
Marketing expenses . . . . .	244,177	117,769	—
Other . . . . .	165,974	113,601	245,090
	\$4,903,881	\$3,123,092	\$2,329,475

***Income Taxes***

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48 (“FIN 48”), “Accounting for Uncertainty in Income Taxes — An Interpretation of FASB No 109.” FIN 48 provides detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in the financial statements in accordance with SFAS No. 109. Tax positions must meet a “more-likely-than-not” recognition threshold at the effective date to be recognized upon the adoption of FIN 48 and in subsequent periods. Upon the adoption of FIN 48, the Company had no unrecognized tax benefits. During the year ended December 31, 2007, the Company recognized no adjustments for uncertain tax benefits.



**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(1) Summary of Significant Accounting Policies – (continued)**

The reconciliation of the effective income tax rate to the federal statutory rate is as follows:

	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>
Federal income tax rate . . . . .	-35.0%	-34.0%	-34%	-34%
Statutory rate over expected future federal benefit . . . . .	1.0%			
Foreign Income tax benefit/loss . . . . .	-15.1%	-10.2%	-18.2%	-1.0%
State tax net of federal benefit . . . . .	-4.9%	-4.3%	-4.9%	-3.4%
Permanent items:				
Intercompany interest income . . . . .	4.2%	5.5%	8.2%	3.6%
Amortization of technology rights . . . . .	-2.4%	-2.8%	-3.4%	-1.3%
R&D Credit . . . . .	—	1.0%	-3.3%	-0.6%
Other . . . . .	-0.1%	0.1%	0.1%	0.1%
Effect of permanent differences . . . . .	1.7%	3.8%	1.6%	1.8%
Effective income tax rate . . . . .	<u>-52.3%</u>	<u>-44.7%</u>	<u>-55.4%</u>	<u>-36.6%</u>
Increase in valuation allowance . . . . .	52.3%	44.7%	55.4%	36.6%
Effective income tax rate . . . . .	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>

As of December 31, 2007, the Company has U.S. tax net operating loss carryforwards of approximately \$157.3 million which expire through 2025. The Company also has unused tax credits of approximately \$1.7 million which expire at various dates through 2025. Utilization of net operating loss carryforwards may be limited in any year due to limitations in the Internal Revenue Code. As of December 31, 2007, 2006, and 2005 other assets in the accompanying consolidated balance sheets include deferred tax assets of approximately \$60.5, \$53.2 and \$50.8 million, respectively (comprised primarily of a net operating loss carryforwards, for which a 100% valuation allowance has been recorded since the realizability of the deferred tax assets is not determinable. With respect to the Company's net operating loss carryforwards, it has not undertaken an analysis to determine whether the utilization of this tax asset would be limited by Section 382 of the Internal Revenue Code.

The Company recognizes interest and penalties, if any, related to uncertain tax positions in general and administrative expenses. No interest and penalties related to uncertain tax positions were accrued at December 31, 2007.

The Company has not been audited by the IRS to date. However, the Company expects no material changes to unrecognized tax positions within the next 12 months.

<u>Deferred Tax Assets (Liabilities)</u>	<u>2007</u>	<u>2006</u>	<u>2005</u>
Share Based Compensation . . . . .	\$ 973,848	\$ 399,519	\$ —
Allowance for doubtful accounts . . . . .	26,525	28,125	9,375
Allowance for returns . . . . .	346,412	465,088	279,706
Inventory reserve . . . . .	71,889	75,000	68,358
Book accumulated depreciation net of tax . . . . .	(8,779)	(21,431)	(50,948)
Accumulated amortization – CRINONE license . . . . .	1,054,663	27,500	—
Vacation accrual . . . . .	14,634	34,978	76,565
Inventory Capitalization . . . . .	17,318	13,497	25,873
Long term debt (beneficial conversion feature net of book amortization) . . . . .	(2,694,844)	(3,169,405)	—
Federal net operating loss . . . . .	58,983,654	53,622,476	48,541,400
Unused R&D credit . . . . .	1,743,065	1,743,065	1,862,756
Net Deferred Tax Assets . . . . .	<u>\$ 60,528,385</u>	<u>\$ 53,218,411</u>	<u>\$ 50,813,085</u>
Less Valuation Allowance:			
Federal . . . . .	<u>(60,528,385)</u>	<u>(53,218,411)</u>	<u>(50,813,085)</u>
Deferred Taxes Assets . . . . .	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

## COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### **(1) Summary of Significant Accounting Policies – (continued)**

The Company files income tax returns as well as multiple state, local and foreign jurisdiction tax returns. Tax years ended December 31, 2004 or later remain subject to examination by the IRS. State and local jurisdiction tax returns remain subject to examination for tax years ended December 31, 2004 or later.

#### ***Revenue Recognition***

*Revenue Recognition* Revenues on sales of products by Columbia are discussed in detail below. Royalties and additional monies owed to the Company based on sales by licensees are recorded as revenue as those sales are made by the licensees. License fees not based on sales are recognized as revenues over the term of the license.

#### ***Sales Return Reserves***

Revenues from the sale of products are recorded at the time goods are shipped to customers. The Company believes that it has not made any shipments in excess of its customers' ordinary course of business inventory levels. The Company's return policy allows product to be returned for a period beginning three months prior to the product expiration date and ending twelve months after the product expiration date. Provisions for returns on sales to wholesalers, distributors and retail chain stores are estimated based on a percentage of sales, using such factors as historical sales information, distributor inventory levels and product prescription data, and are recorded as a reduction to sales in the same period as the related sales are recognized. The Company continually analyzes the reserve for future sales returns and increases such reserve if deemed appropriate. The Company purchases prescription data on all its products from IMS Health, a leading provider of market intelligence to the pharmaceutical and healthcare industries. The Company also purchases certain information regarding inventory levels from its larger wholesale customers. This information includes for each of the Company's products, the quantity on hand, the number of days of inventory on hand, and a 28 day forecast of sales by units. Using this information and historical information, the Company estimates potential returns by taking the number of product units sold by the Company by expiration date and then subtracting actual units and potential units that may be sold to end users (consumers) based on prescription data up to five months prior to the product's expiration date. The Company assumes that its customers are using the first-in, first-out method in filling orders so that the oldest saleable product is used first. The Company also assumes that customers will not ship product that has expiration dating less than six months to a retail pharmacy, but that retail pharmacies will continue to dispense product they have on hand until two months prior to the product's expiration date. The Company's products are used by the consumer immediately so no shelf life is needed. Retail pharmacies tend not to maintain a large supply of products in their inventory, so they order on an "as needed" basis. The Company also subtracts units that have already been returned or, based on notifications received from customers, will be returned. The Company then records a provision for returns on a quarterly basis using an estimated rate and adjusts the provision if the above analysis indicates that the potential for product non-saleability exists.

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(1) Summary of Significant Accounting Policies – (continued)**

An analysis of the reserve for sales returns is as follows:

	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>
Balance at beginning of year . . . . .	\$ 1,240,234	\$ 745,882	\$ 1,992,010	\$ 275,000
Addition related to Crinone® purchase . . . . .	1,000,000	—	—	—
Adjusted Balance at Beginning of year . . . . .	2,240,234	745,882	\$ 1,992,010	275,000
Provision:				
Related to current year sales . . . . .	527,819	210,275	272,913	216,195
Related to prior years' sales . . . . .	500,000	1,592,592	2,158,910	3,120,144
	<u>1,027,819</u>	<u>1,802,867</u>	<u>2,431,823</u>	<u>3,336,339</u>
Returns:				
Related to current year sales . . . . .	(61,125)	(46,825)	(67,928)	—
Related to 2006 Crinone® purchase . . . . .	(328,896)	—	—	—
Related to prior years' sales . . . . .	(954,267)	(1,261,690)	(3,610,023)	(1,619,329)
	<u>(1,344,288)</u>	<u>(1,308,515)</u>	<u>(3,677,951)</u>	<u>(1,619,329)</u>
Balance at end of year . . . . .	<u>\$ 1,923,765</u>	<u>\$ 1,240,234</u>	<u>\$ 745,882</u>	<u>\$ 1,992,010</u>

The Company believes that the greatest potential for uncertainty in estimating sales returns is the estimation of future prescriptions. They are wholly dependent on the Company's ability to sell and market the products. If prescriptions are lower in future periods, then the current reserve will be inadequate.

In the 2006 fourth quarter, the Company purchased the US rights to CRINONE® for \$33 million. As part of the transaction, the Company repurchased inventory and reversed sales of \$0.6 million in the fourth quarter. In 2007, the Company recorded an estimated liability of \$1.0 million for certain sales returns associated with sales made by Merck Serono.

Sales returns provisions for the year 2007 were \$2.0 million including \$1.0 million in the second quarter as an increase in the purchase price of the U.S rights to CRINONE for future returns as a result of product sold by Merck Serono that was still in the channel at the time of purchase of the such rights. The current year's provision in 2007 increased by \$0.3 million from 2006 levels to reflect primarily the increase in sales of progesterone products. During the year, the Company undertook to reduce further its PROCHIEVE® inventory levels in distribution channels. The Company recognized \$0.4 million for the Merck Serono returns during 2007 and reduced the \$1.0 million reserve accordingly.

Sales returns provisions for the year 2006 were \$1.8 million, including \$1.1 million in the fourth quarter. One customer returned approximately \$0.5 million of product due to short dating. In addition, the Company increased its reserve by \$0.4 million. The \$1.8 million charge for 2006 is lower than 2005 which was significantly affected by the 2003 STRIANT® launch activities and the uncertainty in estimating the returns with a launch. The Company carried out a plan in 2006 to bring STRIANT inventory levels in distribution channels to demand levels.

The second quarter 2005 change in estimate, amounting to approximately \$1.6 million, occurred as a result of the adoption by a wholesale customer of a policy to stop selling our products to retail establishments six months prior to the expiration date on the packaging. This policy was adopted notwithstanding the fact that retail pharmacies tend not to maintain large supplies of our products in their inventory, order on an "as needed" basis, and turn their inventory over rapidly. Also the Company's products are normally used up by the patient within a 30-day period after a prescription is presented. As discussed above, we have revised our estimating procedure to include this shortened period of saleability.

## COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### **(1) Summary of Significant Accounting Policies – (continued)**

The fourth quarter 2004 change in estimate of approximately \$3.0 million was principally related to the failure of a major customer to sell product on a first-in, first-out (“FIFO”) basis by lot expiration date. The Company’s estimate for its reserve for sales returns always assumed that our customers maintained their inventory on a FIFO basis. Based on discussions with this customer, we discovered that it had ordered product in 2004 and was selling product from these recent purchases rather than product it had purchased in prior years which was still salable. The older inventory had been taken out of current inventory and “morgued” to be shipped back at customer expense when the product approached expiration. We now have ongoing conversations with this customer, as well as other customers, and receive assurances that they fill orders on a FIFO basis. The Company now also purchases information about inventory levels from this same customer.

#### ***License Fees***

License revenue consists of up-front, milestone and similar payments under license agreements and is recognized when earned under the terms of the applicable agreements. Milestone payments represent payments for the occurrence of contract-specified events and coincide with the achievement of a substantive element in a multi-element arrangement (See Note 3). License revenue, including milestone payments, is deferred and recognized in revenues over the estimated product life cycle or the length of relevant patents, whichever is shorter.

#### ***Advertising Expense***

All costs associated with advertising and promoting products are expensed in the year incurred. Advertising and promotion expense was approximately \$.9 million in 2007, \$1.3 million in 2006, \$1.5 in 2005 and \$4.6 million in 2004, and is included in selling and distribution expense.

#### ***Payments to Distributors***

The Company estimates fees it pays its distributors and specialty pharmacies for customer services that include supplemental sales calling, providing information about their customers and the processing of sales returns. The fees for these services are charged to selling and distribution expenses. In 2007, these fees were \$0.6 million.

#### ***Research and Development Costs***

Company-sponsored research and development costs related to future products are expensed as incurred.

#### ***Reclassification***

For comparability, certain 2006 and 2005 amounts in the Consolidated Financial Statements have been reclassified, where appropriate, to conform to the financial statement presentation used in 2007.

#### ***Loss per Share***

Basic loss per share is computed by dividing the net loss plus preferred dividends by the weighted-average number of shares of Common Stock outstanding during the period. Diluted earnings per share gives effect to dilutive options, warrants and other potential Common Stock outstanding during the year. Shares to be issued upon the exercise of the outstanding options and warrants or the conversion of the preferred stock are not included in the computation of diluted loss per share as their effect is anti-dilutive. Outstanding options and warrants excluded from the calculation amounted to 9,704,058, 9,554,307, 6,678,725, and 6,204,400 at December 31, 2007, 2006, 2005, and 2004, respectively.

#### ***Statements of Cash Flows***

For purposes of the statements of cash flows, the Company considers all investments purchased with an original maturity of three months or less to be cash equivalents.

## COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### (1) Summary of Significant Accounting Policies – (continued)

##### *Share-based Compensation*

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), “Share-Based Payment,” (“SFAS 123(R)”) which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors including employee stock options based on estimated fair values. SFAS 123(R) supersedes previous accounting under Accounting Principles Board Opinion No. 25, “Accounting for Stock Issued to Employees” (“APB 25”) for periods beginning in fiscal year 2006. In March 2005, the SEC issued Staff Accounting Bulletin No. 107 (“SAB 107”) providing supplemental implementation guidance for SFAS 123(R). The Company has applied the provisions of SAB 107 at the same time it adopted SFAS 123(R).

SFAS 123(R) requires companies to estimate the fair value of stock-based awards on the date of grant using an option pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company’s Consolidated Statements of Operations. The Company adopted SFAS 123(R) using the modified prospective transition method which requires the recognition of expense relative to existing, unvested awards from January 1, 2006. The Company’s Consolidated Financial Statements, as of and for the years ended December 31, 2007 and 2006, reflect the impact of SFAS 123(R). Employee stock-based compensation expense for the years ended December 31, 2007 and 2006, was \$ 1,490,059 and \$1,065,383 respectively, which consisted primarily of stock-based compensation expense related to employee stock options recognized under SFAS 123(R).

Prior to the adoption of SFAS 123(R), the Company accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25 (except as disclosed in Note 7) as allowed under Statement of Financial Accounting Standards No. 123, “Accounting for Stock-Based Compensation” (“SFAS 123”). Under the intrinsic value method, no stock-based compensation expense for employee stock options had been recognized in the Company’s Consolidated Statements of Operations, because the exercise price of the Company’s stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant. In accordance with the modified prospective transition method the Company used in adopting SFAS 123(R), the Company’s results of operations prior to fiscal year 2006 have not been restated to reflect, and do not include, the possible impact of SFAS 123(R).

