

Columbia Laboratories, Inc.

(Nasdaq: CBRX)

2013 Annual Report



March 30, 2014

To my fellow shareholders:

2013 was a transformational year for Columbia Labs. We transitioned to a lower-cost operating model and relocated our corporate office to Boston; secured the long-term supply of CRINONE® progesterone vaginal gel for our most important customer, Merck Serono; and, in September, acquired Molecular Profiles Limited, a U.K. based company providing pharmaceutical development, clinical trial manufacturing, and advanced analytical and consulting services to the pharmaceutical industry.

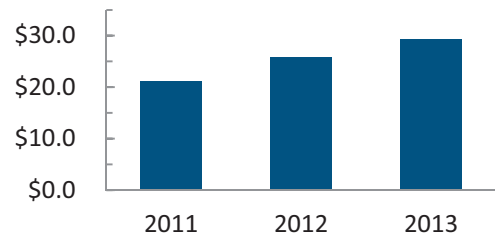
Our strong results for fiscal 2013 show the positive impact of Merck Serono’s increased product shipments during the first three quarters of the year and the Molecular Profiles acquisition.

- Total net revenues grew 13% to \$29.2 million;
- Product revenues from Merck Serono were up 19%
- Gross profit increased 23% to \$16 million; and,
- Gross margin improved from 50% to 55%.

As a result, Columbia’s income from operations increased 109% to \$5.9 million for fiscal 2013.

Furthermore the Company generated \$7.1 million in cash flow from operations, a record high, and closed the year with over \$20 million in cash and equivalents.

CORE REVENUE GROWTH
(in millions)

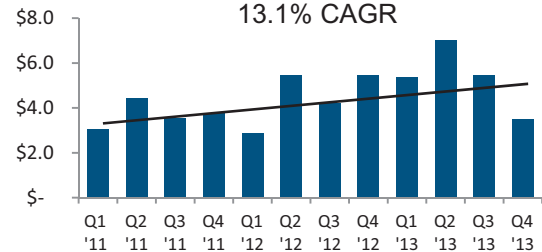


Long-term Growth for CRINONE Worldwide

In 2013, we extended our exclusive supply agreement with Merck Serono through 2020. Merck Serono markets CRINONE in over 60 countries outside the U.S.

During the first three quarters last year, Merck Serono built up its inventory of CRINONE for one of its higher-volume, higher-margin markets in anticipation of a routine license renewal. The renewal period began in the fourth quarter of 2013, and will likely continue through the first half of 2014. Merck Serono is not expected to ship CRINONE into this market during this time. As a result, we expect lower product revenues through the first half of 2014.

EX-U.S. CRINONE REVENUE
13.1% CAGR



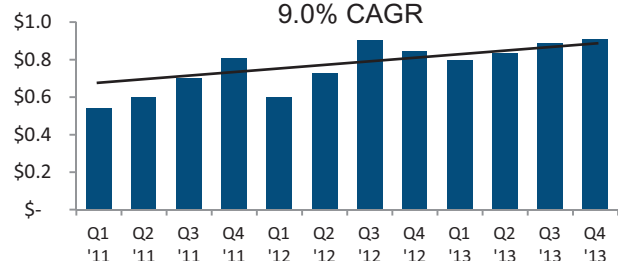
Underlying in-market sales of CRINONE ex-US should continue to increase throughout 2014 and beyond. We expect Merck Serono will continue to build the franchise throughout the life of our extended supply agreement through a combination of entries into new major markets and further organic growth; the latter should benefit from the significant growth potential for fertility products in China, where the government is easing its one-child policy, as well as other emerging markets. We believe our long-term revenue stream from Merck Serono is solid.

CRINONE Royalties from Actavis

In the U.S., CRINONE is manufactured and marketed by Actavis Inc. We receive a 10% royalty on U.S. net sales of CRINONE.

In early 2014, Actavis launched a next-generation CRINONE product, signifying its commitment to the brand. We expect future volume and price gains will drive continued growth in royalty revenue from Actavis.

U.S. ROYALTY REVENUE GROWTH
9.0% CAGR



Welcoming Our New Addition: Molecular Profiles

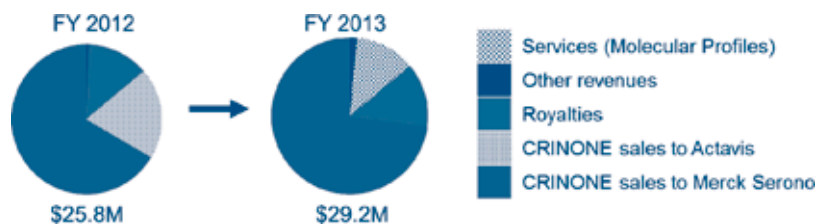
Last September, Columbia acquired Molecular Profiles (MP) for \$25 million in cash and stock, our first strategic acquisition to date. This immediately accretive transaction met all of our key criteria: MP has a strong, diverse revenue stream; is cash flow positive; has synergies with Columbia's business; and, broad capabilities that address a significant growth opportunity in a growing market.

Through MP, Columbia provides pharmaceutical development services, manufacturing for clinical trials and advanced analytical and consulting services to the pharmaceutical industry.

The outsourced pharmaceutical development services market that MP competes in is currently valued at \$21.5 billion. MP's capabilities span oral, topical, and inhaled dosage forms, with a wide range of enabling technologies. They have specific expertise in formulating challenging molecules. MP continues to broaden their service offering to meet client needs, and their new state-of-the-art facility can accommodate growth.

MP's world-class range of pharmaceutical development services are underpinned by its internationally acclaimed scientific knowledge and expertise, differentiating them from the competition. Together, we are implementing fresh initiatives to attract new customers and leverage existing relationships to further capitalize on the growth of the outsourcing market.

As an added benefit, the MP acquisition de-risked our business by reducing our reliance on CRINONE. Columbia today has a far more diverse revenue stream, particularly given that many different clients comprise Services revenues.



R&D Opportunity

Columbia has a strong heritage in pharmaceutical development, particularly in women's healthcare and drug delivery. In 2013, we gained world-class capabilities in materials characterization, analytics, formulation development, and manufacturing. We also have intellectual property that could be applied to the development of new proprietary products.

Our new in-house capabilities provide Columbia the potential, for a relatively low level of investment, to add value to known chemical entities to create new, commercially viable therapeutics in areas of unmet medical need. If we decide to pursue such opportunities, our ultimate goal would be to deliver a healthy ROI upon partnering or out-licensing any candidate for later-stage development & commercialization.

Confidence in Our Business

In March 2014, we repurchased Actavis' 1.4 million share position at a 10.75% discount to market. This accretive transaction testifies to our solid financial position and our belief in Columbia's strong growth prospects. Even after this \$8.5 million buy-back, the Company has a solid balance sheet and our operations continue to generate positive cash flow.

Columbia today has a strong footing in the fast-growing outsourced pharmaceutical development market, streamlined U.S. operating expenses, and a diversified revenue stream led by sales of CRINONE to Merck Serono. Growth catalysts in all areas of the business should enable Columbia to build on the successes of 2013.

In addition to our many talented employees, I want to thank our customers, partners, and especially our loyal shareholders for their ongoing support as we work to deliver long-term revenue growth and build lasting value.

Sincerely,

Stephen G. Kasnet
Chairman of the Board
Columbia Laboratories, Inc.

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

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, 2013

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.)

4 Liberty Square
Boston, Massachusetts
(Address of principal executive offices)

02109
(Zip Code)

Registrant's telephone number, including area code:
(617) 639-1500

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

Common Stock, \$.01 par value
(Title of each class)

NASDAQ Global Market
(Name of exchange on which registered)

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

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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, 2013, the last business day of the registrant's most recently completed second fiscal quarter, based on the adjusted closing price on that date of \$5.17, was \$48,856,955.

Number of shares of Common Stock of Columbia Laboratories, Inc. issued and outstanding as of February 27, 2014 is 12,155,461.

Documents Incorporated By Reference

Portions of the Columbia Laboratories, Inc. ("Columbia" or the "Company") Proxy Statement for the 2014 Annual Meeting of Shareholders (the "Proxy Statement") are incorporated by reference into Part III of this Form 10-K.

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Fiscal Year Ended December 31, 2013**

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Forward-Looking Information

This Annual Report on Form 10-K contains forward-looking statements, that involve risk and uncertainties. The words “may,” “will,” “plan,” “believe,” “expect,” “intend,” “anticipate,” “potential,” “should,” “estimate,” “predict,” “project,” “would,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to differ materially from those projected in the forward-looking statements.