Share-based compensation expense recognized during a period is based on the value of the portion of share-based awards that is ultimately expected to vest. Stock-based compensation expense recognized in the years ended December 31, 2007 and 2006 included compensation expense for share-based awards granted prior to, but not yet vested as of December 31, 2005, based on the fair value on the grant date estimated in accordance with the pro forma provisions of SFAS 123, and compensation expense for the stock-based awards granted or modified subsequent to December 31, 2005, based on the fair value on the grant date estimated in accordance with the provisions of SFAS 123(R). In conjunction with the adoption of SFAS 123(R), the Company is continuing to use the straight line method of attributing the value of stock-based compensation expense. Compensation expense for all stock-based awards granted prior to January 1, 2006 will be recognized using the straight line approach, and compensation expense for all stock-based awards granted subsequent to December 31, 2005, will also be recognized using the straight line method. Because stock-based compensation expense to be recognized in the results for periods beginning after December 31, 2005, is based on awards ultimately expected to vest, the amounts will be reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to 2006, the Company accounted for forfeitures as they occurred for the purposes of pro forma information under SFAS 123, as disclosed in the Notes to Consolidated Financial Statements for the related periods.



## COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### (1) Summary of Significant Accounting Policies – (continued)

##### *Recent Accounting Pronouncements*

In December 2006, the Financial Accounting Standards Board (“FASB”) issued a FASB Staff Position (“FSP”) EITF 00-19-2 “*Accounting for Registration Payment Arrangements*” (“FSP 00-19-2”). FSP 00-19-2 defines a registration payment arrangement as an arrangement where the issuer (i) will endeavor to file a registration statement for the resale of financial instruments, have the registration statement declared effective, or maintain its effectiveness and (ii) transfer consideration to the counterparty if the registration statement is not declared effective or its effectiveness is not maintained. The Company entered into certain registration payment arrangements in connection with the private placement of Common Stock in March 2006, and the issuance of our convertible notes in December 2006. This FSP specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5 “*Accounting for Contingencies*.” The guidance in this FSP amends FASB Statements No. 133, “*Accounting for Derivative Instruments and Hedging Activities*,” and No. 150, “*Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*,” as well as FASB Interpretation No. 45, “*Guarantor’s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*” to include scope exceptions for registration payment arrangements. This FSP is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issuance of this FSP. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of this FSP, this is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. FSP 00-19-2 did not have a material impact on our consolidated results of operations and financial position in 2007.

In September 2006, the FASB issued SFAS No. 157, “*Fair Value Measurements*” (“SFAS 157”), which clarifies the definition of fair value, establishes guidelines for measuring fair value, and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements and eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS No. 157 and FSP 157-b are effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. As proposed the effective date of SFAS No. 157 would be deferred to Fiscal years beginning after November 15, 2008 and for interim periods within those years for certain non financial assets and liabilities. The Company is currently evaluating the impact that adopting SFAS 157 will have on its financial position, cash flows or results of operations.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, “*The Fair Value Option for Financial Assets and Financial Liabilities*” (“SFAS No. 159”). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between entities that choose different measurement attributes for similar assets and liabilities. SFAS No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company has not yet determined the impact, if any, that the implementation of SFAS No. 159 will have on its results of operations or financial position.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), “*Business Combinations*” (“SFAS 141(R)”). SFAS 141(R) will change the accounting for business combinations. Under SFAS 141(R), an acquiring entity will be required to recognize all the assets acquired and liabilities assumed in a transaction at the acquisition-date fair value with limited exceptions. SFAS 141(R) will change the accounting treatment and disclosure for certain specific items in a business combination. SFAS 141(R) applies prospectively to



## COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### (1) Summary of Significant Accounting Policies – (continued)

business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. SFAS 141(R) will impact the Company in the event of any future acquisition.

In December 2007, the FASB issued SFAS 160, “*Non-controlling Interests in Consolidated Financial Statements* — an amendment of Accounting Research Bulletin 51 “(SFAS 160)”. SFAS 160 establishes new accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. The Company does not believe that SFAS 160 will have a material impact on its consolidated financial statements.

The Company does not believe that any other recently issued, but not yet effective, accounting standards would have a material effect on the Company’s consolidated financial position, results of operations or cash flows.

#### (2) Restatement

On March 18, 2008, the Company filed a Current Report on Form 8-K stating its intention to restate its financial statements for the years ended December 31, 2005 and December 31, 2006, and for the quarterly periods ended March 31, June 30, September 30, 2006 and 2007, to correct accounting errors. The restatements are the result of the following:

With respect to its Pharma-Bio Financing Agreements, when the Company initially recorded each transaction, it applied the yield to maturity method for accounting for the interest expense, but did not recognize the interim payment obligations which resulted in implicit interest rates of 13% and 11%, respectively. The Company has determined that it should have applied the effective yield method called for in Accounting Principles Board Opinion 21 (“APB 21”) to account for interest expense, should have included the impact of the interim payments on the implicit interest rates, and should not have separately recorded a loss on early extinguishment. Under APB 21, the implicit interest rates would have been approximately 17% and 15%, respectively. Therefore, the Company overstated its interest expense in 2006 by \$0.1 million and understated its interest expense for fiscal years 2005 (\$0.8 million), and 2004 (\$0.9 million). Further, if not corrected, the Company would be overstating its interest expense for 2007, 2008, 2009, and 2010. Over the life of each financing agreement, however, the total payments and the recorded interest expense would be equal under both accounting methods. Further the adjustments do not change current cash flows or repayment obligations.

The Company has concluded that the timing difference in interest expense should be reflected in 2004 and 2005, as higher interest expense for each period and lower interest expense in 2006. The Company increased its beginning 2004 accumulated deficit by \$0.4 million. The change in interest expense results in an increase of \$0.9 million and \$0.8 million for 2004 and 2005 and a \$0.1 million interest expense reduction in 2006. The Company restated its Statement of Operations by these amounts. These changes also had the cumulative effect of decreasing Shareholders’ Equity by \$2.0 million by the end of 2006. Total cash interest expense over the term of the financing agreements did not change. The July 2002 financing agreement was fully paid on February 29, 2008.

With respect to its contingently redeemable Series C Preferred Stock, the Company recorded the amount as Shareholders’ Equity on its balance sheet. The Company reclassified its contingently redeemable Series C Convertible Preferred Stock on its Balance Sheet from Shareholders’ Equity to temporary equity, because the holders have redemption rights for certain events that are not controlled by the Company. The terms of the Series C Preferred Stock have not changed from the original issuance in 1999.

Shareholders’ Equity was reduced in total by approximately \$5.2 million, and \$5.4 million as of December 31, 2006, and 2005, respectively, for both the accounting adjustments and the reclassification.

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(2) Restatement – (continued)**

The restatements also affect amounts disclosed in Notes 3, 5, 6, 7 and 8 to the accompanying Consolidated Financial Statements.

All amounts referenced in this Annual Report reflect the relevant amounts on a restated basis. The previously issued Financial Statements for the periods noted above should no longer be relied upon.

**(2A) Adjustments to Audited Financial Statements**

	<u>Restated 2006</u>	<u>Adjustments</u>	<u>As Reported 2006</u>	<u>Restated 2005</u>	<u>Adjustments</u>	<u>As Reported 2005</u>			
Balance sheet data:									
Long-term portion of financing agreements . . .	\$ 13,276,784	\$ 2,047,007	\$ 11,229,777	\$ 10,921,092	\$ 2,173,349	\$ 8,747,743			
Total liabilities . . . . .	<u>50,022,376</u>	<u>2,047,007</u>	<u>47,975,369</u>	<u>32,054,436</u>	<u>2,173,349</u>	<u>29,881,087</u>			
Contingently redeemable Series C preferred stock . . . . .	<u>3,200,000</u>	<u>3,200,000</u>	<u>—</u>	<u>3,250,000</u>	<u>3,250,000</u>	<u>—</u>			
Stockholders' equity (deficiency):									
Series C convertible preferred stock . . . . .	<u>—</u>	<u>(32)</u>	<u>32</u>	<u>—</u>	<u>(32)</u>	<u>32</u>			
Capital in excess of par value . . . . .	218,687,977	(3,199,968)	221,887,945	172,090,055	(3,249,968)	175,340,023			
Accumulated deficit . . . . .	(206,741,406)	(2,047,007)	(204,694,399)	(193,258,323)	(2,173,349)	(191,084,974)			
Shareholders' equity . . . . .	<u>12,616,368</u>	<u>(5,247,007)</u>	<u>17,863,375</u>	<u>(20,572,886)</u>	<u>(5,423,349)</u>	<u>(15,149,537)</u>			
Total liabilities and stockholders' equity (deficiency) . . . . .	<u>\$ 65,838,744</u>	<u>\$ —</u>	<u>\$ 65,838,744</u>	<u>\$ 14,731,550</u>	<u>\$ —</u>	<u>\$ 14,731,550</u>			
<b>Statement of Operations Selected Data:</b>	<u>Restated 2006</u>	<u>Adjustments</u>	<u>As Reported 2006</u>	<u>Restated 2005</u>	<u>Adjustments</u>	<u>As Reported 2005</u>	<u>Restated 2004</u>	<u>Adjustments</u>	<u>As Reported 2004</u>
Other income (expense):									
Interest income . . . . .	862,068		862,068	165,886		165,886	241,342		241,342
Interest expense . . . . .	(2,669,771)	\$(153,658)	(2,516,113)	(3,491,234)	\$(797,193)	(2,694,041)	(3,928,156)	(937,020)	(2,991,136)
Loss on early debt extinguishment . . . . .	<u>—</u>	<u>280,000</u>	<u>(280,000)</u>	<u>—</u>		<u>—</u>			
Net loss . . . . .	<u>\$(12,485,379)</u>	<u>\$ 126,342</u>	<u>\$(12,611,721)</u>	<u>\$(10,104,329)</u>	<u>\$(797,193)</u>	<u>\$(9,307,136)</u>	<u>\$(26,066,644)</u>	<u>\$(937,020)</u>	<u>\$(25,129,624)</u>
Loss per common share – basic and diluted . . . . .	<u>\$ (0.26)</u>	<u>\$ 0.01</u>	<u>\$ (0.27)</u>	<u>\$ (0.25)</u>	<u>\$ (0.02)</u>	<u>\$ (0.23)</u>	<u>\$ (0.64)</u>	<u>\$ (0.02)</u>	<u>\$ (0.62)</u>
<b>Cash Flow Data:</b>	<u>Restated 2006</u>	<u>Adjustments</u>	<u>As Reported 2006<sup>(1)</sup></u>	<u>Restated 2005</u>	<u>Adjustments</u>	<u>As Reported 2005<sup>(1)</sup></u>	<u>Restated 2004</u>	<u>Adjustments</u>	<u>As Reported 2004<sup>(1)</sup></u>
Net loss . . . . .	\$(12,485,379)	\$ 126,342	\$(12,611,721)	\$(10,104,329)	(797,193)	\$(9,307,136)	\$(26,066,644)	(937,020)	\$(25,129,624)
Interest accrued on financing agreements net of payments made . . . . .	(4,539,253)	153,658	(4,692,911)	1,667,223	797,193	870,030	2,638,385	937,020	1,701,365
Loss on early extinguishment of financing agreement . . . . .	<u>—</u>	<u>(280,000)</u>	<u>280,000</u>	<u>—</u>		<u>—</u>			
Net cash used in operating activities . . . . .	<u>(13,080,977)</u>	<u>—</u>	<u>(13,080,977)</u>	<u>(8,283,473)</u>	<u>—</u>	<u>(8,283,473)</u>	<u>(20,977,088)</u>	<u>—</u>	<u>(20,977,088)</u>

(1) As reported amounts reflect a reclassification of payments of interest on financing agreements from financing activities to operating activities.

## COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### (3) Strategic Alliance Agreements

In May 1995, the Company entered into a worldwide license and supply agreement, except for South Africa, with American Home Products Corporation (“Wyeth”) under which its Wyeth-Ayerst Laboratories division marketed CRINONE®. The Company supplied CRINONE to Wyeth at a price equal to 30% of Wyeth’s net selling price. On July 2, 1999, Wyeth assigned the license and supply agreement to Ares-Serono (now “Merck Serono”). In June 2002 the Company acquired the right to market a second brand of its 8% and 4% progesterone gel products under the trade name “PROCHIEVE®” to obstetricians, gynecologists and all other physicians in the United States that were not on Merck Serono’s target list of fertility specialists. Under this agreement the Company paid a 30% royalty to Merck Serono based on net sales of the product and an additional royalty of 40% of PROCHIEVE’s net sales to the infertility specialist market. The Company paid approximately \$1,365,000 and \$699,000 to Merck Serono in accordance with this agreement for the years 2006 and 2005, respectively. In December 2006, the Company acquired the U.S. marketing rights to CRINONE from Merck Serono and eliminated the future PROCHIEVE® royalty payments. The Company continues to supply CRINONE to Merck Serono for all ex-U.S. requirements. On April 1, 2007, the Company recorded a liability from the contract with Merck Serono for certain sales returns associated with sales made by Merck Serono pursuant to the December 2006 acquisition agreement. The Company recorded the estimated liability of \$1.0 million as an increase in the purchase price that is being amortized over the remaining term of the patent life of the product.

In March 1999, the Company entered into a license and supply agreement with Mipharm SpA under which Mipharm SpA will be the exclusive marketer of the Company’s previously unlicensed women’s health-care products in Italy, Portugal, Greece and Ireland, with a right of first refusal for Spain. Under the terms of the agreement, the Company has received \$0.5 million, net of expenses, and expects to receive future milestone payments as products are made available by the Company.

Effective May 5, 2000, the Company sold various tangible and intangible assets related to the U.S. rights for Replens®, to Lil’ Drug Store for a total of \$4.5 million cash. The purchaser agreed to pay future royalties of up to \$2.0 million equal to 10% of future U.S. sales of Replens. The royalties were fully paid in October 2005. Additionally, effective May 5, 2000, the Company licensed its Legatrin® PM brand to Lil’ Drug Store. Under the terms of this agreement, the Company receives license fees equal to 20% of the licensee’s net sales of Legatrin PM. This agreement had a five-year term with provisions for renewal and contains an option that allows the licensee to acquire this brand from the Company; the license for Advanced Formula Legatrin PM renewed automatically to May 2010.

On July 31, 2002, the Company and Quintiles Transnational Corp. (“Quintiles”) entered into an agreement to commercialize the Company’s portfolio of women’s healthcare products in the United States. Under the terms of this agreement, Quintiles’ commercialization unit, Innovex, provided a dedicated team of 55 sales representatives on a three-year, fee-for-service basis, to commercialize the Company’s women’s healthcare products. On March 5, 2003, the Company and Quintiles announced an agreement to commercialize STRIANT® in the United States. Under the terms of this agreement, Innovex provided a dedicated team of approximately 75 sales representatives for two-and-a-half years. In January 2004, the Company and Innovex restructured the sales force. The restructured sales force was comprised of nine Company district managers as well as 80 sales representatives divided evenly between the Company and Innovex. In February 2005, the Company and Innovex reduced the sales force to 28 individuals, which included 23 sales representatives divided evenly between the Company and Innovex. The Company took responsibility for all sales force support. Columbia hired the remaining Innovex sales representatives as Columbia employees on November 1, 2005.

On October 16, 2002, the Company and Ardana Bioscience, Ltd. (“Ardana”) entered into a license and supply agreement for STRIANT® in 18 European countries (excluding Italy). Under the terms of the agreement, Ardana markets, distributes and sells STRIANT. In exchange for the license, the Company will receive total payments of approximately \$8 million, including \$4 million in signature and milestone fees received in

## COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### (3) Strategic Alliance Agreements – (continued)

the fourth quarter of 2002. Initial regulatory approval of the U.K. application, received in the first quarter of 2004, was the basis for mutual recognition applications filed in the rest of Europe. Additional milestone payments totaling \$2 million (of which \$0.8, \$0.4 and \$0.8 million were received in 2006, 2005 and 2004, respectively) are due upon marketing approvals in major European countries included in the agreement. Additionally, a performance payment of \$2 million is due upon achievement of a certain level of sales. Ardana is obligated to purchase its requirements of product from the Company during the term of the agreement. The agreement shall continue for a period of the later of 10 years from the first commercial sale of the finished product by Ardana or the date of expiration or lapse of the last of the Company's patent rights to expire or lapse in the territory, determined on a country by country basis. The Company is recognizing the license revenue on this agreement over a 132 month period and accordingly has recognized revenue of \$0.7, \$0.7, \$0.5 and \$0.5 million in 2007, 2006, 2005 and 2004, respectively. The remaining \$3.2 million as of December 31, 2007 is shown as deferred revenue in the accompanying consolidated balance sheets.

In May 2003, the Company and Mipharm entered into an agreement under which Mipharm will market, distribute and sell STRIANT in Italy. In exchange for these rights, Mipharm is obligated to pay the Company an aggregate of \$1.4 million upon achievement of certain milestone events, including \$350,000 that was paid in 2003. The Company received a payment of \$100,000, less VAT withholding, in 2004 on account of the UK approval of STRIANT and a payment of \$150,000, less VAT withholding, in 2007 on marketing authorization in Italy in late 2006. Mipharm will provide additional performance payments upon the achievement of certain levels of sales in Italy, and the Company will receive a percentage markup on the cost of goods for each unit sold. Mipharm is a manufacturer of STRIANT under a May 2002 agreement. The Company is recognizing the license revenue on this agreement over a 132 month period and accordingly has recognized revenue of \$53,199, \$41,574, \$41,573 and \$38,003 in 2007, 2006, 2005 and 2004, respectively. The remaining \$356,093 as of December 31, 2007 is shown as deferred revenue in the accompanying consolidated balance sheets.

In June 2004, the Company sold the worldwide rights to its over-the-counter products Advantage-S<sup>®</sup> Contraceptive Gel and RepHresh<sup>®</sup> Vaginal Gel and the foreign rights to Replens<sup>®</sup> Vaginal Moisturizer to Lil' Drug Store. The Company also sold its existing finished goods inventory of these products to Lil' Drug Store. Additionally, the companies executed a five year supply agreement and a two and one-half year agreement for the Company's sales force to promote these products to obstetricians and gynecologists in the United States. Upon closing, the Company received payments amounting to \$832,000, which were paid in 2004, from the sale of the rights and inventory. In June 2004, the Company recorded a loss of \$577,917 on the loss of the sale of the intangible assets associated with the products. The professional services agreement expired in December 2006. The production and sale of Advantage-S was discontinued during 2006. The Company continues to receive revenues from the manufacture and sale of RepHresh and Replens to Lil' Drug Store and royalties on sales of these products manufactured by third parties.

On September 27, 2007, the Company entered into a License and Supply Agreement with Ascend Therapeutics, Inc. ("Ascend"), pursuant to which the Company granted Ascend an exclusive, five year license to market and sell the Company's PROCHIEVE<sup>®</sup> 4% (progesterone gel) product in the United States effective January 1, 2008. Ascend will purchase product from Columbia at a transfer price equal to 35% of Ascend's net selling price with minimum annual purchase obligations that increase over the life of the agreement.

#### (4) Notes Payable

On December 22, 2006, the Company raised approximately \$40 million in gross proceeds to the Company from the sale of convertible subordinated notes to a group of existing institutional investors. The notes bear interest at a rate of 8% per annum and are subordinated to the PharmaBio financing agreements (see Note 5) and mature on December 31, 2011. They are convertible into a total of approximately 7.6 million shares of Common Stock at a conversion price of \$5.25. Investors also received warrants to purchase 2,285,714 shares of Common Stock at an exercise price of \$5.50 per share. The warrants became exercisable on June 20, 2007, and expire on December 22, 2011, unless earlier exercised or terminated. The Company

## COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### (4) Notes Payable – (continued)

used the proceeds of this offering to acquire from Merck Serono the U.S. marketing rights to CRINONE® for \$33.0 million and purchased Merck Serono's existing inventory of that product. The balance of the proceeds will be used to pay other costs related to the transaction and for general corporate purposes.

The Company recorded original issue discounts of \$6,272,566 to the notes based upon the fair value of warrants granted. In addition, beneficial conversion features totaling \$8,482,090 have been recorded as a discount to the notes. These discounts are being amortized at an imputed rate over the five year term of the related notes. For the years ended December 31, 2007 and 2006, \$2,237,043 and \$53,793, respectively, of amortization related to these discounts is classified as interest expense in the consolidated statements of operations. Unamortized discounts of \$12,463,822 and \$14,700,863 have been reflected as a reduction to the face value of the convertible notes in the consolidated balance sheets as of December 31, 2007 and 2006 respectively.

On March 16, 1998, the Company issued to an institutional investor a \$10 million convertible subordinated note due March 15, 2005. The note was subordinate to other senior securities of the Company and bore interest at 7.125% which was payable semiannually on March 15 and September 15. The note was paid in full on March 15, 2005.

#### (5) Financing Agreements

In an agreement dated July 31, 2002, Quintiles' strategic investment group, PharmaBio Development ("PharmaBio"), agreed to pay \$4.5 million, to be paid in four equal quarterly installments commencing third quarter 2002, for the right to receive a 5% royalty on the net sales of the Company's women's healthcare products in the United States for five years beginning in the first quarter of 2003. The royalty payments were subject to minimum (\$8 million) and maximum (\$12 million) amounts, and because the minimum amount exceeds \$4.5 million, the Company has recorded the amounts received as liabilities. The excess of the minimum (\$8 million) to be paid by the Company over the \$4.5 million received by the Company is being recognized as interest expense over the five-year term of the agreement, assuming an interest rate of 17% (12.51% prior to the restatement described in Note 2). The Company recorded \$617,016, \$615,709, \$677,354, and \$884,765 as interest expense for the years 2007, 2006, 2005 and 2004, respectively. The agreement called for a true-up payment, if by February 28, 2005, the Company had not made \$2,750,000 in royalty payments to PharmaBio. The amounts paid to PharmaBio were \$647,884 for 2007, \$548,464 for 2006, \$2,290,662 (which included the \$1,891,944 true-up) for 2005, and \$423,137 for 2004. The final payment of \$3.6 million was made on February 29, 2008.

In an agreement dated March 5, 2003 (the "STRIANT® Agreement"), PharmaBio agreed to pay the Company \$15 million in five quarterly installments commencing with the signing of the STRIANT Agreement. In return, PharmaBio will receive a 9% royalty on net sales of STRIANT in the United States up to agreed annual sales revenues, and a 4.5% royalty of net sales above those levels. The royalty term is seven years. Royalty payments commenced in the 2003 third quarter and are subject to minimum (\$30 million) and maximum (\$55 million) amounts. Because the minimum amount exceeds the \$15 million received by the Company, the Company has recorded the amounts received as liabilities. The excess of the minimum (\$30 million) to be paid by the Company over the \$15 million received by the Company is being recognized as interest expense over the seven-year term of the STRIANT Agreement, assuming an interest rate of 15% (10.67% prior to the restatements described in Note 2). The Company recorded \$1,648,756, \$1,900,640, \$2,658,300, and \$2,288,032 as interest expense in 2007, 2006, 2005, and 2004 respectively. The STRIANT Agreement called for a true-up payment on November 14, 2006 equal to the difference between royalties paid through and for the third quarter of 2006 and \$13,000,000. On April 14, 2006, the Company entered into a letter agreement (the "Letter Agreement") with PharmaBio pursuant to which the Company agreed to pay approximately \$12 million of this true-up payment seven months early. Accordingly, on April 14, 2006, the Company paid PharmaBio \$11,585,235 (the "Early Payment"), which was the present value of a November 14, 2006 \$12 million true-up payment using a six percent (6%) annual discount factor. In consideration of



**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(5) Financing Agreements – (continued)**

such payment, PharmaBio agreed that PharmaBio would be deemed (solely for purposes of the STRIANT Agreement) to have received on account of that payment \$12 million for purposes of the true-up payment. In the event that, as of the payment date for the true-up payment, the aggregate amount of royalties paid under the STRIANT Agreement, including the Early Payment, exceeded \$13 million, the Company would have been entitled to have such excess reimbursed. Including the Early Payment, the Company has paid PharmaBio approximately \$13,100,000 through 2007.

Liabilities from financing agreements consist of the following:

	December 31,		
	2007	2006	2005
		(Restated)	(Restated)
July 31, 2002 financing agreement . . . . .	\$ 3,620,653	\$ 3,749,941	\$ 3,682,697
March 5, 2003 financing agreement . . . . .	11,591,486	10,080,790	20,078,556
	15,212,139	13,830,731	23,761,253
Less: current portion . . . . .	3,786,538	553,947	12,840,161
	\$11,425,601	\$13,276,784	\$10,921,092

**(6) Contingently Redeemable Series C Convertible Preferred Stock**

In January 1999, the Company raised approximately \$6.4 million, net of expenses, from the issuance and sale of Series C Convertible Preferred Stock (“Series C Preferred Stock”). The Series C Preferred Stock, sold to 24 accredited investors, has a stated redemption value of \$1,000 per share. The Series C Preferred Stock is convertible into Common Stock at the lower of: (i) \$3.50 per common share or (ii) 100% of the average of the closing prices during the three trading days immediately preceding the conversion notice (not to exceed 2,705,236 shares). The Series C Preferred Stock pays a 5% dividend, payable quarterly in arrears on the last day of the quarter. In 2003, 500 shares of Series C Preferred Stock were converted into 142,857 Common Shares, in 2006, 50 shares of Series C Preferred Stock were converted into 14,285 Common Shares, and in 2007, 2,075 shares of Series C Preferred Stock were converted into 1,564,548 Common Shares. Each holder of Series C Preferred Stock has the right to redeem all or a portion of their shares in cash and upon the occurrence of certain events under the Series C Preferred Stock certificate of designations. The terms of the contingently redeemable Series C Convertible Preferred Stock remain as originally stated.

**(7) Shareholder’s Equity**

***Preferred Stock***

Authorized Preferred Stock is 1,000,000 shares at a par value of \$0.01 per share.

In August 1991, the Company completed a private placement of 150,000 shares of Series B Convertible Preferred Stock (“Series B Preferred Stock”). Each share of Series B Preferred Stock is convertible into 20.57 shares of Common Stock.

Upon liquidation of the Company, the holders of the Series B Preferred Stock are entitled to \$100 per share. The Series B Preferred Stock will be automatically converted into Common Stock upon the occurrence of certain events. Holders of the Series B Preferred Stock are entitled to one vote for each share of Common Stock into which the preferred stock is convertible.

On March 12, 2002, the Company adopted a Shareholder Rights Plan (“Rights Plan”) designed to protect company shareholders in the event of takeover activity that would deny them the full value of their investment. The Rights Plan was not adopted in response to any specific takeover threat. In adopting the Rights Plan, the Board declared a dividend distribution of one preferred stock purchase right for each outstanding share of Common Stock of the Company, payable to shareholders of record at the close of business



## COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### **(7) Shareholder's Equity – (continued)**

on March 22, 2002. The rights will become exercisable only in the event, with certain exceptions, a person or group of affiliated or associated persons acquires 15% or more of the Company's voting stock, or a person or group of affiliated or associated persons commences a tender or exchange offer, which if successfully consummated, would result in such person or group owning 15% or more of the Company's voting stock. The rights will expire on March 12, 2012. Each right, once exercisable, will entitle the holder (other than rights owned by an acquiring person or group) to buy one one-thousandth of a share of a series of the Company's Series D Junior Participating Preferred Stock at a price of \$30 per one-thousandth of a share, subject to adjustments. In addition, upon the occurrence of certain events, holders of the rights (other than rights owned by an acquiring person or group) would be entitled to purchase either the Company's preferred stock or shares in an "acquiring entity" at approximately half of market value. Further, at any time after a person or group acquires 15% or more (but less than 50%) of the Company's outstanding voting stock, subject to certain exceptions, the Board of Directors may, at its option, exchange part or all of the rights (other than rights held by an acquiring person or group) for shares of the Company's Common Stock having a fair market value on the date of such acquisition equal to the excess of (i) the fair market value of preferred stock issuable upon exercise of the rights over (ii) the exercise price of the rights. The Company generally will be entitled to redeem the rights at \$0.01 per right at any time prior to the close of business on the tenth day after there has been a public announcement of the beneficial ownership by any person or group of 15% or more of the Company's voting stock, subject to certain exceptions. These rights are deemed to have no value and accordingly have not been recorded in the accompanying financial statements.

On May 10, 2005, the Company raised \$6.9 million from the issuance and sale of 69,000 shares of Series E Convertible Preferred Stock ("Series E Preferred Stock"). The Series E Preferred Stock has a stated value of \$100 per share. Each share of the Series E Preferred Stock may be converted by the holder into 50 shares of Common Stock, subject to adjustment, and will automatically be converted into Common Stock at that rate upon the date that the average of the daily market prices of the Company's Common Stock for the 20 consecutive trading days preceding such date exceeds \$6.00 per share. The Series E Preferred Stock pays no dividends and contains voting rights equal to the number of shares of Common Stock into which each share of Series E Preferred Stock is convertible. Upon liquidation of the Company, the holders of the Series E Preferred Stock are entitled to \$100 per share. In 2007, 5,453 shares of Series E Preferred Stock were converted into 272,650 shares of Common Stock.

#### ***Common Stock***

During 2007, the Company issued 43,050 shares of Common Stock for the exercise of stock options with proceeds of \$63,241, and 155,690 shares of restricted Common Stock were granted to its key employees and to members of the Board of Directors.

In March 2006, the Company issued 7,428,220 shares of its Common Stock to a group of new and existing investors, which resulted in the Company receiving \$28,766,126, after expenses.

In 2005, the Company issued 2,850 shares of its Common Stock for the exercise of stock options with proceeds of \$8,253.