These forward-looking statements include, among other things, statements about:

- Successful marketing of CRINONE[®] by Actavis, Inc. and Merck Serono S.A. in their respective markets;
- The anticipated timing of future batch orders of CRINONE from our customers;
- Our ability to manufacture our product with minimal difficulties and delays;
- Our dependence on single source third-party manufacturers and suppliers;
- Our ability to successfully integrate and strengthen the Molecular Profiles Limited business and brand;
- Our ability to retain current and attract new customers;
- Our compliance with Federal Drug Administration (“FDA”), Medicines and Healthcare Products Regulatory Agency (“MHRA”) and other governmental regulations applicable to manufacturing facilities, products, and/or business;
- Our intellectual property portfolio;
- Our strategy of growing through acquisitions;
- Our ability to develop a portfolio of new therapeutic entities; and
- Our estimates regarding expenses, future revenues, and capital requirements.

Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside our control. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you are cautioned not to place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K for the year ended December 31, 2013, particularly in Part 1 – Item 1A and in our other public filings with the Securities and Exchange Commission that could cause actual results or events to differ materially from the forward-looking statements that we make.

You should read this Annual Report and the documents that we have filed as exhibits to the Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. While we may elect to update forward-looking statements at some point in the future, we do not undertake any obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future events or otherwise.

PART I

Item 1. Business

Overview

Columbia Laboratories, Inc., and its subsidiaries (herein referred to as “Columbia”, the “Company”, “we”, “us” or “our”) have historically been in the business of developing, licensing, manufacturing and selling to our marketing partners pharmaceutical products that utilize proprietary drug delivery technologies to treat various medical conditions. Presently, our focus is on the supply of CRINONE to our marketing partner and providing pharmaceutical development, clinical trial manufacturing, and advanced analytical and consulting services to the pharmaceutical industry through our newly acquired wholly-owned subsidiary, Molecular Profiles Limited (“Molecular Profiles”).

We have a history of developing and bringing to market products: five bioadhesive vaginal gel products that provide patient-friendly solutions for infertility, pregnancy support, amenorrhea, and other women’s health conditions, and a bioadhesive buccal system for male hypogonadism. We have partnered or sold each of these products for commercialization in various regions of the world.

All of the products we have developed 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; 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.

On September 12, 2013, we acquired all of the outstanding capital stock of Molecular Profiles, a U.K.-based pharmaceutical development services company. We subsequently integrated all of our operating activities specifically for the CRINONE supply chain into Molecular Profiles. The main service lines that have been added to our portfolio as a result of the acquisition include:

- Pharmaceutical Development Services – Preformulation and Chemistry Manufacturing and Controls (“CMC”), solid state form optimization and formulation development.
- Clinical Trial Manufacturing Services – Manufacturing of tablets, capsules, topicals, dry powder inhaled products (“DPI’s”) and liquids.
- Advanced Analytical and Consulting Services – Detailed analytical characterization to support pharmaceutical development, trouble-shooting process issues, materials characterization, and testing and consultancy relating to intellectual property.

We have retained Molecular Profiles’ brand name because of its recognition and valuable reputation.

Product and Service Portfolio

Columbia’s revenues are comprised of:

- Product revenues, which primarily consist of sales of CRINONE to Merck Serono S.A. (“Merck Serono”);
- Royalty revenues, which primarily consist of royalty revenues from Actavis, Inc. (“Actavis”) (formerly Watson Pharmaceuticals, Inc.) on sales of CRINONE;
- Service revenues, which primarily consists of pharmaceutical development, clinical trial manufacturing, and advanced analytical and consulting services provided to the pharmaceutical industry; and
- Other revenues

CRINONE

Progesterone is a hormone manufactured by a woman's ovaries in the second half of the menstrual cycle and by the placenta during pregnancy. 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.

CRINONE our primary product, is a sustained release gel that delivers natural progesterone vaginally. CRINONE 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™." It is the first product designed and FDA-approved to deliver progesterone directly to the uterus, thereby providing a therapeutic benefit and avoiding high blood levels of metabolites that are generally seen with orally-delivered synthetic progestins.

CRINONE 8% (progesterone gel) was approved in the U.S. in 1997 for progesterone supplementation or replacement as part of an Assisted Reproductive Technology ("ART") treatment for infertile women with progesterone deficiency. CRINONE is also approved in the U.S. for the treatment of secondary amenorrhea (loss of menstrual period).

Outside the U.S., CRINONE has been approved for marketing for one or more medical indications in over 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 postmenopausal women receiving hormone replacement therapy ("HRT"); the reduction of symptoms of premenstrual syndrome ("PMS"); menstrual irregularities; dysmenorrhea; and dysfunctional uterine bleeding.

The most common side effects of CRINONE 8% are breast enlargement, constipation, somnolence, nausea, headache, and perineal pain. CRINONE 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.

CRINONE is sold outside the U.S. by Merck Serono under a worldwide (excluding the U.S.) license from the Company.

Within the U.S., CRINONE is marketed by Actavis pursuant to a Purchase and Collaboration Agreement dated March 2010. Pursuant to the terms of this agreement Actavis purchased certain of our assets and we agreed to collaborate with Actavis with respect to the development of certain progesterone gel products. In July 2010, and in connection with this agreement, we entered into a License Agreement with Actavis, which provided them exclusive rights to develop, manufacture and offer to sell and commercialize these progesterone gel products in the U.S. We also entered into a Supply Agreement with Actavis, dated July 2010, which made us the exclusive supplier to Actavis for CRINONE.

In April 2011, we filed a New Drug Application ("NDA 22-139") to expand the labeled uses of progesterone vaginal gel 8% to include its use in the reduction of risk of preterm birth in women with a singleton gestation and a short uterine cervical length in the mid-trimester of pregnancy. NDA 22-139 was reviewed by the FDA's Advisory Committee for Reproductive Health Drugs in January 2012. While Committee members generally agreed that progesterone vaginal gel 8% is safe, the Committee stated that more information is needed to support approval. On February 10, 2012, we transferred NDA 22-139 to Actavis pursuant to the second closing of our sale of assets to Actavis under the Purchase and Collaboration Agreement. On February 24, 2012, Actavis received a Complete Response Letter ("CRL") from the FDA indicating that the review cycle for NDA 22-139 was complete but the application was not ready for approval in its present form. The CRL stated that the effect of treatment with progesterone vaginal gel 8% in reducing the risk of preterm birth in women with a short uterine cervical length at $\leq 32 \frac{6}{7}$ weeks gestation ($p=0.022$) did not meet the level of statistical significance generally expected to support the approval of the product in the U.S. market from a single trial. In the CRL, the FDA stated

that additional clinical work would be required to support the approval. Actavis held an “End-of-Review” meeting with the FDA to discuss the issues outlined in the CRL. Actavis continued discussions with the FDA to determine a viable pathway forward and in August 2012 filed a Formal Dispute Resolution Request (“FDRR”) related to this application. The FDA denied Actavis’s FDRR in October 2012. We have discontinued further development of this program.

In November 2013, Columbia and Actavis terminated the Supply Agreement. The Purchase and Collaboration Agreement remains in effect through July 2, 2020.

STRIANT

STRIANT® buccal system is used to treat men with low testosterone levels. STRIANT utilizes the Company’s proprietary BDS technology and is designed to adhere to the gum or inner cheek. It provides a sustained release of testosterone through the buccal mucosa as the buccal system slowly hydrates. In November 2009, the Company and The Urology Company, Ltd (“TUC”) entered into a license and supply agreement under which TUC licensed and sold STRIANT in the United Kingdom. In March 2011 the license and supply agreement was extended to cover the rest of Europe. In April 2011, we entered into a license agreement for STRIANT with Auxilium Pharmaceuticals, Inc (“Auxilium”, formerly Actient, Inc.) for distribution of STRIANT within the U.S. In July 2011 we entered into a license agreement with Invaron Pharmaceuticals Inc. (“Invaron”) for STRIANT in Canada. Under the terms of these agreements, TUC and Invaron will seek regulatory approvals for, and will market STRIANT in their territories and the Company will receive a royalty on annual net sales of STRIANT. On February 25, 2013, TUC entered into administration, which is equivalent to a bankruptcy filing. The Company does not expect any further revenues from TUC. Revenues are not expected to be material from Auxilium or Invaron.

Advanced Formula Legatrin PM

In May 2000, we licensed Advanced Formula Legatrin PM®, a product designed for the relief of occasional pain and sleeplessness associated with minor muscle aches, to Lil’ Drug Store, which 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® has been renewed until May 2015.