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(7) Shareholder's Equity – (continued)**

***Warrants***

As of December 31, 2007, the Company had warrants outstanding for the purchase of 4,867,755 shares of Common Stock. Information on outstanding warrants is as follows:

Exercise Price	Warrants
\$4.81	200,000
5.39	1,857,041
5.50	2,285,714
5.85	100,000
7.50	75,000
8.35	350,000
\$5.69	4,867,755

During 2006, warrants to purchase 1,857,041 shares of the Company's Common Stock at an exercise price of \$5.39 per share were issued to investors in the March 2006 financing which by their terms expire March 11, 2011. Also in 2006, warrants to purchase 2,285,714 shares of the Company's Common Stock at an exercise price of \$5.50 per share were issued to investors in the December 2006 financing and by their terms expire on December 22, 2011.

No warrants were exercised in 2007, 2006 and 2005.

As of December 31, 2007, 4,867,755 warrants were exercisable.

***Stock-based Compensation***

On January 1, 2006, the Company adopted SFAS 123(R) using the modified prospective transition method. SFAS 123(R) requires the measurement and recognition of compensation expense for all stock-based awards made to the Company's employees and directors including employee stock options and other stock-based awards based on estimated fair values.

The following table summarizes the impact of the adoption of SFAS 123(R) on stock-based compensation costs on the Company's Consolidated Statements of Operations for the years ended December 31, 2007, 2006, 2005 and 2004:

	Year Ended December 31,			
	2007	2006	2005	2004
Employee share-based compensation in:				
Cost of revenue . . . . .	\$ 148,589	\$ 82,720	\$—	\$—
Selling and distribution . . . . .	160,573	87,032	—	—
General and administrative . . . . .	1,014,702	733,695	—	—
Research and development . . . . .	166,195	161,936	—	—
Total employee share-based compensation in operating expenses . . . . .	1,341,470	982,663	—	—
Total employee share-based compensation . . . . .	\$1,490,059	\$1,065,383	\$—	\$—

Stock compensation for consultants amounted to \$157,863 and \$183,065 for 2007 and 2006, respectively. No tax benefit has been recognized due to net losses during the periods presented. In 2006, the Company took a charge of \$181,000 for extending the term of vested stock options for one of its former officers.

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(7) Shareholder's Equity – (continued)**

The table below reflects the pro forma information for the years ended December 31, 2005 and 2004 reflecting the impact of stock-based compensation as if accounted for under SFAS 123(R):

	<u>2005</u>	<u>2004</u>
	(Restated) (Proforma)	(Restated) (Proforma)
Net loss, before share-based compensation for employees, prior period . . . . .	\$(10,104,329)	\$(26,066,644)
Add: share-based compensation expense for employees determined under fair-value based method . . . . .	<u>(1,609,735)</u>	<u>(2,101,241)</u>
Net loss, after effect of share-based compensation for employees . . . . .	<u>\$(11,714,064)</u>	<u>\$(28,167,885)</u>
Net loss per share:		
Basic and diluted – as reported in prior year . . . . .	<u>\$ (0.25)</u>	<u>\$ (0.64)</u>
Basic and diluted – after effect of share-based compensation for employees . . . . .	<u>\$ (0.29)</u>	<u>\$ (0.69)</u>

As of December 31, 2007, total unamortized share-based compensation cost related to non-vested stock options was \$1,648,743 which is expected to be recognized over the remaining vesting period of the outstanding options, up to the next 29 months. The Company selected the Black-Scholes option pricing model as the most appropriate model for determining the estimated fair value for share-based awards. The use of the Black-Scholes model requires the use of extensive actual employee exercise behavior data and the use of a number of complex assumptions including expected volatility, risk-free interest rate, and expected dividends.

The assumptions used to value options granted are as follows:

	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>
Risk free interest rate . . . . .	4.53%	4.87%	4.03%	3.01%
Expected term . . . . .	4.52 years	4.84 years	6.67 years	4.95 years
Dividend yield . . . . .	0.0	0.0	0.0	0.0
Expected volatility . . . . .	85.68%	72.42%	81.90%	86.37%

The Company estimated the volatility of its stock based on expected volatility of the Company's stock which includes consideration of historical volatility in accordance with guidance in SFAS 123(R) and SAB 107. The Company did not consider implied volatility because there are no options traded on its stock. The risk-free interest rate assumption is based upon observed interest rates appropriate for the estimated term of the employee stock options. The dividend yield assumption is based on the Company's history and expectation of dividend payouts on Common Stock.

The expected term of employee stock options represents the weighted-average period that employees are expected to hold the options before exercise. The Company derived the expected term assumption based on the Company's historical settlement experience, while giving consideration to options that have life cycles less than the contractual terms and vesting schedules in accordance with guidance in SFAS 123(R) and SAB 107. Prior to the adoption of SFAS 123(R), the Company used historical settlement experience to derive the expected term for the purposes of pro forma information under SFAS 123, as disclosed in the Notes to the Company's Consolidated Financial Statements for the related periods.

***Stock Option Plans***

In October 1996, the Company adopted the 1996 Long-term Performance Plan ("1996 Plan") which provides for the grant of stock options, stock appreciation rights and restricted stock to certain designated employees of the Company, non-employee directors of the Company and certain other persons performing significant services for the Company as designated by the Compensation/Stock Option Committee of the

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(7) Shareholder's Equity – (continued)**

Board of Directors. The stock options have a maximum term of ten years after the date of grant and generally vest fully after four years. Options granted prior to 2006 have a ten year term. Since 2006, the Company has been issuing stock options with a seven year term. Options generally vest over a four-year period, with 25% vesting on each of the first four anniversaries of the date of grant. The 2007 annual option grant to employees vested 25% of the grant upon the grant date with the balance to vest equally over the next three years. The Company's general policy is to issue new shares upon the exercise of stock options

Pursuant to the Performance Plan, an aggregate of 8,000,000 shares of Common Stock have been reserved for issuance. Under the 1988 Stock Option Plan, as amended (the "88" Plan"), a total of 5.0 million shares of Common Stock were authorized for issuance upon exercise of the options. As of October 1996, no further options were granted pursuant to this plan and, in 2006, the remaining outstanding options expired.

A summary of the status of the Company's two stock option plans as of December 31, 2007, 2006, 2005 and 2004 and changes during the years ending on those dates is presented below:

	2007		2006		2005		2004	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
Outstanding at beginning of year	4,686,552	\$ 8.57	5,960,525	\$7.79	5,479,400	\$8.73	6,087,050	\$8.57
Granted	1,710,850	1.50	434,900	4.29	976,680	2.56	852,400	4.51
Exercised	(43,050)	1.47	(335,049)	3.05	(2,850)	2.90	—	—
Forfeited	(1,418,017)	12.84	(1,373,824)	6.27	(492,705)	7.89	(1,460,050)	5.60
Outstanding at end of year	<u>4,936,335</u>	4.64	<u>4,686,552</u>	8.57	<u>5,960,525</u>	7.79	<u>5,479,400</u>	8.73
Options exercisable at year end	<u>3,196,121</u>		<u>3,782,060</u>		<u>4,645,938</u>		<u>4,141,314</u>	

The weighted average grant date fair values of options granted in 2007, 2006, 2005 and 2004 was \$1.50, \$4.29, \$2.56 and \$4.51 per share respectively.

The following table summarizes the range of exercise prices and the weighted average prices for options outstanding, options exercisable and unvested options at December 31, 2007:

Range of Exercise Prices	Options Outstanding			Options Exercisable			Unvested Options	
	Number Outstanding at 12/31/07	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price	Number Exercisable at 12/31/07	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price	Number Unvested at 12/31/07	Weighted-Average Exercise Price
\$1.42	1,474,170	6.16	\$1.42	355,418	6.16	\$1.42	1,118,752	\$1.42
\$1.91 – \$3.44	1,024,815	5.48	2.66	691,965	5.31	2.77	332,850	\$2.45
\$3.51 – \$5.75	1,026,350	5.19	4.48	745,363	4.69	4.56	280,987	\$4.29
\$5.87 – \$11.63	<u>1,411,000</u>	1.84	9.56	<u>1,403,375</u>	1.81	9.58	<u>7,625</u>	\$6.54
\$1.42 – \$11.63	<u>4,936,335</u>	4.58	4.64	<u>3,196,121</u>	3.72	6.03	<u>1,740,214</u>	\$2.10

The weighted average exercise price and the weighted average remaining contractual life of the outstanding options expected to vest at December 31, 2007 amounted to \$6.01 and 3.91 years, respectively.

The aggregate intrinsic value of options outstanding, options expected to vest and options exercisable at December 31, 2007 were \$1,313,322, \$1,181,990, and \$340,201 respectively.

During 2007, cash received from the exercise of options was \$63,241.

Restricted stock grants consist of grants of the Company's Common Stock that may vest in the future. The Board has set a one, two, or four year vesting period for most of the issued restricted shares. The fair

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(7) Shareholder's Equity – (continued)**

value of each restricted share grant is equal to the market price of the Company's Common Stock at the date of grant. Expense relating to restricted shares is at the closing price amortized ratably over the vesting period.

A summary of the Company's restricted stock activity and related information for 2007 is as follows:

	2007	
	Shares	Weighted-Average Grant Date Fair Value
Unvested at beginning of period . . . . .	146,875	\$4.49
Granted . . . . .	159,390	\$1.79
Vested . . . . .	(105,469)	\$1.69
Forfeited . . . . .	(3,700)	\$1.40
Unvested at December 31, 2007 . . . . .	197,096	\$2.36

As of December 31, 2007, there was \$0.3 million of total unrecognized compensation costs related to non-vested restricted share-based compensation. The remaining cost is expected to be recognized over a weighted average period of 0.7 years. The total fair value of shares vested during the years ended December 31, 2007, 2006, 2005 and 2004 was \$0.2, \$0.1, \$0.0 and \$0.0 respectively.

*Adjustments for Stock-Based Compensation on Prior Year Financial Statements*

As of January 1, 2006, the Company adopted SFAS 123R, using the modified prospective transition method. SFAS 123R requires the measurement and recognition of compensation expense for all stock-based awards made to the Company's employees and directors including stock options and other stock-based awards based on estimated fair values. Prior to January 1, 2006, the Company accounted for share-based compensation granted under its stock option plans using the recognition and measurement provisions of APB 25. Under APB 25, a company was not required to recognize compensation expense for stock options issued to employees if the exercise price of the stock options was at least equal to the quoted market price of the Company's Common Stock on the "measurement date." APB 25 defined the measurement date as the first date on which both the number of shares that an individual employee was entitled to receive and the option price, if any, were known.

As previously disclosed, a review of the Company's stock option granting practices from October 1996 through 2006 resulted in the recording for the year ended December 31, 2006, of an equity reclassification of \$998,000 to reflect additional prior period stock-based compensation expense under APB 25, the accounting method in effect at the time, relating to the Company's historical stock option practices. The majority of such amount was attributable to options granted in 1997, with related compensation expense allocable to the years ended December 31, 1997 and 1998. In determining the appropriate method to account for the understatement of compensation expense, the Company considered SEC Staff Accounting Bulletin (SAB) No. 99, *Materiality*. In accordance with the transition provisions of Staff Accounting Bulletin (SAB) No. 108, *Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements*, the Company recorded a reclassification within the equity section of the consolidated balance sheet as an increase in additional paid-in capital and an increase in accumulated deficit for the year ended December 31, 2006, of \$998,000, excluding any related tax effect. Because the Company substantially reported losses during this period, the impact to income taxes was not considered material. This reclassification represented the effect of the adjustment resulting from the non-cash charges discussed above, all of which relate to prior fiscal years.

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(8) Loss per Common Share**

The calculation of basic and diluted loss per common share is as follows:

	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>
		(Restated)	(Restated)	(Restated)
Net loss . . . . .	\$(14,291,790)	\$(12,485,379)	\$(10,104,329)	\$(26,066,644)
Less: Preferred stock dividends . . . . .	<u>(76,894)</u>	<u>(161,379)</u>	<u>(162,500)</u>	<u>(162,500)</u>
Net loss applicable to common stock . . . . .	<u>\$(14,368,684)</u>	<u>\$(12,646,758)</u>	<u>\$(10,266,829)</u>	<u>\$(26,229,144)</u>
Basic and diluted Weighted-average number of common shares outstanding . . . . .	<u>51,124,266</u>	<u>48,088,516</u>	<u>41,752,422</u>	<u>40,984,083</u>
Basic and diluted net loss per common share . . . . .	<u>\$ (0.28)</u>	<u>\$ (0.26)</u>	<u>\$ (0.25)</u>	<u>\$ (0.64)</u>

**(9) Commitments and Contingencies**

***Cash and Cash Equivalents***

The Company maintains its cash in bank deposit accounts which, at times, may exceed federally insured limits. The Company believes that there is no credit risk with respect to these accounts.

***Leases***

The Company leases office space and office equipment under noncancelable operating leases. Lease expense for each of the four years ended December 31, 2007, 2006, 2005 and 2004 totaled \$209,478, \$223,122, \$265,620 and \$355,055 respectively. Future minimum lease payments as of December 31, 2007 are as follows:

2008 . . . . .	\$ 239,801
2009 . . . . .	243,005
2010 . . . . .	244,156
2011 . . . . .	237,765
2012 . . . . .	<u>420,097</u>
Thereafter . . . . .	<u>\$1,384,824</u>

***Royalties***

In 1989, the Company purchased the assets of Bio-Mimetics Inc., which assets consisted of the patents underlying the Company's Bioadhesive Delivery System (BDS), other patent applications and related technology, for \$2,600,000, in the form of 9% convertible debentures which were converted into 500,000 shares of Common Stock during 1991, and \$100,000 in cash. In addition, Bio-Mimetics, Inc. is entitled to a royalty equal to 2% of the net sales of products based on the BDS up to an aggregate amount of \$7,500,000. The royalty payments are payable over the life of the patent(s) which are specific to each product or fifteen years, whichever is longer. The Company is required to prepay 25% of the remaining royalty obligation, in cash or stock at the option of the Company, if the closing price of the Company's Common Stock is \$20 or more on March 2, or within 30 days after the date, of any year. The Company may not assign the patents underlying the BDS without the prior written consent of Bio-Mimetics, Inc. until the aggregate royalties have been paid. Royalty expense under this agreement amounted to \$114,466, \$245,416, \$405,798 and \$339,706 in 2007, 2006, 2005 and 2004, respectively. The Company determined that royalty payments on STRIANT®, PROCHIEVE®, and CRINONE® terminated in September of 2006, with the expiration of a certain Canadian patent, but continue on Replens® and RepHresh®. On December 28, 2007, Bio-Mimetics filed a complaint in



## COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### **(9) Commitments and Contingencies – (continued)**

the United States District Court for Massachusetts (*Bio-Mimetics, Inc. v. Columbia Laboratories, Inc.*) alleging breach of contract, violation of the covenant of good faith and fair dealing, and unjust enrichment for the Company's failure to continue royalty payments on STRIANT<sup>®</sup>, PROCHIEVE<sup>®</sup>, and CRINONE<sup>®</sup>. The Company intends to defend this action vigorously.

#### ***Employment Agreements***

In March 2006, the Company entered into a two-year employment agreement with an individual to serve as President and Chief Executive Officer of the Company. The agreement was due to expire on March 31, 2008, but was renewed pursuant to its terms for one year to expire March 31, 2009. Pursuant to the employment agreement, the employee is entitled to a base salary of \$390,000 per year plus a target 50% bonus.

In March 2006, the Company entered into a two-year employment agreement with an individual to serve as Senior Vice President, General Counsel and Secretary of the Company. The agreement was due to expire on March 31, 2008, but was renewed pursuant to its terms for one year to expire March 31, 2009. Pursuant to the employment agreement, the employee is entitled to a base salary of \$295,700 per year plus a target 40% bonus.

In December 2006, the Company entered into an employment agreement with an individual to serve as Senior Vice President, Chief Financial Officer and Treasurer of the Company. The agreement was due to expire on March 31, 2008, but was renewed pursuant to its terms for one year to expire March 31, 2009. Pursuant to the employment agreement, the employee is entitled to a base salary of \$275,000 per year plus a target 35% bonus.

#### ***Legal Proceedings***

Claims and lawsuits have been filed against the Company from time to time. Although the results of pending claims are always uncertain, the Company does not believe the results of any such actions, individually or in the aggregate, will have a material adverse effect on the Company's financial position or results of operation. Additionally, the Company believes that it has adequate reserves or adequate insurance coverage in respect of these claims, but no assurance can be given as to the sufficiency of such reserves or insurance in the event of any unfavorable outcome resulting from these actions. It is the policy of management to disclose the amount or range of reasonably possible losses in excess of recorded amounts.

In connection with the 1989 purchase of the assets of Bio-Mimetics, Inc., which assets consisted of the patents underlying the Company's BDS, other patent applications, and related technology, the Company agreed to pay Bio-Mimetics a royalty equal to two percent of the net sales of products based on the assets up to an aggregate of \$7.5 million or until the last of the relevant patents expired. The Company determined that royalty payments on STRIANT<sup>®</sup>, PROCHIEVE<sup>®</sup>, and CRINONE<sup>®</sup> terminated in September of 2006, with the expiration of a certain Canadian patent, but continue on Replens<sup>®</sup> and RepHresh<sup>®</sup>. On December 28, 2007, Bio-Mimetics filed a complaint in the United States District Court for Massachusetts (*Bio-Mimetics, Inc. v. Columbia Laboratories, Inc.*) alleging breach of contract, violation of the covenant of good faith and fair dealing, and unjust enrichment for the Company's failure to continue royalty payments on STRIANT<sup>®</sup>, PROCHIEVE<sup>®</sup>, and CRINONE<sup>®</sup>. The Company intends to defend this action vigorously.

#### **(10) Geographic Information and Customer Concentration**

##### ***Geographic Information***

The Company and its subsidiaries are engaged in one line of business, the development, licensing and sale of pharmaceutical products. The Company conducts its international business through its Bermuda subsidiary which contracts with various manufacturers located in the United Kingdom, Switzerland and Italy, to make product for both its international and domestic operations. Most arrangements with licensees are made

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(10) Geographic Information and Customer Concentration – (continued)**

by the Bermuda company. These customers sell their products into several countries. The Company's largest international customer is MerckSerono with Lil' Drug store next in revenue size and Ardana and Mipharm who are small contributors.

The following table shows selected information by geographic area:

	<u>Revenues</u>	<u>Long Lived Assets</u>
As of and for the year ended December 31, 2007		
United States . . . . .	\$15,257,884	\$30,397,655
Switzerland . . . . .	8,101,831	—
Other European Countries . . . . .	6,267,923	824,389
Subtotal International . . . . .	<u>14,369,754</u>	<u>824,389</u>
	<u>\$29,627,638</u>	<u>\$31,222,044</u>
As of and for the year ended December 31, 2006		
United States . . . . .	\$ 7,950,735	\$34,625,301
Switzerland . . . . .	5,716,289	—
Other European Countries . . . . .	3,726,057	539,206
Subtotal International . . . . .	<u>9,442,346</u>	<u>539,206</u>
	<u>\$17,393,081</u>	<u>\$35,164,507</u>
As of and for the year ended December 31, 2005		
United States . . . . .	\$10,970,046	\$ 509,653
Switzerland . . . . .	5,404,847	—
Other European Countries . . . . .	5,665,949	617,683
Subtotal International . . . . .	<u>11,070,796</u>	<u>617,683</u>
	<u>\$22,040,842</u>	<u>\$ 1,127,336</u>
As of and for the year ended December 31, 2004		
United States . . . . .	\$11,236,330	\$ 628,418
Switzerland . . . . .	3,320,908	—
Other European Countries . . . . .	3,303,166	699,763
Subtotal International . . . . .	<u>6,624,074</u>	<u>699,763</u>
	<u>\$17,860,404</u>	<u>\$ 1,328,181</u>

***Customer Concentration***

The following table presents information about Columbia's revenues by customer, including royalty and license revenue:

	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>
MerckSerono . . . . .	\$ 8,151,292	\$ 8,234,198	\$ 9,765,387	\$ 8,512,147
Cardinal Healthcare . . . . .	6,098,510	2,060,152	1,773,811	1,419,962
Lil' Drug Store Products, Inc. . . . .	5,958,925	4,637,928	6,906,358	3,565,760
McKesson . . . . .	3,888,354	1,892,728	1,620,188	1,218,438
AmerisourceBergen . . . . .	2,800,555	—	—	—
All others (none over 5%) . . . . .	2,730,002	568,075	1,975,098	3,144,097
	<u>\$29,627,638</u>	<u>\$17,393,081</u>	<u>\$22,040,842</u>	<u>\$17,860,404</u>

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(10) Geographic Information and Customer Concentration – (continued)**

Revenues from sales of CRINONE® to Merck Serono S.A. were \$8.2 million in 2007 and 2006, \$9.8 million in 2005 and \$8.5 million in 2004. The 2007 figure represents the sales of CRINONE® to Merck Serono ex-United States only whereas previously the Company sold product to Merck Serono for both the US and international markets. At the end of 2006, the Company acquired the US rights to Crinone®. The 2006 figure reflects the reduction in sales of approximately \$0.6 million relating to the reversal of sales previously recorded in 2006 upon repurchase of Serono's U.S. CRINONE product inventory.

**(11) Quarterly Financial Information (Unaudited)**

The following table summarizes selected quarterly data for the years ended December 31, 2007 2006 and 2005:

<b>2007</b>	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>	<b>Full Year</b>
	(Restated)	(Restated)	(Restated)		
Net Revenues . . . . .	\$ 6,684,620	\$ 7,287,014	\$ 7,308,079	\$ 8,347,925	\$ 29,627,638
Gross profit . . . . .	4,612,433	4,483,725	5,578,997	5,937,943	20,613,098
Loss from operations	(1,842,496)	(1,865,255)	(1,886,598)	(2,513,499)	(8,107,848)
Net loss . . . . .	(3,535,976)	(3,589,375)	(3,724,362)	(3,442,077)	(14,291,790)
Basic and diluted loss per common share	\$ (0.07)	\$ (0.07)	\$ (0.07)	\$ (0.07)	\$ (0.28)
<b>2006</b>	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>	<b>Full Year</b>
	(Restated)	(Restated)	(Restated)	(Restated)	(Restated)
Net Revenues . . . . .	\$ 4,545,377	\$ 5,523,113	\$ 4,946,387	\$ 2,378,204	\$ 17,393,081
Gross profit . . . . .	2,667,109	3,219,374	2,772,406	914,349	9,573,238
Loss from operations	(2,148,353)	(1,925,036)	(2,266,429)	(4,820,286)	(11,160,104)
Net loss . . . . .	(2,940,189)	(2,244,065)	(2,561,410)	(4,739,715)	(12,485,379)
Basic and diluted loss per common share	\$ (0.07)	\$ (0.05)	\$ (0.05)	\$ (0.09)	\$ (0.26)
<b>2005</b>	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>	<b>Full Year</b>
	(Restated)	(Restated)	(Restated)	(Restated)	(Restated)
Net Revenues . . . . .	\$ 4,280,577	\$ 6,333,845	\$ 6,533,942	\$ 4,892,478	\$ 22,040,842
Gross profit . . . . .	2,463,572	4,088,410	4,143,828	3,233,535	13,929,345
Loss from operations	(3,553,014)	(958,944)	(649,653)	(2,069,070)	(7,230,681)
Net loss . . . . .	(4,472,538)	(1,765,343)	(1,458,897)	(2,407,551)	(10,104,329)
Basic and diluted loss per common share	\$ (0.11)	\$ (0.04)	\$ (0.04)	\$ (0.06)	\$ (0.25)

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(11) Quarterly Unaudited Financial Statements for 2007 and 2006 Restatements — See Note 2**

As disclosed in Note 2, the Company is restating within this Annual Report on Form 10K, its unaudited condensed consolidated financial statements for the first, second, and third quarters of 2007 and 2006. These restatements and revisions primarily reflect adjustments to:

Correct previously reported interest expense for financing arrangements for understatement or overstatements in each of the quarters of 2007 and 2006 along with the respective increase or decrease in net loss and the impact on outstanding balances of financing agreements and to increase or decrease the accumulated deficit.

Correct the classification of the contingently redeemable Series C Convertible Preferred Stock from Shareholders' Equity to temporary equity for the quarters ended 2007.

***Background***

As described in Note 2, when the Company initially recorded the Pharma-Bio Financing Agreements, it applied the yield to maturity method for accounting for the interest expense, but did not recognize the interim payment obligations that resulted in implicit interest rates of 13% and 11%, respectively. The Company has determined that it should have applied the effective yield method called for in Accounting Principles Board Opinion 21 ("APB 21") to account for interest expense, and should have included the impact of the interim payments on the implicit interest rates. Under APB 21, the implicit interest rates would have been approximately 17% and 15%, respectively. Over the life of each financing agreement, however, the payments and the recorded interest expense would be equal under both accounting methods. Further, the adjustments do not change current cash flows or repayment obligations.

Within the quarters ended March 31, June 30, and September 30, 2007 and 2006, interest expense, the financing agreement liability and accumulated deficit have been adjusted as per the tables below.

In addition, the Company had previously recorded the contingently redeemable Series C Convertible Preferred Stock amount as Shareholders' Equity on its balance sheets. The Company reclassified its contingently redeemable Series C Convertible Preferred Stock from Shareholders' Equity to temporary equity, because the holders have redemption rights for certain events that are not controlled by the Company. The terms of the Series C Convertible Preferred Stock have not changed from the original issuance in 1999.

For the quarters ended March 31, June 30, and September 30, 2007 and 2006, the Company revised its interest expense by the following amounts:

	<b>Interest Expense 2007</b>	<b>Interest Expense Year to Date 2007</b>	<b>Interest Expense 2006</b>	<b>Interest Expense Year to Date 2006</b>
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Quarter ended March 31 . . . . .	(193,189)	(193,189)	193,867	193,867
Quarter ended June 30 . . . . .	(193,982)	(387,171)	(234,746)	(40,879)
Quarter ended September 30 . . . . .	(205,937)	(593,108)	4,013	(36,866)

The net effects of the restatement adjustments on the condensed balance sheets as of the quarters ended March 31, June 30, and September 30, 2007 are indicated in the following table.

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

**Unaudited**

	<u>Restated March 31, 2007</u>	<u>March 31, Adjust- ments</u>	<u>As Reported March 31, 2007</u>	<u>Restated June 30, 2007</u>	<u>June 30, Adjust- ments</u>	<u>As Reported June 30, 2007</u>	<u>Restated September 30, 2007</u>	<u>September 30, Adjustments</u>	<u>As Reported September 30, 2007</u>
	(Unaudited)		(Unaudited)	(Unaudited)		(Unaudited)	(Unaudited)		(Unaudited)
<b>ASSETS:</b>									
Cash and cash equivalents . . . . .	\$20,269,847		\$20,269,847	\$19,994,621		\$19,994,621	\$19,226,558		\$19,226,558
Accounts receivable, net . . . . .	4,872,451		4,872,451	4,214,478		4,214,478	3,935,860		3,935,860
Inventories . . . . .	2,456,656		2,456,656	2,184,540		2,184,540	2,243,022		2,243,022
Prepaid expenses and other current assets	753,122		753,122	473,702		473,702	382,630		382,630
Total current assets	28,352,076		28,352,076	26,867,341		26,867,341	25,788,070		25,788,070
Property and equipment, net . . . . .	710,632		710,632	659,071		659,071	614,066		614,066
Intangible Assets, net	31,643,335		31,643,335	31,382,152		31,382,152	30,120,970		30,120,970
Other Assets . . . . .	1,677,058		1,677,058	1,620,019		1,620,019	1,633,020		1,633,020
Total Assets . . . . .	<u>\$62,383,101</u>		<u>\$62,383,101</u>	<u>\$60,528,583</u>		<u>\$60,528,583</u>	<u>\$58,156,126</u>		<u>\$58,156,126</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>									
Current portion of financing agreements . . . . .	\$ 3,745,244		\$ 3,745,244	\$ 3,800,806		\$ 3,800,806	\$ 3,829,484		\$ 3,829,484
Accounts payable . . . . .	2,458,341		2,458,341	2,280,245		2,280,245	2,125,640		2,125,640
Accrued expenses . . . . .	2,850,793		2,850,793	3,732,613		3,732,613	4,110,557		4,110,557
Total Current Liabilities . . . . .	9,054,378		9,054,378	9,813,664		9,813,664	10,065,681		10,065,681
Notes Payable . . . . .	25,837,064		25,837,064	26,385,162		26,385,162	26,951,333		26,951,333
Deferred revenue . . . . .	4,119,368		4,119,368	3,939,853		3,939,853	3,760,351		3,760,351
Long-term portion of financing agreements <sup>(1)</sup> . . . . .	10,498,485	1,853,818	8,644,667	10,788,812	1,659,836	9,128,976	11,096,321	1,453,899	9,642,422
Total Liabilities . . . . .	49,509,295	1,853,818	47,655,477	50,927,491	1,659,836	49,267,655	51,873,686	1,453,899	50,419,787
Commitments and contingencies									
Contingently Redeemable Series C Convertible Preferred Stock <sup>(2)</sup>	1,400,000	1,400,000	—	1,125,000	1,125,000	—	1,125,000	1,125,000	—
1,400, 1,125, and 1,125 shares issued and outstanding in first, second and third quarter, liquidation preference of \$1,400,000, \$1,125,000, and \$1,250,000 respectively. . . . .									