Pharmaceutical Development Services

Our business is focused on the development of “challenging” compounds. We have adopted a science-based strategy to our customer’s development requirements by considering the physiochemical properties of the drug substance, the end use need, and the destination of delivery. The Company offers approaches such as particle size reduction (down to nano-scale), solid solutions/dispersions, self emulsifying systems (e.g. SEDDS or SMEDDS) or spray dried drug-polymer matrices, which allows the Company to develop a diverse range of dosage forms.

Clinical Trial Manufacturing Services

We hold a U.K. manufacturer’s authorization for an investigational medicinal products license (“IMP”) for the manufacture, testing and certification of products for use in human clinical trials and have equipment suitable for provision of IMP’s for Phase I and Phase II studies. The Company’s clinical trial manufacturing services are supported by its analytical and advanced materials characterization services.

Advanced Analytical and Consulting Services

We believe we have an established reputation for resolving some of the toughest issues in pharmaceutical and pharmaceutical drug substance and formulation optimization using our innovative problem-to-solution approaches. The Company, backed by a wide range of physical, chemical and surface analytical equipment, provides rapid integrated solutions during development, scale-up, manufacture and life-cycle management.

Collaboration Agreements

Our primary product is CRINONE (progesterone gel) which is formulated in a 4% and an 8% bio-adhesive vaginal gel. We have licensed CRINONE to Merck Serono, outside the U.S., and have sold the rights to CRINONE to Actavis, in the United States.

Merck Serono S.A.

We sell CRINONE 8% to Merck Serono at a price determined on a country-by-country basis that is the greater of (i) thirty percent (30%) of the net selling price in the country, or (ii) our direct manufacturing cost plus 20%. Certain quantity discounts apply to annual purchases over 10 million, 20 million, and 30 million units.

On April 4, 2013, our license and supply agreement with Merck Serono for the sale of CRINONE 8% outside the U.S. was renewed for an additional five year term, extending the expiration date from May 19, 2015 to May 19, 2020.

Under the terms of the amended license and supply agreement, we will continue to sell CRINONE to Merck Serono on a country-by-country basis at the greater of (i) cost plus 20% or (ii) a percentage of Merck Serono's net selling price. From 2014 through 2020, the percentage of net selling price will be determined based on a tiered structure, which is based on volume sold. As sales volumes increase our percentage of incremental sales will decrease. These thresholds have been agreed to in order to incentivize Merck Serono to continue to develop existing markets and to enter new markets. Additionally, the parties will cooperate to evaluate and implement manufacturing cost reduction measures, with both parties sharing any reductions realized from these initiatives. If, at the end of the supply term, the parties cannot agree upon mutually acceptable terms for renewal of the supply arrangement, Merck Serono will have an irrevocable fully paid up license to the product.

Merck Serono holds marketing authorizations for CRINONE in over 60 countries outside the United States. With respect to those countries in which sales of CRINONE are material, we hold patents that expire in September 2014 on the delivery system for the product in Australia, Canada, Germany, Hungary, Italy and Russia, but we do not hold patents in Brazil, China, South Korea, Taiwan, Turkey and Vietnam. The Company is the exclusive supplier of CRINONE to Merck Serono. The amended license and supply agreement provides for a forecasting and ordering procedure pursuant to which Merck Serono must provide the Company with a rolling 18-month forecast of its requirements for each country in which the product is marketed. The first four months of each forecast are firm orders. Under the agreement, each party is responsible for new clinical trials and government registrations in its territory and the parties are obligated to consult from time to time regarding the studies. Each party agrees to promptly provide the other party the data from its studies free-of-charge. During the term of the agreement, the Company has agreed not to develop, license, manufacture or sell to another party outside the United States any product for the vaginal delivery of progesterone or progestational agents for hormone replacement therapy or other indications where progesterone or progestational agents are commonly used.

Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.)

From July 2010 to November 2013 we manufactured and sold products to Actavis at our cost plus 10%; the revenues generated from these sales were recorded within product revenues from a related party. Due to a build-up of inventory by Actavis in advance of filing for FDA approval of 8% progesterone gel for use in the prevention of preterm birth in women with premature cervical shortening, and Actavis' decision, in light of the FDA's denial of both our application and Actavis' subsequent appeal, not to continue development of the proposed indication, Actavis had sufficient inventories of CRINONE; therefore there were no orders in 2013. In November 2013, we entered into an early termination of our exclusive supply agreement with Actavis. The early termination of the agreement, which would have otherwise terminated in May 2015, provided for us to receive a one-time payment as a termination fee as well as payment for all raw materials purchased by us to meet forecast requirements. Pursuant to the Purchase and Collaboration Agreement, we will continue to be eligible to receive

royalties until July 2, 2020 equal to a minimum of 10% of annual net sales of CRINONE by Actavis for annual net sales up to \$150 million, 15% for sales above \$150 million but less than \$250 million; and 20% for annual net sales of \$250 million and over.

Lil' Drug Store Products, Inc.

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 2015, and will then automatically renew for a further five-year term until prior notice is given by either party.

Auxilium Pharmaceuticals, Inc. and Invaron Pharmaceuticals, Inc.

In November 2009, and further amended in March 2011, we entered into a license agreement for our STRIANT testosterone product with The Urology Company, Ltd. for distribution in Europe. This agreement was subsequently amended in March 2011. In April 2011 and July 2011, respectively, we entered into license agreements for our STRIANT testosterone product with Auxilium for distribution in the U.S. and Invaron Pharmaceuticals, Inc., for distribution in the U.S. and Canada.

Segments

We currently operate in one segment; the development and analysis of pharmaceuticals, clinical trial manufacturing of pharmaceutical products for pharmaceutical company customers and the potential development of pharmaceuticals for our own behalf. In certain foreign countries, these products may be classified as medical devices or cosmetics by those countries' regulatory agencies. See Note 13 to the consolidated financial statements for information on foreign operations.

We acquired Molecular Profiles, Ltd, a UK-based provider of pharmaceutical development, clinical trial manufacturing, and advanced analytical and consulting services to the pharmaceutical industry, on September, 12, 2013. We view the manufacturing of clinical trial drug supplies for our pharmaceutical company clients and the manufacturing of CRINONE for our license partner to be seamless activities and have therefore sought to capture synergies by transferring all operational activities related to our historic business to Molecular Profiles. These activities, including management of CRINONE manufacturing, quality assurance and logistics and, management of our intellectual property estate are now fully integrated into and managed out of our Nottingham, U.K. facility.

Prior to our acquisition of Molecular Profiles, we had invested heavily in an approximate quadrupling of our capacity. This capacity expansion necessarily has increased the overall cost-base of the Nottingham operations. As such our Chief Executive Officer, as Chief Decision Making Officer (CDMO), currently focuses his decision making attention on the expansion of the Company's revenue base.

Operations

We seek to research and develop new therapeutic entities utilizing our proprietary drug delivery technology for licensing to pharmaceutical companies for commercialization. In addition, through our wholly-owned subsidiary, Molecular Profiles, we now provide advanced physical and chemical analysis, consulting and formulation development services and clinical trial drug manufacturing services to pharmaceutical companies. With the skills and expertise of Molecular Profiles we believe we are well positioned to further advance our therapeutic entities.

Our primary operating facility is based at our Molecular Profiles facility located in Nottingham, United Kingdom. At this location we perform all our advanced physical and chemical analysis, consulting and

formulation services and clinical trial drug manufacturing services. In addition, with the acquisition of Molecular Profiles in September 2013, all logistics and quality operations associated with the manufacturing of CRINONE vaginal gel products for our partner, Merck Serono, were integrated into and are now managed out of our Nottingham, United Kingdom facility.

For the manufacture of CRINONE, we are substantially dependent on three third-party manufacturers. Our CRINONE vaginal gel products are manufactured in bulk by Fleet Laboratories Limited, Watford, Hertfordshire, United Kingdom (“Fleet”), filled into overwrapped single-use disposable applicators by Maropack AG, Zell, Switzerland (“Maropack”) and packaged in commercial cartons by Central Pharma, Bedford, United Kingdom (“Central”), pursuant to standard purchase orders.