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS – (continued)**  
**Unaudited**

	Restated March 31, 2007	March 31, Adjust- ments	As Reported March 31, 2007	Restated June 30, 2007	June 30, Adjust- ments	As Reported June 30, 2007	Restated September 30, 2007	September 30, Adjustments	As Reported September 30, 2007
	(Unaudited)		(Unaudited)	(Unaudited)		(Unaudited)	(Unaudited)		(Unaudited)
Shareholders' equity:									
Series C Convertible Preferred Stock, 1,400, 1,125, 1,125 shares issued and outstanding in first, second, and third quarter, liquidation preference of \$1,400,000, \$1,125,000, and \$1,125,000 respectively <sup>(2)</sup> . . . . .	—	(14)	14	—	(11)	11	—	(11)	11
Preferred Stock, \$0.01 par value; 1,000,000 shares authorized Series B Convertible Preferred Stock, 130 shares issued and outstanding in for three quarters . . . . .	1		1	1		1	1		1
Series E Convertible Preferred Stock, 69,000, 68,742 and 68,742, shares issued and outstanding in first, second, and third quarter, . . . . .	690		690	687		687	687		687
Common Stock, \$0.01 par value; 100,000,000 authorized; 51,188,863, 51,439,651, and 51,470,401 shares issued in first, second and third quarter respectively . . . . .	511,889		511,889	514,391		514,391	514,704		514,704
Capital in excess of par value . . . . .	221,065,991	(1,399,986)	222,465,977	221,665,264	(1,124,989)	222,790,253	222,065,339	(1,124,989)	223,190,328
Less cost of 6,000, 12,000, and 12,000 treasury shares . . . . .	(26,880)		(26,880)	(40,140)		(40,140)	(40,140)		(40,140)
Accumulated deficit . . . . .	(210,277,382)	(1,853,818)	(208,423,564)	(213,866,757)	(1,659,836)	(212,206,921)	(217,591,116)	(1,453,899)	(216,137,217)
Accumulated other comprehensive income . . . . .	199,497		199,497	202,646		202,646	207,965		207,965
Total Shareholders' Equity . . . . .	11,473,806	(3,253,818)	14,727,624	8,476,092	(2,784,836)	11,260,928	5,157,440	(2,578,899)	7,736,339
Total Liabilities and Shareholders Equity . . . . .	\$ 62,383,101	\$ —	\$ 62,383,101	\$ 60,528,583	\$ —	\$ 60,528,583	\$ 58,156,126	\$ —	\$ 58,156,126

(1) Adjustment to correct the amount of interest recorded on financing agreements

(2) Adjustment to reclassify Series C Convertible Preferred Stock to temporary equity due to redemption provisions



The following table sets forth statement of operations data for the quarters ended March 31, June 30, and September 30, 2007 and 2006.

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**

	Three Months Ended March 31,			Six Months Ended June 30,			Nine Months Ended September 30,		
	Restated 2007	Adjustments	As Reported 2007	Restated 2007	Adjustments	As Reported 2007	Restated 2007	Adjustments	As Reported 2007
Net revenues . . . . .	\$ 6,684,620		\$ 6,684,620	\$13,971,634		\$13,971,634	\$ 21,279,713		\$ 21,279,713
Cost of revenues . . . . .	2,072,187		2,072,187	4,875,476		4,875,476	6,604,558		6,604,558
Gross profit . . . . .	4,612,433		4,612,433	9,096,158		9,096,158	14,675,155		14,675,155
Operating expenses:									
Selling and distribution . . . . .	1,897,282		1,897,282	4,061,132		4,061,132	6,908,326		6,908,326
General and administrative . . . . .	1,984,525		1,984,525	3,899,773		3,899,773	5,813,335		5,813,335
Research and development . . . . .	1,350,901		1,350,901	2,359,600		2,359,600	3,803,257		3,803,257
Amortization of licensing right . . . . .	1,222,221		1,222,221	2,483,404		2,483,404	3,744,586		3,744,586
Total operating expenses	6,454,929		6,454,929	12,803,909		12,803,909	20,269,504		20,269,504
Loss from operations . . . . .	(1,842,496)		(1,842,496)	(3,707,751)		(3,707,751)	(5,594,349)		(5,594,349)
Other income (expense):									
Interest income . . . . .	263,556		263,556	505,589		505,589	739,895		739,895
Interest expense <sup>(1)</sup> . . . . .	(1,934,554)	193,189	(2,127,743)	(3,904,416)	387,171	(4,291,587)	(5,908,736)	593,108	(6,501,844)
Other, net . . . . .	(22,482)		(22,482)	(18,773)		(18,773)	(86,522)		(86,522)
Net loss . . . . .	<u>\$(3,535,976)</u>	<u>\$193,189</u>	<u>\$(3,729,165)</u>	<u>\$(7,125,351)</u>	<u>\$387,171</u>	<u>\$(7,512,522)</u>	<u>\$(10,849,712)</u>	<u>\$593,108</u>	<u>\$(11,442,820)</u>
Net loss per common share:									
Basic and diluted . . . . .	<u>\$ (0.07)</u>	<u>\$ 0.01</u>	<u>\$ (0.08)</u>	<u>\$ (0.14)</u>	<u>\$ 0.01</u>	<u>\$ (0.15)</u>	<u>\$ (0.21)</u>	<u>\$ 0.01</u>	<u>\$ (0.23)</u>
Weighted average number of common shares outstanding:									
Basic and diluted . . . . .	<u>50,081,448</u>		<u>50,081,448</u>	<u>50,713,299</u>		<u>50,713,299</u>	<u>50,955,758</u>		<u>50,955,758</u>

(1) Adjusted to correct the amount of interest recorded on financing agreements

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS – (continued)**  
**(Unaudited)**

	Three Months Ended March 31,			Three Months Ended June 30,			Three Months Ended September 30,		
	Restated 2007	Adjustments	As Reported 2007	Restated 2007	Adjustments	As Reported 2007	Restated 2007	Adjustments	As Reported 2007
Net revenues . . . . .	\$ 6,684,620		\$ 6,684,620	\$ 7,287,014		\$ 7,287,014	\$ 7,308,079		\$ 7,308,079
Cost of revenues . . . . .	2,072,187		2,072,187	2,803,289		2,803,289	1,729,082		1,729,082
Gross profit . . . . .	<u>4,612,433</u>		<u>4,612,433</u>	<u>4,483,725</u>		<u>4,483,725</u>	<u>5,578,997</u>		<u>5,578,997</u>
Operating expenses:									
Selling and distribution . . . . .	1,897,282		1,897,282	2,163,850		2,163,850	2,847,194		2,847,194
General and administrative . . . . .	1,984,525		1,984,525	1,915,248		1,915,248	1,913,562		1,913,562
Research and development . . . . .	1,350,901		1,350,901	1,008,699		1,008,699	1,443,657		1,443,657
Amortization of licensing right . . . . .	1,222,221		1,222,221	1,261,183		1,261,183	1,261,182		1,261,182
Total operating expenses . . . . .	<u>6,454,929</u>		<u>6,454,929</u>	<u>6,348,980</u>		<u>6,348,980</u>	<u>7,465,595</u>		<u>7,465,595</u>
Loss from operations . . . . .	<u>(1,842,496)</u>		<u>(1,842,496)</u>	<u>(1,865,255)</u>		<u>(1,865,255)</u>	<u>(1,886,598)</u>		<u>(1,886,598)</u>
Other income (expense):									
Interest income . . . . .	263,556		263,556	242,033		242,033	234,306		234,306
Interest expense <sup>(1)</sup> . . . . .	(1,934,554)	193,189	(2,127,743)	(1,969,862)	193,982	(2,163,844)	(2,004,321)	205,937	(2,210,258)
Other, net . . . . .	(22,482)		(22,482)	3,709		3,709	(67,749)		(67,749)
	<u>(1,693,480)</u>	<u>193,189</u>	<u>(1,886,669)</u>	<u>(1,724,120)</u>	<u>193,982</u>	<u>(1,918,102)</u>	<u>(1,837,764)</u>	<u>205,937</u>	<u>(2,043,701)</u>
Net loss . . . . .	<u>(\$ 3,535,976)</u>	<u>\$193,189</u>	<u>\$ (3,729,165)</u>	<u>\$ (3,589,375)</u>	<u>\$193,982</u>	<u>\$ (3,783,357)</u>	<u>\$ (3,724,362)</u>	<u>\$205,937</u>	<u>\$ (3,930,299)</u>
Net loss per common share:									
Basic and diluted . . . . .	<u>\$ (0.07)</u>	<u>\$ 0.01</u>	<u>\$ (0.08)</u>	<u>\$ (0.07)</u>	<u>\$ 0.00</u>	<u>\$ (0.07)</u>	<u>\$ (0.07)</u>	<u>\$ 0.01</u>	<u>\$ (0.08)</u>
Weighted average number of common shares outstanding:									
Basic and diluted . . . . .	<u>50,081,448</u>		<u>50,081,448</u>	<u>51,342,528</u>		<u>51,342,528</u>	<u>51,432,770</u>		<u>51,432,770</u>

(1) Adjusted to correct the amount of interest recorded on financing agreements

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS – (continued)**  
**(Unaudited)**

	Three Months Ended March 31,			Six Months Ended June 30,			Nine Months Ended September 30,		
	Restated 2006	Adjustments	As Reported 2006	Restated 2006	Adjustments	As Reported 2006	Restated 2006	Adjustments	As Reported 2006
Net revenues . . . . .	\$ 4,545,377		\$ 4,545,377	\$10,068,490		\$10,068,490	\$15,014,877		\$15,014,877
Cost of revenues . . . . .	1,878,268		1,878,268	4,182,007		4,182,007	6,355,988		6,355,988
Gross profit . . . . .	<u>2,667,109</u>		<u>2,667,109</u>	<u>5,886,483</u>		<u>5,886,483</u>	<u>8,658,889</u>		<u>8,658,889</u>
Operating expenses:									
Selling and distribution . . . . .	1,499,979		1,499,979	3,239,490		3,239,490	4,859,602		4,859,602
General and administrative . . . . .	1,588,866		1,588,866	3,348,796		3,348,796	5,064,597		5,064,597
Research and development . . . . .	1,726,617		1,726,617	3,370,370		3,370,370	5,073,292		5,073,292
Total operating expenses.	<u>4,815,462</u>		<u>4,815,462</u>	<u>9,958,656</u>		<u>9,958,656</u>	<u>14,997,491</u>		<u>14,997,491</u>
Loss from operations . . . . .	<u>(2,148,353)</u>		<u>(2,148,353)</u>	<u>(4,072,173)</u>		<u>(4,072,173)</u>	<u>(6,338,602)</u>		<u>(6,338,602)</u>
Other income (expense):									
Interest income . . . . .	100,495		100,495	355,899		355,899	612,691		612,691
Interest expense <sup>(1)</sup> . . . . .	(864,858)	(193,867)	(670,991)	(1,455,591)	40,879	(1,496,470)	(1,984,567)	36,866	(2,021,433)
Other, net . . . . .	(27,473)		(27,473)	(11,173)		(11,173)	(33,970)		(33,970)
	<u>(791,836)</u>	<u>(193,867)</u>	<u>(597,969)</u>	<u>(1,110,865)</u>	<u>40,879</u>	<u>(1,151,744)</u>	<u>(1,405,846)</u>	<u>36,866</u>	<u>(1,442,712)</u>
Net loss . . . . .	<u>\$ (2,940,189)</u>	<u>\$ (193,867)</u>	<u>\$ (2,746,322)</u>	<u>\$ (5,183,038)</u>	<u>\$ 40,879</u>	<u>\$ (5,223,917)</u>	<u>\$ (7,744,448)</u>	<u>\$ 36,866</u>	<u>\$ (7,781,314)</u>
Net loss per common share:									
Basic and diluted . . . . .	<u>\$ (0.07)</u>	<u>\$ (0.01)</u>	<u>\$ (0.06)</u>	<u>\$ (0.11)</u>	<u>\$ (0.00)</u>	<u>\$ (0.11)</u>	<u>\$ (0.17)</u>	<u>\$ 0.00</u>	<u>\$ (0.17)</u>
Weighted average number of common shares outstanding:									
Basic and diluted . . . . .	<u>43,344,655</u>		<u>43,344,655</u>	<u>46,467,128</u>		<u>46,467,128</u>	<u>47,547,819</u>		<u>47,547,819</u>

(1) Adjusted to correct the amount of interest recorded on financing agreements

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS – (continued)**  
**(Unaudited)**

	Three Months Ended March 31,			Three Months Ended June 30,			Three Months Ended September 30,		
	Restated 2006	Adjustments	As Reported 2006	Restated 2006	Adjustments	As Reported 2006	Restated 2006	Adjustments	As Reported 2006
Net revenues . . . . .	\$ 4,545,377		\$ 4,545,377	\$ 5,523,113		\$ 5,523,113	\$ 4,946,387		\$ 4,946,387
Cost of revenues . . . . .	1,878,268		1,878,268	2,303,739		2,303,739	2,173,981		2,173,981
Gross profit . . . . .	<u>2,667,109</u>		<u>2,667,109</u>	<u>3,219,374</u>		<u>3,219,374</u>	<u>2,772,406</u>		<u>2,772,406</u>
Operating expenses:									
Selling and distribution . . . . .	1,499,979		1,499,979	1,739,511		1,739,511	1,620,112		1,620,112
General and administrative . . . . .	1,588,866		1,588,866	1,761,146		1,761,146	1,715,801		1,715,801
Research and development . . . . .	1,726,617		1,726,617	1,643,753		1,643,753	1,702,922		1,702,922
Total operating expenses	<u>4,815,462</u>		<u>4,815,462</u>	<u>5,144,410</u>		<u>5,144,410</u>	<u>5,038,835</u>		<u>5,038,835</u>
Loss from operations . . . . .	<u>(2,148,353)</u>		<u>(2,148,353)</u>	<u>(1,925,036)</u>		<u>(1,925,036)</u>	<u>(2,266,429)</u>		<u>(2,266,429)</u>
Other income (expense):									
Interest income . . . . .	100,495		100,495	255,404		255,404	256,792		256,792
Interest expense <sup>(1)</sup> . . . . .	(864,858)	(193,867)	(670,991)	(590,733)	234,746	(825,479)	(528,976)	(4,013)	(524,963)
Other, net . . . . .	(27,473)		(27,473)	16,300		16,300	(22,797)		(22,797)
	<u>(791,836)</u>	<u>(193,867)</u>	<u>(597,969)</u>	<u>(319,029)</u>	<u>234,746</u>	<u>(553,775)</u>	<u>(294,981)</u>	<u>(4,013)</u>	<u>(290,968)</u>
Net loss . . . . .	<u>\$ (2,940,189)</u>	<u>\$ (193,867)</u>	<u>\$ (2,746,322)</u>	<u>\$ (2,244,065)</u>	<u>\$ 234,746</u>	<u>\$ (2,478,811)</u>	<u>\$ (2,561,410)</u>	<u>\$ (4,013)</u>	<u>\$ (2,557,397)</u>
Net loss per common share:									
Basic and diluted . . . . .	<u>\$ (0.07)</u>	<u>\$ (0.01)</u>	<u>\$ (0.06)</u>	<u>\$ (0.05)</u>	<u>\$ 0.00</u>	<u>\$ (0.05)</u>	<u>\$ (0.05)</u>	<u>\$ 0.00</u>	<u>\$ (0.05)</u>
Weighted average number of common shares outstanding:									
Basic and diluted . . . . .	<u>43,344,655</u>		<u>43,344,655</u>	<u>49,555,297</u>		<u>49,555,297</u>	<u>49,673,962</u>		<u>49,673,962</u>

(1) Adjusted to correct the amount of interest recorded on financing agreements

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(Unaudited)**

	Three Months Ended March 31,			Six Months Ended June 30,			Nine Months Ended September 30,		
	Restated 2007	Adjustments	As Reported 2007 <sup>(2)</sup>	Restated 2007	Adjustments	As Reported 2007 <sup>(2)</sup>	Restated 2007	Adjustments	As Reported 2007 <sup>(2)</sup>
Cash flows from operating activities:									
Net loss . . . . .	\$(3,535,976)	193,189	\$(3,729,165)	\$(7,125,351)	387,171	\$(7,512,522)	\$(10,849,712)	593,108	\$(11,442,820)
Adjustments to reconcile net loss to net cash used in operating activities-									
Depreciation and amortization . . . . .	1,336,005		1,336,005	2,710,728		2,710,728	4,084,445		4,084,445
Amortization on beneficial conversion features . . . . .	303,441		303,441	613,208		613,208	933,767		933,767
Amortization on warrant valuation . . . . .	234,489		234,489	472,819		472,819	718,432		718,432
Provision for doubtful accounts . . . . .	—		—	—		—	—		—
Provision for sales returns . . . . .	309,047		309,047	495,784		495,784	641,023		641,023
Writedown of inventories . . . . .	—		—	—		—	—		—
Accrued Stock based compensation . . . . .	627,023		627,023	957,143		957,143	1,319,712		1,319,712
Interest accrued on financing agreements <sup>(1)</sup> net of payments made . . . . .	412,998	(193,189)	606,187	758,886	(387,171)	1,146,057	1,095,073	(593,108)	1,688,181
Changes in assets and liabilities							—		—
(Increase) decrease in:							—		—
Accounts receivable . . . . .	(2,570,397)		(2,570,397)	(1,909,781)		(1,909,781)	(1,633,986)		(1,633,986)
Inventories . . . . .	(351,618)		(351,618)	(79,502)		(79,502)	(137,984)		(137,984)
Prepaid expenses and other current assets . . . . .	243,646		243,646	520,423		520,423	614,318		614,318
Other assets . . . . .	(202,523)		(202,523)	(205,032)		(205,032)	(278,907)		(278,907)
Increase (decrease) in:									
Accounts payable . . . . .	(328,429)		(328,429)	(506,525)		(506,525)	(661,130)		(661,130)
Accrued expenses . . . . .	(1,381,346)		(1,381,346)	(1,687,197)		(1,687,197)	(1,453,558)		(1,453,558)
Deferred revenue . . . . .	(63,280)		(63,280)	(242,795)		(242,795)	(422,297)		(422,297)
Net cash used in operating activities . . . . .	<u>(4,966,920)</u>	<u>—</u>	<u>(4,966,920)</u>	<u>(5,227,192)</u>	<u>—</u>	<u>(5,227,192)</u>	<u>(6,030,804)</u>	<u>—</u>	<u>(6,030,804)</u>
Cash flows from investing activities:									
Purchase of property and equipment . . . . .	—		—	(1,497)		(1,497)	(9,085)		(9,085)
Net cash used in investing activities . . . . .	<u>—</u>		<u>—</u>	<u>(1,497)</u>		<u>(1,497)</u>	<u>(9,085)</u>		<u>(9,085)</u>

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS – (continued)**  
**(Unaudited)**

	Three Months Ended March 31,			Six Months Ended June 30,			Nine Months Ended September 30,		
	Restated 2007	Adjustments	As Reported 2007 <sup>(2)</sup>	Restated 2007	Adjustments	As Reported 2007 <sup>(2)</sup>	Restated 2007	Adjustments	As Reported 2007 <sup>(2)</sup>
Cash flows from financing activities:									
Proceeds from the sale of common stock, net . . .	—		—	—		—	—		—
Proceeds from exercise of options . . . . .	—		—	11,360		11,360	63,241		63,241
Payment for purchase of treasury stock . . . . .				(13,260)		(13,260)	(13,260)		(13,260)
Dividends paid . . . . .	(34,063)		(34,063)	(48,770)		(48,770)	(62,832)		(62,832)
Net cash used in financing activities . . . . .	(34,063)		(34,063)	(50,670)		(50,670)	(12,851)		(12,851)
Effect of exchange rate changes on cash . . . . .	453		453	3,602		3,602	8,921		8,921
Net decrease in cash . . . . .	(5,000,530)		(5,000,530)	(5,275,757)		(5,275,757)	(6,043,819)		(6,043,819)
Cash, beginning of period . .	25,270,377		25,270,377	25,270,377		25,270,377	25,270,377		25,270,377
Cash end of period . . . . .	<u>\$20,269,847</u>		<u>\$20,269,847</u>	<u>\$19,994,621</u>		<u>\$19,994,621</u>	<u>\$19,226,558</u>		<u>\$19,226,558</u>
Non-cash investing activities									
Accrued US Crinone Licensing Right purchase cost increase . . . . .	<u>\$ 1,000,000</u>			<u>\$ 1,000,000</u>		<u>\$ 1,000,000</u>	<u>\$ 1,000,000</u>		<u>\$ 1,000,000</u>
Non-cash financing activities									
Conversion of preferred Series C&E shares . . . .	<u>\$ 13,789</u>			<u>\$ 13,789</u>		<u>\$ 13,789</u>	<u>\$ 15,751</u>		<u>\$ 15,751</u>

- (1) Adjustment to correct the amount of interest expense recorded on financing agreements and to separate related payments between principal and interest.
- (2) As reported amounts reflect a reclassification of payments of interest on financing agreements from financing activities to operating activities.



**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS – (continued)**  
**(Unaudited)**

	Three Months Ended March 31,			Six Months Ended June 30,			Nine Months Ended September 30,		
	Restated 2006	Adjustments	As Reported 2006 <sup>(2)</sup>	Restated 2006	Adjustments	As Reported 2006 <sup>(2)</sup>	Restated 2006	Adjustments	As Reported 2006 <sup>(2)</sup>
Cash flows from operating activities:									
Net loss . . . . .	\$(2,940,189)	(193,867)	\$(2,746,322)	\$(5,183,038)	40,879	\$(5,223,917)	\$ (7,744,448)	36,866	\$ (7,781,314)
Adjustments to reconcile net loss to netcash used in operating activities-									
Depreciation and amortization . . . . .	65,674		65,674	131,018		131,018	192,543		192,543
Amortization on beneficial conversion features . . . . .	—		—	—		—	—		—
Amortization on warrant valuation . . . . .	0		0	—		—	—		—
Provision for doubtful accounts . . . . .	721		721	55,855		55,855	105,855		105,855
Provision for sales returns . . . . .	208,014		208,014	620,868		620,868	712,908		712,908
Writedown of inventories	158,275		158,275	349,722		349,722	455,393		455,393
Stock based compensation . . . . .	101,057		101,057	390,054		390,054	701,086		701,086
Accrued Interest expense on financing agreements net of Payments made <sup>(1)</sup> . . . . .	775,201	193,867	581,334	(4,980,634)	239,121	(5,219,755)	(4,661,339)	243,134	(4,904,473)
Loss on partial extinguishment of financing agreement . . . . .				—	(280,000)	280,000	—	(280,000)	280,000
Loss on disposal of fixed asset . . . . .	2,177		2,177	2,178		2,178	3,275		3,275
Changes in assets and liabilities									
(Increase) decrease in:									
Accounts receivable . . . . .	167,173		167,173	169,559		169,559	(211,839)		(211,839)
Inventories . . . . .	(229,758)		(229,758)	(297,045)		(297,045)	(297,298)		(297,298)
Prepaid expenses and other current assets . . . . .	(313,188)		(313,188)	(98,667)		(98,667)	(483,377)		(483,377)
Other assets . . . . .	(145)		(145)	4,552		4,552	4,566		4,566
Increase (decrease) in:									
Accounts payable . . . . .	1,426,703		1,426,703	(142,215)		(142,215)	(165,469)		(165,469)
Accrued expenses . . . . .	(752,468)		(752,468)	(913,350)		(913,350)	(279,745)		(279,745)
Deferred revenue . . . . .	243,846		243,846	477,593		477,593	300,950		300,950
Net cash used in operating activities . . . . .	<u>(1,086,907)</u>	<u>—</u>	<u>(1,086,907)</u>	<u>(9,413,550)</u>	<u>—</u>	<u>(9,413,550)</u>	<u>(11,366,939)</u>	<u>—</u>	<u>(11,366,939)</u>

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS – (continued)  
(Unaudited)**

	Three Months Ended March 31,			Six Months Ended June 30,			Nine Months Ended September 30,		
	Restated 2006	Adjustments	As Reported 2006 <sup>(2)</sup>	Restated 2006	Adjustments	As Reported 2006 <sup>(2)</sup>	Restated 2006	Adjustments	As Reported 2006 <sup>(2)</sup>
Cash flows from investing activities:									
Purchase of property and equipment . . . . .	(9,500)		(9,500)	(9,500)		(9,500)	(14,210)		(14,210)
Net cash used in investing activities . .	(9,500)		(9,500)	(9,500)		(9,500)	(14,210)		(14,210)
Cash flows from financing activities:									
Proceeds from the sale of common stock, net . . .	28,813,385		28,813,385	28,766,126		28,766,126	28,766,126		28,766,126
Proceeds from exercise of options . . . . .	260,045		260,045	972,511		972,511	1,021,759		1,021,759
Payments for purchase of treasury stock . . . . .				—		—	—		—
Principal Payments pursuant to financing agreements . . . . .				(5,391,268)		(5,391,268)	(5,391,268)		(5,391,268)
Dividends paid . . . . .	(40,625)		(40,625)	(81,250)		(81,250)	(121,379)		(121,379)
Net cash provided by (used in) financing activities . . . . .	29,032,805		29,032,805	24,266,119		24,266,119	24,275,238		24,275,238
Effect of exchange rate changes on cash . . . . .	7,125		7,125	23,754		23,754	21,143		21,143
Net increase (decrease) in cash . . . . .	27,943,523		27,943,523	14,866,823		14,866,823	12,915,232		12,915,232
Cash, beginning of period . .	7,136,854		7,136,854	7,136,854		7,136,854	7,136,854		7,136,854
Cash end of period . . . . .	<u>\$35,080,377</u>		<u>\$35,080,377</u>	<u>\$22,003,677</u>		<u>\$22,003,677</u>	<u>\$20,052,086</u>		<u>\$20,052,086</u>

foots

- (1) Adjustment to correct the amount of interest expense recorded ont financing agreements and to separate related payments between principal and interest.
- (2) As reported amounts reflect a reclassification of payments of interest on financing agreements from financing activities to operating activities.

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**

**INDEX TO FINANCIAL STATEMENT SCHEDULE**

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Schedule II — Valuation and Qualifying Accounts .....	F-48

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders  
of Columbia Laboratories, Inc.

Our audits of the consolidated financial statements and internal control over financial reporting referred to in our report dated March 25, 2008 included elsewhere in this Annual Report on Form 10-K also included the 2007 information in the financial statement schedule of Columbia Laboratories, Inc. listed in Item 15(a) of this Form 10-K. This schedule is the responsibility of Columbia Laboratories, Inc.'s management. Our responsibility is to express an opinion based on our audits of the consolidated financial statements.

In our opinion, the 2007 information in the financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly in all material respects the information set forth therein.

/s/ McGladrey & Pullen, LLP  
McGLADREY & PULLEN, LLP

New York, NY  
March 25, 2008

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders  
of Columbia Laboratories, Inc.:

We have audited in accordance with the standards of the Public Company Accounting Oversight Board (United States), the financial statements of Columbia Laboratories, Inc. and Subsidiaries for each of the three years in the period ended December 31, 2006 included in this Form 10-K and have issued our report thereon dated March 15, 2007. Our audits were made for the purpose of forming an opinion on the basic financial statements taken as a whole. Schedule II is the responsibility of the Company's management and is presented for purposes of complying with the Securities and Exchange Commission's rules and is not part of the basic financial statements. This schedule has been subjected to the auditing procedures applied in the audits of the basic financial statements and, in our opinion, fairly states in all material respects the financial data required to be set forth therein in relation to the basic financial statements taken as a whole.