Fleet. In December 2009, our wholly owned subsidiary, Columbia Laboratories (Bermuda) Ltd., entered into a supply agreement with Fleet, our long standing manufacturer of our progesterone vaginal gel. Pursuant to the agreement, Fleet, using a dedicated suite and dedicated equipment that we have purchased, exclusively manufactures and supplies, and we exclusively purchase from Fleet, our requirements of bulk progesterone gel. Pursuant to the agreement, the price may be adjusted annually to take into account any documented decrease or increase in the cost of raw materials or any other decrease or increase in the cost of manufacturing. The initial term of the agreement is five (5) years, and the agreement automatically renews for additional periods of two (2) years unless either party gives to the other party, not less than six (6) months prior to expiration of the agreement, written notice of its intention not to extend the agreement; provided, however, that upon termination of the agreement, Fleet agrees to perform its obligations under the agreement until the earlier of one (1) year and Columbia’s engagement and qualification of an alternative manufacturer. Payments under the agreement are made in British Pounds sterling. This agreement was most recently amended, effective on December 31, 2013, to among other things, extend the term of the agreement to December 2020.

Maropack. In October 1993, Columbia Laboratories (Bermuda) Ltd. entered into an agreement with Maropack to fill our bulk progesterone gel into overwrapped single-use disposable applicators. We have purchased and own certain equipment that is dedicated to Columbia products. The current term of the agreement is 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 forecast production volumes. Payments under the agreement are made in Swiss francs.

Central. In July 2006, our wholly-owned subsidiary, Columbia Laboratories (Bermuda) Ltd., entered into a Technical Agreement with Central to provide final packaging and distribution services. We have purchased our own equipment that is unique to and dedicated to Columbia products. The agreement is reviewable every two years at our determination. Payments under the agreement are made in British Pounds sterling.

Aspen Oss B.V. is the only supplier of progesterone approved by the regulatory agencies worldwide excluding the U.S. in marketing licenses for CRINONE.

Lubrizol, Inc. (“Lubrizol”) is the only supplier of medical grade, cross-linked polycarbophil, the polymer used in our BDS-based products. We do not have a long-term supply agreement with Lubrizol.

We regularly evaluate the performance of our third-party manufacturers with the objective of confirming their continuing capabilities to meet our needs efficiently and economically. Manufacturing facilities, both foreign and domestic, are subject to inspections by or under the authority of the FDA and by other federal, state, local or foreign authorities. A failure by any of our third-party manufacturers to pass an inspection could adversely affect our ability to continue to supply product to our partners and thus negatively impact our revenues.

Any initiative to qualify additional or alternate suppliers would require agreement with, and filing of regulatory amendments by Merck Serono.

We have established a quality assurance program intended to ensure our third-party manufacturers and service providers produce materials and provide services, when applicable, in accordance with the FDA's current Good Manufacturing Practices, or cGMP, and other applicable regulations.

Research and Development

In 2013 there were no research and development expenses as the Company eliminated its research and development activities in 2011 as a result of the FDA's denial of Actavis' FSRR. We spent \$0.8 million in 2012 and \$2.8 million in 2011 on research and development activities. In 2011, these expenditures were primarily costs associated with the Company's clinical study of PROCHIEVE 8% (progesterone gel) for the reduction of risk of preterm birth in women with premature cervical shortening as measured by transvaginal ultrasound, and related filing of NDA 22-139. In 2012, all costs related to NDA 22-139 and in 2011 a large portion of the costs associated with the completion of the preterm birth trial and NDA 22-139 were reimbursed by Actavis as part of the Purchase and Collaboration Agreement. We are currently evaluating initiating research and development activities again. We cannot predict if we do initiate research and development activities whether we will be successful in the development of the products listed below or any other product candidates.

Generally our drug development activities have taken 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 incorporated them in our BDS technology. This has meant that certain Phase I studies have not always been required for our product candidates. Phase II studies involve volunteer patients (people with the disease intended to be treated) to assess the drug's effectiveness and to further evaluate its safety. 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, we and our development partner, if any, analyze all of the data and file 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 or its licensee must continue to submit periodic reports to the FDA, disclosing any cases of adverse reactions and providing appropriate quality-control records. For some drugs, the FDA requires additional studies after approval (Phase IV studies) to evaluate long-term effects of the drug. The FDA also has the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. 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.

Vaginally Administered Lidocaine (COL-1077). The Company has conducted pre-clinical and clinical development activities for a vaginally-administered lidocaine product for treating or preventing pelvic pain. The

further development of this product candidate is currently being considered for a new indication to prevent pain associated with routine gynecological procedures.

Vaginally Administered Peroxide (COL-2401). The Company has completed limited pre-clinical development activities for a vaginally-administered peroxide product for treating or preventing vaginal infections. The product candidate is being investigated to determine the benefit of releasing a very low concentration of peroxide over an extended period of time, in order to treat or prevent bacterial infections of the vagina. In July 2012, the Company granted to Scientelle LLC (“Scientelle”) an exclusive (even as to the Company) transferable worldwide license to the Company’s patents and related know-how.

Patents, Trademarks and Proprietary Information

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

<u>Year Granted</u>	<u>Nature of Patent</u>
2013	Extended, controlled-release pharmaceutical compositions using charged polymers.
2011	Progesterone for the treatment or prevention of spontaneous preterm birth. ¹
2010	Low concentration of peroxide for treating or preventing vaginal infections. ²
2006	Bioadhesive progressive hydration tablets using desmopressin or prostaglandin E2 as the active ingredient.
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	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.

¹ *Progesterone-specific patents were transferred to Actavis in connection with the first closing of the Actavis transaction in July 2010. Columbia receives royalties from Actavis on quarterly net sales of the progesterone-based products covered by these patents.*

² *The peroxide-specific patent was licensed to Scientelle in connection with a worldwide license agreement in July 2012.*

We continue to maintain and expand its patent families globally. 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 U.S. patents for the marketed BDS products and current development projects.

<u>Subject of Patent</u>	<u>Year of Expiration</u>	<u>Product or Project</u>
Progesterone to prevent or treat preterm birth ¹	2028	PROCHIEVE 8%/ progesterone vaginal gel 8% COL-2401
Low concentration of peroxide for treating or preventing vaginal infections ²	2023	
Progressive hydration tablets	2019	STRIANT
First Uterine Pass Effect™	2018	COL-1077
Progesterone delivery ¹	2013	CRINONE /PROCHIEVE

¹ Progesterone-specific patents were transferred to Actavis in conjunction with the first closing of the Actavis transaction in July 2010. Columbia receives royalties from Actavis on quarterly net sales of the progesterone-based products covered by these patents.

² The peroxide-specific patent was licensed to Scientelle in connection with a worldwide license agreement in July 2012.

Our licensee markets STRIANT (testosterone buccal system) in the U.S. We hold patents that expire in August 2019 on the product formulation around the world, including the U.S., Canada and the United Kingdom.

Merck Serono holds marketing authorizations for CRINONE in over 60 countries outside the United States. With respect to those countries in which sales of CRINONE are material, we hold patents that expire in September 2014 on the delivery system for the product in Australia, Canada, Italy, Ireland, Russia, and the United Kingdom, but we do not hold patents in Brazil, China, India, South Korea, Taiwan, Thailand, Turkey, and Vietnam. Given the clinical and regulatory hurdles a potential generic competitor to CRINONE would likely face, we do not expect these patent expirations will have a significant impact on our product revenues.

Actavis owns registrations for the “CRINONE” and “PROCHIEVE” trademarks in the U.S. Merck Serono owns registrations for the CRINONE trademark throughout the rest of the world. Our licensees own registrations for “STRIANT” and “STRIANT SR” as trademarks in several countries throughout the world, including the U.S. and United Kingdom where it is marketed. There can be no assurance that such trademarks will afford adequate protection or that licensees will have the financial resources to enforce their rights under such trademarks.

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.

Success of Marketing Efforts

We rely on partners to successfully market the pharmaceutical products we developed internally. Their success and ours is dependent on market acceptance of our products by physicians, healthcare payors, patients, and the medical community. Medical doctors’ willingness to prescribe our products, the willingness for payors to make payments for our products and the general acceptance by patients and the broad medical community 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; and
- The pricing, reimbursement and third-party coverage of our products.

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

We market and sell our pharmaceutical development, consulting and analytic services directly and through partners to emerging, regional and multi-national pharmaceutical companies that are seeking to develop new pharmaceutical products.

We target potential customers through client visits, trade shows and workshops. We also conduct tours from time to time at our facility so that potential customers can see the range of services we offer. We believe that these tradeshows and workshops enhance customer loyalty and provide us with new sales opportunities. We also feel that they provide public awareness of our organization and our expertise, which enables us to remain at the leading edge in product offering and customer service. We actively maintain a public relations program to promote coverage of our products and services on popular social media outlets. In addition, our services are featured in several publications around the world and we have twice been awarded in the United Kingdom with the Queen's Award for Enterprise in the category of Innovation.

Factors that could affect the success of our marketing efforts as well as those of our partners for our services include:

- The effectiveness of our analytical and pharmaceutical development services;
- The successful marketing of our services by our sales force;
- Our reputation in the marketplace; and
- The success of competing products and services.

Competition

We and our marketing partners compete against established pharmaceutical companies which market products and services addressing similar needs. Further, numerous companies are developing, or may develop, enhanced delivery systems, products and services that compete with our present and proposed products and services. 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, regulatory requirements change, 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 competitors and start-ups and can quickly render existing products, technologies and services 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, our partners may not gain, and may lose, market share.

CRINONE, a natural progesterone product, competes in markets with other progestins, both synthetic and natural, that may be delivered by pharmacy-compounded injections or vaginal suppositories, with Prometrium®

(oral micronized progesterone) marketed by Abbott Laboratories, and Endometrin® (progesterone vaginal insert) marketed by Ferring Pharmaceuticals, Inc. CRINONE and Endometrin are the only progestin products approved by the FDA for use in infertility.

There are various competitors who compete with our Molecular Profiles brand with different services offered within their specific niches in the market. Some of these competitors have greater financial and human resources than we do and have established reputations, as well as worldwide distribution channels and sales and marketing capabilities that are larger and more established than ours.

Additional competitors may enter the market, and we are likely to compete with new companies in the future. Our service offerings also compete against companies performing services such as:

- Pharmaceutical Development Services – Preformulation and Chemistry Manufacturing and Controls (“CMC”), solid state form optimization and formulation development.
- Clinical Trial Manufacturing Services – Manufacturing of tablets, capsules, topicals, dry powder inhaled products (“DPI’s”) and liquids.
- Advanced Analytical and Consulting Services – Detailed analytical characterization to support pharmaceutical development, troubleshooting process issues, materials characterization, and testing and consultancy relating to intellectual property.

Competition amongst organizations providing pharmaceutical development and analytical services is characterized by significant technical expertise, breadth of technical services and the ability to deliver to customer requirements and timelines. There are many barriers that would prevent new entrants or existing competitors from replicating our services. There are, however, many companies, both public and private, that do provide a range of development and analytical services. Accordingly, our success depends in part on establishing our client base, offering new innovative services to our client’s inquiries and establishing and fully utilizing the new facility that was built and completed in 2013. To compete effectively, we have to demonstrate that our products and services are attractive alternatives to others by differentiating our services on the basis of technical expertise, performance, reputation, quality of customer support and price. Breadth of service offerings is also important. We believe that we perform favorably with respect to each of these factors. However, we have encountered and expect to continue to encounter potential customers who choose the services offered by our competitors. Potential customers also may decide not to purchase our services, or to delay such purchases, due to technical, clinical, regulatory or financial considerations beyond our control. In addition, we expect that competitive pressures may result in price competition and could affect our profitability from time to time.

Customers

We have a long-term product supply agreement with Merck Serono who places firm purchase orders 90 to 120 days in advance of the expected shipping date.

Our pharmaceutical development, consulting and analytics services are offered to customers that range from emerging to regional and multi-national pharmaceutical companies of various sizes. These customers are typically in an innovative phase of drug development and are looking to find answers to why a pharmaceutical drug or molecule behaves in a particular manner or demonstrates certain characteristics. These tend to be discrete contracts and we must continue to compete on performance and price to win new and repeat business. Many of our customers are developing novel therapeutic products and may discontinue development at any time due to technical, clinical, regulatory or financial considerations beyond our control.

Revenues

Revenues by Source

The following table sets forth the percentage of the Company's consolidated revenues, including product sales, royalty and license revenue, and service revenue attributable to each revenue source accounting for 10% or more of consolidated revenues in any of the three years ended December 31:

	<u>2013</u>	<u>2012</u>	<u>2011</u>
CRINONE royalties, milestone and license fees	13%	13%	57%
CRINONE product sales	73	86	42
Services	13	—	—
Other	<u>1</u>	<u>1</u>	<u>1</u>
Total	<u>100%</u>	<u>100%</u>	<u>100%</u>

Revenues by Customer

The following table sets forth the percentage of the Company's consolidated revenues, including product sales, royalty and license revenue, and service revenue attributable to each customer accounting for 10% or more of consolidated revenues in any of the three years ended December 31:

	<u>2013</u>	<u>2012</u>	<u>2011</u>
Actavis	13%	31%	65%
Merck Serono	73%	67%	34%
All others	<u>14%</u>	<u>2%</u>	<u>1%</u>
Total	<u>100%</u>	<u>100%</u>	<u>100%</u>

The revenues from Actavis above include product sales, royalties on sales by Actavis and, in 2011, the amortization of the deferred revenues from the sales of the progesterone assets to Actavis.

Revenues by Geographic Area

The following table sets forth the Company's consolidated revenues, based on sales by geographic area, for each area accounting for 10% or more of consolidated revenues in any of the three years ended December 31:

(in millions)	<u>2013</u>	<u>2012</u>	<u>2011</u>
United States	\$ 5.5	\$ 8.6	\$28.4
Switzerland	21.7	17.2	14.7
Other	2.0	—	—
Subtotal International	<u>23.7</u>	<u>17.2</u>	<u>14.7</u>
Total	<u>\$29.2</u>	<u>\$25.8</u>	<u>\$43.1</u>

Long-lived Assets

For information concerning our long-lived assets by geographic area, see footnote 13 of our 2013 consolidated financial statements, which information is incorporated herein by reference.

Employees

As of March 1, 2014, the Company had 77 employees, including 3 executive officers, 11 in supply chain management and quality, 7 in sales and marketing functions, 45 in technical and other production functions and

11 in other administrative functions. We also use consultants as necessary to support key 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.

Available Information

The Company's Internet address is *www.columbialabs.com*. Through a link on the "Investor" section of this website, 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 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 4 Liberty Square, Boston Massachusetts 02109, and our telephone number is (617) 639-1500. The Company's wholly-owned subsidiaries are Columbia Laboratories (Bermuda) Ltd. ("Columbia Bermuda"), Columbia Laboratories (France) SA ("Columbia France"), Columbia Laboratories (UK) Limited ("Columbia UK"), and Molecular Profiles (UK) Limited ("Molecular Profiles").

Item 1A. Risk Factors

We may fail to obtain new contracts or renew the existing contracts of our wholly-owned subsidiary, Molecular Profiles, which may adversely affect our business.

Many of Molecular Profiles' contracts with its customers are short-term in duration. As a result, we must continually replace those contracts with new contracts. In the event we are unable to replace these contracts in a timely manner or at all, our revenues may not be able to be sustained or may decline. In addition, certain of Molecular Profile's long-term contracts may be cancelled or delayed by clients for any reason upon notice. Multiple cancellations, non-renewals, or renewals on less favorable terms to us related to significant contracts could materially impact our business. While we intend to seek to negotiate new or extended agreements, if new contracts cannot be completed or existing contracts extended on terms acceptable to us or at all, our business, results of operation and financial condition could be materially adversely affected.

Uncertainty about our acquisition of Molecular Profiles may adversely affect our relationships with our respective customers, suppliers and employees.

As a result of our acquisition of Molecular Profiles, existing or prospective customers or suppliers of Molecular Profiles or the Company may:

- Delay, defer or cease purchasing goods or services from or providing goods or services to us;
- Delay or defer other decisions concerning us or refuse to extend credit to us; or,
- Otherwise seek to change the terms on which they do business with us.

Any such delays or changes to terms could seriously harm our business.

In addition, as a result of the acquisition, current and prospective employees of Molecular Profile could experience uncertainty about their future with us. These uncertainties may impair our ability to retain, recruit or motivate key personnel.

If our internal controls and disclosure controls are not effective, investors could lose confidence in our financial reporting.

Section 404 of the Sarbanes-Oxley Act of 2002 requires companies to conduct a comprehensive evaluation of their internal control over financial reporting. To comply with this statute, we are required to document and test our internal control over financial reporting and our management is required to assess and issue a report concerning our internal control over financial reporting.

As described elsewhere in this Annual Report on Form 10-K, our management recently identified a material weakness in our internal control over financial reporting, which led to an overstatement of the change in fair value of our outstanding common stock warrants for the three- and nine-month periods ended September 30, 2013, and affected, among other things, our reported net (loss) income and net (loss) income per common share (basic and diluted). The identification of this error resulted in the restatement of our unaudited interim consolidated financial statements for such periods (the "Restatement"). In connection with the Restatement, our management reevaluated our internal controls over financial reporting and our disclosure controls and procedures and concluded that such controls were not effective as of September 30, 2013, nor were they effective as of December 31, 2013.