/s/ Goldstein Golub Kessler LLP  
GOLDSTEIN GOLUB KESSLER LLP

New York, New York  
March 15, 2007

**COLUMBIA LABORATORIES, INC. AND SUBSIDIARIES**  
**SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS**  
**For the Four Years Ended December 31, 2007**

Description	Balance at Beginning of Year	Charged to (Credited to) Costs and Expenses	Deductions <sup>(A)</sup>	Balance at End of Year
YEAR ENDED DECEMBER 31, 2007:				
Allowance for doubtful accounts . . . . .	<u>\$100,000</u>	<u>\$ 15,000</u>	<u>\$ 19,267</u>	<u>\$ 95,733</u>
YEAR ENDED DECEMBER 31, 2006:				
Allowance for doubtful accounts . . . . .	<u>\$ 50,000</u>	<u>\$105,855</u>	<u>\$ 55,855</u>	<u>\$100,000</u>
YEAR ENDED DECEMBER 31, 2005:				
Allowance for doubtful accounts . . . . .	<u>\$ 86,114</u>	<u>\$187,962</u>	<u>\$224,076</u>	<u>\$ 50,000</u>
YEAR ENDED DECEMBER 31, 2004:				
Allowance for doubtful accounts . . . . .	<u>\$120,000</u>	<u>\$ 48,917</u>	<u>\$ 82,803</u>	<u>\$ 86,114</u>

(A) Deductions represent the write-off of uncollectible accounts



## EXHIBIT INDEX

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of the Company, as amended <sup>(14)</sup>
3.2	Amended and Restated By-laws of Company <sup>(3)</sup>
4.1	Certificate of Designations, Preferences and Rights of Series C Convertible Preferred Stock of the Company, dated as of January 7, 1999 <sup>(3)</sup>
4.2	Securities Purchase Agreement, dated as of January 7, 1999, between the Company and each of the purchasers named on the signature pages thereto <sup>(3)</sup>
4.3	Securities Purchase Agreement, dated as of January 19, 1999, among the Company, David M. Knott and Knott Partners, L.P. <sup>(3)</sup>
4.4	Form of Warrant to Purchase Common Stock <sup>(3)</sup>
4.5	Warrant to Purchase Common Stock granted to James J. Apostolakis on September 23, 1999
4.6	Certificate of Designations of Series E Convertible Preferred Stock, filed May 10, 2005 with the Delaware Secretary of State <sup>(13)</sup>
4.7	Preferred Stock Purchase Agreement, dated as of May 10, 2005, among Columbia Laboratories, Inc., Perry Partners L.P. and Perry Partners International, Inc. <sup>(13)</sup>
4.8	Securities Purchase Agreement, dated March 10, 2006, by and between Columbia Laboratories, Inc. and the Purchasers listed on Exhibit A thereto <sup>(15)</sup>
4.9	Form of Restricted Stock Agreement <sup>(18)</sup>
4.10	Form of Option Agreement <sup>(18)</sup>
4.11	Securities Purchase Agreement, dated December 21, 2006, by and between Columbia Laboratories, Inc. and the Purchasers listed on Exhibit A thereto <sup>(21)</sup>
10.1	1996 Long-term Performance Plan, as amended, of the Company <sup>(2)</sup>
10.2	Asset Purchase, License and Option Agreement between Bio-Mimetics, Inc. and Columbia Laboratories, Inc., dated November 22, 1989 <sup>(1)</sup>
10.3	License and Supply Agreement by and between the Company and Mipharm S.p.A. dated March 5, 1999 <sup>(4)</sup>
10.4	Settlement Agreement and Release dated as of March 16, 2000 between Columbia Laboratories (Bermuda) Ltd. and Lake Consumer Products, Inc. <sup>(5)</sup>
10.5	License Agreement dated April 18, 2000, between the Company and Lil' Drug Store Products, Inc. <sup>(6)</sup>
10.6	Rights Agreement dated as of March 13, 2002, by and between Columbia Laboratories, Inc. and First Union National Bank, as Rights Agent <sup>(7)</sup>
10.7†	Semi-Exclusive Supply Agreement dated May 7, 2002 between the Company and Mipharm S.p.A. <sup>(8)</sup>
10.8†	Amended and Restated License and Supply Agreement dated June 4, 2002 between the Company and Ares Trading S.A. <sup>(8)</sup>
10.9†	Marketing License Agreement dated June 4, 2002 between the Company and Ares Trading S.A. and Serono, Inc. <sup>(8)</sup>
10.10†	Investment and Royalty Agreement dated July 31, 2002 between the Company and PharmaBio Development Inc. <sup>(8)</sup>
10.11†	License and Supply Agreement dated October 16, 2002 between the Company and Ardana Bioscience Limited <sup>(9)</sup>

Exhibit No.	Description
10.12†	Development and License Agreement dated December 26, 2002 between the Company and Ardana Bioscience Limited <sup>(9)</sup>
10.13†	Investment and Royalty Agreement dated March 5, 2003 between the Company and PharmaBio Development Inc. <sup>(9)</sup>
10.14†	License and Supply Agreement Dated May 27, 2003 between the Company and Mipharm S.p.A. <sup>(10)</sup>
10.15	Form of Indemnification Agreement for Officers and Directors <sup>(11)</sup>
10.16	Form of Executive Change of Control Severance Agreement <sup>(11)</sup>
10.17†	Asset Purchase Agreement Dated June 29, 2004, between the Company and Lil' Drug Store Products, Inc. <sup>(12)</sup>
10.18†	Supply Agreement dated June 29, 2004, between the Company and Lil' Drug Store Products, Inc. <sup>(12)</sup>
10.19†	Professional Promotion Agreement dated June 29, 2004, between the Company and Lil' Drug Store Products, Inc. <sup>(12)</sup>
10.20	Employment Agreement by and between Columbia Laboratories, Inc. and Robert S. Mills dated March 30, 2006 <sup>(16)</sup>
10.21	Employment Agreement by and between Columbia Laboratories, Inc. and Michael McGrane dated March 30, 2006 <sup>(16)</sup>
10.22	Letter Agreement Supplement to STRIANT® Investment and Royalty Agreement dated April 14, 2006 <sup>(17)</sup>
10.23	Employment Agreement by and between Columbia Laboratories, Inc. and James Meer dated December 6, 2006 <sup>(19)</sup>
10.24	Separation Agreement by and between Columbia Laboratories, Inc. and David L. Weinberg effective as of December 12, 2006 <sup>(20)</sup>
10.25†	Agreement, dated December 21, 2006, by and among Ares Trading S.A., Serono, Inc., the Company and its wholly-owned subsidiary, Columbia Laboratories (Bermuda), Ltd <sup>(21)</sup>
10.26	Amendment No. 1 to the Amended and Restated License and Supply Agreement, entered into December 21, 2006, by and between Ares Trading S.A and Columbia Laboratories (Bermuda), Ltd. <sup>(21)</sup>
10.27	Description of the Registrant's Compensation and Reimbursement Practices for Non-employee Directors. <sup>(22)</sup>
10.28	Columbia Laboratories, Inc., Incentive Plan <sup>(22)</sup>
10.29	Lease Agreement between Allwood Associates I and Columbia Laboratories, Inc., dated July 6, 2007 <sup>(22)</sup>
10.30†	License and Supply Agreement between Columbia Laboratories, Inc. and Ascend Therapeutics, Inc., dated September 27, 2007 <sup>(23)</sup>
10.31	Supply Agreement between Columbia Laboratories (Bermuda) Limited and Fleet Laboratories Limited, dated July 12, 1996 <sup>(24)</sup>
10.32	Packaging Agreement between Columbia Laboratories (Ireland) Ltd. and Maropack AG, dated October 28, 1993 <sup>(24)</sup>
14	Code of Ethics of the Company <sup>(11)</sup>
21	Subsidiaries of the Company <sup>(24)</sup>
23.1	Consent of Goldstein Golub Kessler LLP <sup>(24)</sup>
23.2	Consent of McGladrey & Pullen, LLP <sup>(24)</sup>

Exhibit No.	Description
31(i).1	Certification of Chief Executive Officer of the Company <sup>(24)</sup>
31(i).2	Certification of Chief Financial Officer of the Company <sup>(24)</sup>
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 <sup>(24)</sup>
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. <sup>(24)</sup>

† Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

- (1) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 33-31962) declared effective on May 14, 1990
- (2) Incorporated by reference to the Registrant's Proxy Statement dated May 10, 2000
- (3) Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998
- (4) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1999
- (5) Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999
- (6) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000
- (7) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated March 12, 2002
- (8) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q dated August 14, 2002
- (9) Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002
- (10) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q dated August 14, 2003
- (11) Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003
- (12) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q dated August 4, 2004
- (13) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated May 12, 2005
- (14) Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005
- (15) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated March 16, 2006
- (16) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated April 3, 2006
- (17) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated April 17, 2006
- (18) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated May 17, 2006
- (19) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated December 7, 2006
- (20) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated December 15, 2006
- (21) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated December 26, 2006
- (22) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, dated August 8, 2007
- (23) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, dated November 8, 2007
- (24) Filed herewith

## **SUBSIDIARIES OF THE COMPANY**

Columbia Laboratories (Bermuda) Ltd.

Columbia Laboratories (France) SA

Columbia Laboratories (UK) Limited

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in Registration Statements on Form S-3 (No. 333-125671, 333-75275, 333-38230, 333-132803 and 333-140107 ) and Form S-8 (333-116072) of Columbia Laboratories, Inc. of our report dated March 15, 2007 relating to our audits of the consolidated financial statements, which includes an explanatory paragraph stating that we did not audit the adjustments relating to the correction of errors, and our report dated March 15, 2007 relating to our audits of the financial statement schedule, which appear in this Annual Report on Form 10-K of Columbia Laboratories, Inc. for the year ended December 31, 2007.

/s/ GOLDSTEIN GOLUB KESSLER LLP  
GOLDSTEIN GOLUB KESSLER LLP

New York, New York  
March 25, 2008

**INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statements (No. 333-125671, 333-75275, 333-38230, 333-132803 and 333-140107 ) on Form S-3 and Form S-8 (333-116072) of Columbia Laboratories, Inc. of our reports dated March 25, 2008 relating to our audits of the consolidated financial statements, the financial statement schedule, the restatement adjustments to the consolidated financial statements for the years ended December 31, 2006, 2005 and 2004, and the internal control over financial reporting for the year ended December 31, 2007 which appear in this Annual Report on Form 10-K of Columbia Laboratories, Inc. for the year ended December 31, 2007. Our report dated March 25, 2008 included an explanatory paragraph that effective January 1, 2007, Columbia Laboratories, Inc. adopted Financial Accounting Standards Board Interpretation No. 48, "Accounting for Uncertainty in Income Taxes — an Interpretation of FASB Statement No. 109".

Our report dated March 25, 2008 on the effectiveness of internal control over financial reporting as of December 31, 2007, expressed an opinion that Columbia Laboratories, Inc. had not maintained effective internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ McGLADREY & PULLEN, LLP  
McGLADREY & PULLEN, LLP

New York, New York  
March 25, 2008



**CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Robert S. Mills, Chief Executive Officer of the Company, certify that:

1. I have reviewed this report on Form 10-K of Columbia Laboratories, Inc.;
2. Based on my knowledge, this annual 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 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 13(a)-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 annual 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
5. The registrant's other certifying officer 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 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: March 25, 2008

/s/ Robert S. Mills

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Robert S. Mills  
Chief Executive Officer

**CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, James A. Meer, Chief Financial Officer of the Company, certify that:

1. I have reviewed this report on Form 10-K of Columbia Laboratories, Inc.;
2. Based on my knowledge, this annual 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 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 13(a)-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 annual 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
5. The registrant's other certifying officer 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 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: March 25, 2008

/s/ James A. Meer

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James A. Meer  
Chief Financial 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 Annual Report of Columbia Laboratories, Inc. (the "Company") on Form 10-K for the period ended December 31, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert S. Mills, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 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.

March 25, 2008

/s/ Robert S. Mills

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Robert S. Mills  
Chief Executive 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 Annual Report of Columbia Laboratories, Inc. (the “Company”) on Form 10-K for the period ended December 31, 2007 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, James A. Meer, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 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.

March 25, 2008

/s/ James A. Meer

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James A. Meer  
Chief Financial Officer









### Management Team

from left to right

#### Michael McGrane

Senior Vice President, General Counsel and Secretary

#### George W. Creasy

Vice President, Clinical Research and Development

#### Robert S. Mills

President and Chief Executive Officer

#### Carl Worrell

Head of Sales and Marketing

#### James A. Meer

Senior Vice President,  
Chief Financial Officer and Treasurer

### Board of Directors

#### Stephen G. Kasnet

Chairman of the Board

#### Edward A. Blechschmidt

Vice Chairman of the Board

#### Valerie L. Andrews

Vice President, Deputy General Counsel and  
Chief Compliance Officer, Vertex Pharmaceuticals, Inc.

#### James S. Crofton

Senior Vice President and Chief Financial Officer,  
Sarnoff Corporation

#### Robert S. Mills

President and Chief Executive Officer,  
Columbia Laboratories, Inc.

#### Denis M. O'Donnell, M.D.

Managing Director, Seaside Advisors LLC

#### Selwyn P. Oskowitz, M.D.

Director, Boston IVF  
Assistant Professor, Harvard Medical School

### Corporate Officers

#### Robert S. Mills

President and Chief Executive Officer

#### Michael McGrane

Senior Vice President, General Counsel and Secretary

#### James A. Meer

Senior Vice President, Chief Financial Officer  
and Treasurer

### Corporate Headquarters

#### Columbia Laboratories, Inc.

354 Eisenhower Parkway  
Plaza I, Second Floor  
Livingston, NJ 07039  
(973) 994-3999 Phone  
(973) 994-3001 Fax  
www.columbialabs.com  
www.cbrxir.com  
www.crinoneusa.com

### Independent Auditors

McGladrey & Pullen, LLP  
New York, NY 10036

### Registrar and Transfer Agent

American Stock Transfer &  
Trust Company  
6201 15th Street  
Brooklyn, NY 11219  
(718) 921-8124 Phone  
(800) 937-5449 Toll-free  
www.amstock.com  
investors@amstock.com

### Annual Meeting

The Annual Meeting of Shareholders will be held on Tuesday, May 13, 2008, at 10:00 a.m. at the Hilton New York, 1335 Avenue of the Americas, New York, New York 10019. The record date for the meeting will be March 31, 2008.

### Stockholder Inquiries

Questions regarding stock transfer requirements, lost certificates, and changes of address should be directed to the transfer agent listed herein. Other stockholder or investor inquiries, including requests for our filings with the U.S. Securities and Exchange Commission, investor packets, or other information, should be directed to James A. Meer, Chief Financial Officer, at the Company's headquarters.

### Securities and Related Information

The Company's Common Stock is traded on the NASDAQ Global Market under the symbol CBRX. It began trading there on February 13, 2004, prior to which it traded on the American Stock Exchange under the symbol COB. As of March 31, 2008, there were approximately 300 holders of record of the Company's common stock and approximately 7,000 beneficial owners.

### Dividend Policy

The Company has never declared or paid a cash dividend on its common stock, and expects that its earnings will continue to be retained for use in the operation and expansion of its business.

### Safe Harbor Statement

This annual report contains forward-looking statements about Columbia Laboratories, Inc.'s expectations regarding the Company's strategic direction, prospects and future results, which statements are indicated by the words "will," "plan," "expect," "believe" and similar expressions. Such forward-looking statements are subject to certain risks and uncertainties; actual results may differ materially from those projected in the forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of March 31, 2008. Factors that might cause future results to differ include, but are not limited to, the following: the successful marketing of CRINONE® 8% (progesterone gel), PROCHIEVE® 8% (progesterone gel) and STRIANT® (testosterone buccal tablet) in the U.S.; the timely and successful completion of clinical studies, including the PREGNANT (PROCHIEVE® Extending Gestation A New Therapy) Study of PROCHIEVE 8% to reduce the risk of preterm birth in women with a short cervix at mid-pregnancy and clinical studies for our vaginally-administered lidocaine product; the impact of competitive products and pricing; competitive economic and regulatory factors in the pharmaceutical and healthcare industry; general economic conditions; and other risks and uncertainties that may be detailed, from time-to-time, in Columbia's reports filed with the Securities and Exchange Commission. Columbia Laboratories undertakes no obligation to publicly update any forward-looking statements.

**Columbia Laboratories, Inc.**

354 Eisenhower Parkway

Plaza 1, Second Floor

Livingston, NJ 07039

(973) 994-3999 *Tel*

(973) 994-3001 *Fax*

[www.columbialabs.com](http://www.columbialabs.com) *Corporate Website*

[www.cbrxir.com](http://www.cbrxir.com) *Investor Website*

[www.crinoneusa.com](http://www.crinoneusa.com) *CRINONE 8% U.S. Website*

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