Our management has begun taking steps to develop a plan and timetable for the implementation of remediation measures (to the extent not already implemented). We believe that these actions will remediate the control deficiency we have identified and strengthen our internal control over financial reporting. Although we have begun the process of remediating the material weakness, this process will take time, and we will not be able

to assert that we have remediated the material weakness until the procedures that we put in place have been working for a sufficient period of time for us to determine that they are effective.

Although we believe we are taking appropriate actions to remediate the internal control deficiency we have identified, we cannot assure you that we will not discover other material weaknesses in the future. Any failure to maintain or implement new or improved controls, or any difficulties we encounter in implementation, could cause us to fail to meet our annual or periodic reporting obligations or result in material misstatements in our financial statements, and substantial costs and resources may be required to rectify these or other internal control deficiencies. If we cannot produce reliable financial reports, investors could lose confidence in our reported financial information, the market price of our common stock could decline significantly, and our business and financial condition could be harmed. Our failure to maintain effective internal control over financial reporting could also result in investigation or sanctions by regulatory authorities or litigation, and our failure to meet our annual or periodic reporting obligations could result in our common stock being delisted from The Nasdaq Global Market.

Our business is dependent on the continued sale of Progesterone Products to Merck Serono.

Our operating results are dependent on the product revenues from Merck Serono derived from the sale of CRINONE in countries outside the U.S. Revenues from the sales to Merck Serono during the years ended December 31, 2013, 2012 and 2011 constituted approximately 73%, 67% and 34% of our total revenues, respectively. We do not control the amount and timing of marketing resources that Merck Serono may or may not devote to our product. The failure of Merck Serono to effectively market our products could have a material adverse effect on our business, financial condition and results of operations. Our license and supply agreement with Merck Serono expires on May 19, 2020.

Through the acquisition of Molecular Profiles, we have made significant capital investments with regard to the facilities acquired to meet our potential future needs and, as a result, if we are not able to utilize the facilities to capacity, our margins could be adversely affected.

We have made substantial investments in our facilities located in Nottingham, United Kingdom. With the acquisition of these facilities, our fixed costs have increased. In particular, Molecular Profiles completed the expansion of its development and manufacturing capacity to support expected growth in this area of our business. If development or supply agreements do not generate the revenues that we expect, we may have excess fixed costs associated with our increased development and manufacturing capacity due to the expansion, which could adversely affect our results of operations.

We may be unable to successfully integrate the business of Molecular Profiles and realize the anticipated benefits of the acquisition.

The integration of Molecular Profiles will continue to require the significant devotion of management and other resources. Delays in this process could adversely affect our business, financial results, financial condition, and stock price.

Realizing the anticipated benefits of the acquisition will depend, in part, on the successful integration of operations, personnel and technology of Molecular Profiles into our company. If we are unable to successfully integrate Molecular Profiles' business into our business in a manner that permits the combined company to achieve the operating synergies and cost savings anticipated to result from the acquisition, the anticipated benefits of the acquisition may not be realized fully or at all or may take longer to realize than expected.

Potential difficulties the combined Company may encounter in the integration process include the following:

- Lost revenues and customers as a result of Molecular Profiles' customers deciding not to do business with the combined company;

- The inability to procure goods and services on favorable terms as a result of our suppliers or Molecular Profile’s suppliers deciding not to do business with the combined company;
- The inability to retain, recruit or motivate key personnel;
- Managing the complexities associated with the combined businesses;
- Difficulties associated with integrating personnel from diverse corporate cultures while maintaining focus on providing consistent, high quality services and customer service;
- Potential unknown liabilities and unforeseen increased expenses or delays associated with the integration process;
- Performance shortfalls as a result of the diversion of management’s attention to the integration process;
- Disruption or interruption of, or loss of momentum in, our ongoing business; and,
- Inconsistencies in standards, controls, procedures, policies, and regulatory reporting.

Any of these difficulties could adversely affect our ability to maintain relationships with suppliers, customers and employees or our ability to achieve the anticipated benefits of the acquisition, or could reduce our earnings or otherwise adversely affect the business and financial results of the combined company.

Even if we are able to integrate Molecular Profile’s business operations successfully with ours, this integration may not result in the realization of the full benefits of synergies, cost savings, innovation and operational efficiencies that may be possible from this integration and these benefits may not be achieved within a reasonable period of time.

Charges to earnings resulting from the application of the acquisition method of accounting may adversely affect the market value of our common stock.

In accordance with generally accepted accounting principles in the United States, the acquisition is being accounted for using the acquisition method of accounting, which will result in charges to earnings that could have an adverse impact on the market value of our common stock. Under the acquisition method of accounting, the total purchase price has been allocated to Molecular Profiles’ net tangible and identifiable intangible assets based on their respective fair values as of the acquisition date. Any excess of the purchase price over those fair values is being recorded as goodwill. The combined company will incur additional amortization expense related to the identifiable amortizable intangible assets acquired. Additionally, to the extent the value of goodwill or identifiable intangible assets or other long-lived assets become impaired, the combined company will be required to incur material charges relating to the impairment. These amortization and potential impairment charges could have a material impact on the combined company’s results of operations.

The price of our common stock has been and may continue to be volatile.

The market prices and volume of securities of small specialty pharmaceutical companies, including ours, from time to time experience significant price and volume fluctuations. Historically, the market price of our common stock has fluctuated over a wide range. Between 2011 and 2013, our common stock traded in a range from \$4.41 to \$34.48 per share. In 2013, our common stock traded in a range from \$4.49 to \$8.37 per share. It is likely that the price of our common stock will continue to fluctuate. In particular, the market price of our common stock may fluctuate significantly due to a variety of factors, including: the results of operations and our ability to develop additional products and services. 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.

A decline in the price of our common stock could affect our ability to raise further working capital and adversely impact our ability to continue operations.

Any sudden or prolonged decline in the price of our common stock could result in a reduction in the liquidity of our common stock and a reduction in our ability to raise capital. Such reductions may force us to reallocate funds from other planned uses and may have a significant negative impact on our business plans and operations, including our ability to invest in growing our services, developing our own proprietary technologies and product candidates and continuing our current operations. If we are unable to raise sufficient capital in the future, and we are unable to generate funds from operations sufficient to meet our obligations, we will not have the resources to continue our normal operations.

We face increased competition, which could adversely affect the operating results of our business

We compete directly with the in-house research departments of pharmaceutical companies and biotechnology companies, as well as contract research companies, and research and academic institutions. We also experience significant competition from foreign companies operating under lower cost structures. Many of our competitors have greater financial and other resources than we have. As new companies enter the market and as more advanced technologies become available, we currently expect to face increased competition. In the future, any one of our competitors may develop technological advances that render the services that we provide obsolete. While we plan to develop technologies, which will give us competitive advantages, our competitors plan to do the same. We may not be able to develop the technologies we need to successfully compete in the future, and our competitors may be able to develop such technologies before we do or provide those services at a lower cost. Consequently, we may not be able to successfully compete in the future.

Any significant change in government regulation of the drug development process could have a material adverse effect on the Company.

The manufacturing of pharmaceutical products is subject to extensive regulation by governmental authorities, including the FDA, Medicines and Healthcare products Regulatory Agency (“MHRA”), the European Medicines Agency (“EMA”) and comparable regulatory authorities in other countries. Our business, as well as our customers’ business, depends in part on strict government regulation of the drug development process. Legislation may be introduced and enacted to modify existing regulations or impose new regulations to be administered by the FDA, MHRA or the EMA governing the manufacture of drugs and the drug approval process. Any significant change in regulations governing the manufacture of clinical trial drugs or reduction in the scope of regulatory requirements or the introduction of simplified drug approval procedures could have a material adverse effect our business.

Our progesterone delivery patent for CRINONE expired in 2013 in the U.S. and expires in 2014 outside the U.S. and a generic product to CRINONE may become available.

Our U.S. progesterone delivery patent for the current formulation of CRINONE expired in September 2013. These patent expirations could enable a generic bioadhesive progesterone vaginal gel product to enter the infertility marketplace. Actavis has developed a next generation progesterone product utilizing a new applicator. We have no assurance this development will prevent new competitors from entering the market. However due to the clinical and regulatory hurdles that a potential generic competitor would likely face, we believe the risk of generic entry is not high.

Outside the U.S., we hold patents on the delivery system for CRINONE in the following countries in which sales of CRINONE are material: Australia, Canada, Ireland, Italy, Russia, and the United Kingdom, which patents expire in September 2014. We do not hold patents on the delivery system for CRINONE in the following countries in which sales of CRINONE are material: Brazil, China, India, South Korea, Taiwan, Thailand, Turkey, and Vietnam. Merck Serono holds marketing authorizations for CRINONE in over 60 countries outside the United States.

We face significant competition from pharmaceutical companies that may adversely impact our market share.

Our marketing partners compete against established pharmaceutical companies that market products addressing similar needs. Further, the pharmaceutical development services that we offer are also offered by numerous larger companies that may have better technology, products and services that compete with our present and proposed product and service offerings. 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 drug delivery technologies are developed, new products enter the market, generic versions of existing drugs become available, and service and technology offerings 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 and services 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.

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

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 either party 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 management of our supply chain, our pharmaceutical development, analytical and consulting services business and, or, our development of future products and product candidates. If we are unable to attract and retain qualified and talented senior management personnel, our business may suffer.

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 that 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 progesterone gels.

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

The ability of our partners 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 or our partners succeed in bringing new prescription products to market or expand the approved label for existing products, 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.

Government health agencies, private health maintenance organizations and other third-party payors use one or more of multiple tools including price controls, profit or reimbursement caps, and use of 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 products marketed by our partners from which we derive sales revenues and royalties 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 payor organization, reimbursement may be lost entirely or be reduced 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. Our partners may also decide to enter into discount or formulary fee arrangements with payors, which could result in lower or discounted prices for CRINONE or future products.

Healthcare law and policy changes, based on recently enacted legislation, may have a material adverse effect on us.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the U.S. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Most notably, the PPACA increased Medicaid rebates, expanded Medicaid eligibility, extended Public Health Service eligibility, imposed annual reporting requirements on certain entities, including pharmaceutical companies, to disclose certain financial relationships with physicians and teaching hospitals, and established a new Patient-Centered Outcomes Research Institute, an entity charged with examining the relative health outcomes, clinical, effectiveness and appropriateness of difficult medical treatments. Many of these provisions could have the effect of reducing our revenue generated by our partners' sales of CRINONE and any future commercial products we may develop. In addition, we anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the price that we receive for any approved product, which may harm our business. Insurers may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals.

We are dependent on single-source 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, Lubrizol. We believe that Lubrizol 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 Lubrizol 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. While we purchase polycarbophil from Lubrizol, Inc. from time to time, we do not have an agreement with them concerning future purchases. The Company's policy is to have in inventory at least a 12 month supply of polycarbophil.

Only one supplier of progesterone is approved by regulatory authorities outside the U.S. If our supplier is unable or unwilling to satisfy our needs, we will be required to seek alternative sources of supply. While alternative sources of progesterone 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 single-source third-party manufacturers, the loss of which could result in a loss of revenues.

We rely on third parties to manufacture our products, including Fleet, which manufactures CRINONE in bulk, Maropack, which fills CRINONE into applicators, and Central Pharma, which packages CRINONE in final

containers. 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 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.

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.

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 U.S. and foreign patents upon which our original BDS 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.

Bio-Mimetics, Inc. (“Bio-Mimetics”) originally held the patent upon which our original BDS was based until we purchased it from them. Bio-Mimetics’ patent contained broad claims covering controlled release products that include a bioadhesive. However, this U.S. patent and its corresponding foreign patents expired in November 2003 and 2004, respectively. 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. Some of these patents expired in 2013 for the U.S. and expire in 2014 for the rest of the world. We cannot assure you that any remaining 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 are subject to government regulation, which could affect our partners' ability to sell products.

Nearly every aspect of the development, manufacture and commercialization of pharmaceutical products is subject to time-consuming and costly regulation by various governmental entities, including the MHRA, as well as regulatory agencies in those foreign countries in which our products are manufactured or distributed. The National Drug agencies may have 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 required under applicable governmental 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 potential development of our pharmaceutical products is uncertain and subject to a number of significant risks.

In order to develop future pharmaceutical products, 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;
- The proprietary rights of others and their competing products and technologies may prevent our product candidates from being effectively commercialized; and
- Our ability to attract development and commercialization partners.

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, competing clinical studies, 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 could 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, if needed, 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.

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

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 or our partners fail to obtain regulatory approval for our future product candidates or expanded indications for currently marketed products, we will be unable to receive income from the sale of such products and indications.

As part of the regulatory approval process, we and our partners 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 such particular product candidate.

The results of initial clinical trials of 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 a 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 selected may not meet the applicable requirements; and
- Changes in their approval policies or adoption of new regulations may require additional clinical trials, other data or removal from the market.

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

We may observe adverse side effects of our future potential product candidates in clinical trials, which could delay or halt product development.

Our future potential product candidates may demonstrate serious adverse side effects in clinical trials. These adverse side effects could interrupt, delay or halt clinical trials of product candidates and could result in FDA or other regulatory authorities denying approval of product candidates for any or all targeted indications. An IRB or independent data safety monitoring board, the FDA, other regulatory authorities, or we ourselves or our customers may suspend or terminate clinical trials at any time. Product candidates may prove not to be safe for human use. In such circumstances we may not be able to complete development and successful licensing of our own internal programs and our customers may not place additional contracts with us and may cancel existing contracts.

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

As of December 31, 2013, we had certain net operating loss carryforwards of approximately \$160 million that may be used to reduce our future U.S. federal income tax liabilities, if we become profitable on a federal income tax basis. If unused, these tax loss carryforwards will begin to expire between 2018 and 2034. Our ability to use these loss carryforwards to reduce our future U.S. federal income tax liabilities could also 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 of 1986 (“Code”), as amended. If we were to lose the benefits of these loss carryforwards, our future earnings and cash resources would be materially and adversely affected.

On November 29, 2010, we amended and restated our Rights Agreement, dated as of March 13, 2002, as amended (the “Rights Plan”). The Rights Plan is intended to preserve the value of our net operating loss carryforwards by reducing the likelihood that we will experience an ownership change by discouraging (i) any person (together with such person’s affiliates and associates), without the approval of our board of directors from acquiring 4.99% or greater of our outstanding voting stock (as defined in the Rights Plan) and (ii) any person that currently beneficially owns 4.99% or more of the outstanding voting stock from acquiring more shares of our voting stock, other than by exercise or conversion of currently existing warrants, convertible securities or other equity-linked securities. On September 20, 2011 we further amended the Rights Plan to extend the expiration date from March 12, 2012 to July 3, 2013. On May 1, 2013, we further amended the Rights Plan to extend the expiration date from July 3, 2013 to July 3, 2016. There is no guarantee that the Rights Plan will prevent an ownership change within the meaning of Section 382(g) of the Internal Revenue Code and therefore, no guarantee that the value of our net operating loss carryforwards will be preserved.

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

As of March 1, 2014, we had 12,155,461 shares of common stock outstanding, of which 10,122,800 shares were freely tradable. As of that date, approximately 2,032,661 shares of our common stock were held by affiliates. We also have the following securities outstanding: series B convertible preferred stock, contingently redeemable series C convertible preferred stock, common stock warrants, and options. If all of these securities are exercised or converted, an additional 1.6 million shares of our common stock will be outstanding, all of which will be available for resale under the Securities Act. The exercise and conversion of these securities would likely 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 (as discussed above, this plan was amended and restated on November 29, 2010), 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 our 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 our 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 our common stock, and, as a result, their issuance could have a material adverse effect on the market value of our common stock.

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

We are a small company and we rely heavily on third parties to conduct many important functions. As a pharmaceutical development and services 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. 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.

Anti-takeover provisions could impede or discourage a third-party acquisition of the 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 (as discussed above, this plan was amended and restated on November 29, 2010, extended on September 20, 2011, and extended further on May 1, 2013) 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 acquirer 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.

Our operations involve hazardous materials and are subject to environmental, health and safety controls and regulations.

We are subject to environmental, health and safety laws and regulations, including those governing the use of hazardous materials, and we spend considerable time complying with such laws and regulations. Our business activities involve the controlled use of hazardous materials and although we take precautions to prevent accidental contamination or injury from these materials, we cannot completely eliminate the risk of using these materials. In the event of an accident or environmental discharge, we may be held liable for any resulting damages, which may materially harm our business, financial condition and results of operations.

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

With four international subsidiaries and third party manufacturers in Europe, economic and political developments in the European Union, including the ongoing European debt problems, 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.

We could be negatively impacted by securities class action complaints.

Between February 1, 2012 and February 6, 2012, two putative securities class action complaints were filed against us and certain of our officers and directors in the United States District Court for the District of New Jersey. These actions were filed under the captions *Wright v. Columbia Laboratories, Inc., et al.*, and *Shu v. Columbia Laboratories, Inc., et al* and asserted claims under sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated under the Exchange Act on behalf of an alleged class of purchasers of the our common stock during the period from December 6, 2010 through January 20, 2012. Both actions were consolidated into a single proceeding entitled *In re Columbia Laboratories, Inc., Securities Litigation*, under which Actavis, Inc., and three of its officers have been added as defendants. The Consolidated Amended Complaint alleged that we and two of our officers, one of whom is a director, omitted to state material facts that they were under a duty to disclose, and made materially false and misleading statements that related to the results of Columbia's PREGNANT study and the likelihood of approval by the FDA of an NDA to market progesterone vaginal gel 8% for the prevention of preterm birth in women with premature cervical shortening. According to the amended complaint, these alleged omissions and misleading statements had the effect of artificially inflating the market price of the common stock. The plaintiffs sought unspecified damages on behalf of the putative class and an award of costs and expenses, including attorney's fees. On June 11, 2013, the Court dismissed the amended complaint for failure to state a claim upon which relief could be granted, holding that the plaintiffs did not adequately plead facts supporting an inference of intent to deceive investors. The Court permitted the plaintiffs to file a second amended complaint, and they did so on July 11, 2013. We moved to dismiss the second amended complaint. On October 21, 2013, the Court dismissed the second amended complaint. The Court ruled that changes the plaintiffs made to their first amended complaint "still do not create a strong inference that Columbia acted with intent to deceive, manipulate or defraud." The Court ordered that if the plaintiffs sought to attempt to plead a cognizable action for in third amended complaint, they must do so within thirty days and specifically address why the attempt would not be futile. The plaintiffs chose not to file any further amendments and, on December 20, 2013, appealed the dismissals to the United States Court of Appeals for the Third Circuit. The Third Circuit will consider the matter after briefing is completed. We believe that the appealed action is without merit, and we intend to defend it vigorously. At this time, it is not possible to determine the likely outcome of, or estimate the liability related to this action, and Columbia has not made any provision for losses in connection with it.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease a 3,300 square foot facility in Boston, Massachusetts which houses our executive offices and certain administrative functions. The lease on this facility expires in April 2016. We own two facilities in Nottingham, United Kingdom. The first is an 8,000 square foot facility primarily used for administrative offices and to complete certain laboratory and production work. The second building is a purpose built 30,000 square foot facility primarily used for laboratory and production work.

Item 3. Legal Proceedings

Claims and lawsuits are filed against the Company from time to time. Although the results of pending claims are always uncertain, 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 coverage in the event of any unfavorable outcome resulting from these actions.

Between February 1, 2012 and February 6, 2012, two putative securities class action complaints were filed against us and certain of our officers and directors in the United States District Court for the District of New Jersey. These actions were filed under the captions *Wright v. Columbia Laboratories, Inc., et al.*, and *Shu v. Columbia Laboratories, Inc., et al* and asserted claims under sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated under the Exchange Act on behalf of an alleged class of purchasers of our common stock during the period from December 6, 2010 through January 20, 2012. Both actions were consolidated into a single proceeding entitled *In re Columbia Laboratories, Inc., Securities Litigation*, under which Actavis, Inc., and three of its officers have been added as defendants. The Consolidated Amended Complaint alleged that we and two of our officers, one of whom is a director, omitted to state material facts that they were under a duty to disclose, and made materially false and misleading statements that related to the results of Columbia's PREGNANT study and the likelihood of approval by the FDA of an NDA to market progesterone vaginal gel 8% for the prevention of preterm birth in women with premature cervical shortening. According to the amended complaint, these alleged omissions and misleading statements had the effect of artificially inflating the market price of the common stock. The plaintiffs sought unspecified damages on behalf of the putative class and an award of costs and expenses, including attorney's fees. On June 11, 2013, the Court dismissed the amended complaint for failure to state a claim upon which relief could be granted, holding that the plaintiffs did not adequately plead facts supporting an inference of intent to deceive investors. The Court permitted the plaintiffs to file a second amended complaint, and they did so on July 11, 2013. We moved to dismiss the second amended complaint. On October 21, 2013, the Court dismissed the second amended complaint. The Court ruled that changes the plaintiffs made to their first amended complaint "still do not create a strong inference that Columbia acted with intent to deceive, manipulate or defraud." The Court ordered that if the plaintiffs sought to attempt to plead a cognizable action in a third amended complaint, they must do so within thirty days and specifically address why the attempt would not be futile. The plaintiffs chose not to file any further amendments and, on December 20, 2013, appealed the dismissals to the United States Court of Appeals for the Third Circuit. The Third Circuit will consider the matter after briefing is completed. We believe that the appealed action is without merit, and we intend to defend it vigorously. At this time, it is not possible to determine the likely outcome of, or estimate the liability related to this action, and the company has not made any provision for losses in connection with it.

Item 4. Mine Safety Disclosures

Not Applicable.

PART II

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

Market Price of and Dividends on Our Common Stock and Related Stockholder Matters.

Our 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.

	<u>High</u>	<u>Low</u>
Fiscal Year Ended December 31, 2013		
First Quarter	\$ 5.24	\$4.56
Second Quarter	5.82	4.49
Third Quarter	8.37	5.20
Fourth Quarter	7.36	6.12
Fiscal Year Ended December 31, 2012		
First Quarter	\$23.68	\$4.96
Second Quarter	6.16	4.88
Third Quarter	9.20	5.44
Fourth Quarter	9.84	4.41

At March 1, 2014 there were approximately 200 shareholders of record of our common stock, one shareholder of record of our Series B convertible preferred stock (“Series B Preferred Stock”) and two shareholders of record of the our Series C Convertible Preferred Stock (“Series C Preferred Stock”). We estimate that there were approximately 4,000 beneficial owners of our common stock on such date.

On August 9, 2013, the Company effected a 1-for-8 reverse stock split, which was previously approved by the Board of Directors on July 26, 2013. The reverse stock split was approved by Columbia’s stockholders at its annual meeting of stockholders on May 1, 2013. All share and per share amounts relating to the common stock, stock options and warrants included in the financial statements and accompanying footnotes have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an equal amount to the reduction in par value of common stock to additional paid-in capital. The reverse stock split did not result in a retroactive adjustment to the share amounts for any of the classes of the Company’s preferred stock.

On September 12, 2013, Columbia acquired all of the outstanding capital stock of Molecular Profiles, a U.K.-based pharmaceutical development services company. As a result of the transaction, former Molecular Profiles stockholders, received as consideration for their shares of Molecular Profiles common stock an aggregate of \$16.7 million in cash and 1,051,323 shares of Columbia common stock. The total consideration is valued at \$24.0 million, based upon the closing price of our common stock adjusted for a discount for lack of marketability on September 12, 2013.

At December 31, 2013, 130 shares of our Series B Preferred Stock remain outstanding. Each share of Series B Preferred Stock is convertible into 2.5 shares of common stock. Upon our liquidation, 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.

The contingently redeemable series C Preferred Stock has a stated value of \$1,000 per share, and is convertible into common stock at the lower of: (i) \$28.00 per share of common stock; or, (ii) 100% of the

average of the closing prices during the three trading days immediately preceding the conversion notice, not to exceed 294,045 shares as of December 31, 2013. The Series C Preferred Stock pays a 5% dividend, payable quarterly in arrears on the last day of each quarter. The security holders of Series C Preferred Stock have certain redemption rights due to events beyond our control such as delisting, dividend defaults and certain other defaults. The terms of the Series C Preferred Stock have remained the same since inception.

The Series E Preferred Stock has a stated value of \$100 per share. On November 14, 2013, 22,740 shares of Series E Preferred Stock were converted into 142,125 shares of our common stock. As of December 31, 2013 there are no shares of Series E Preferred Stock outstanding.

On July 2, 2010, we purchased approximately \$40 million in aggregate principal amount of our outstanding convertible notes (the "Notes") pursuant to a Note Purchase Agreement. The aggregate purchase price for the Notes was approximately \$26 million in cash (plus accrued and unpaid interest through but excluding the date of the closing of the Note purchases), warrants to purchase 968,750 shares of common stock at an exercise price of \$10.80 per share and 925,925 shares of common stock.

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.

In October 2009, we raised approximately \$11.8 million in gross proceeds from the issuance and sale of 1,362,500 shares of our common stock at a price of \$8.64 per share and warrants to purchase 681,250 shares of common stock with an exercise price of \$12.16 per share in a registered offering. The warrants became exercisable on April 30, 2010, and expire on April 30, 2015, unless earlier exercised or terminated. On July 2, 2010, we issued 1,400,000 shares of common stock as part of the Actavis Transactions and 925,925 shares of common stock as part of the Note Purchase Agreement.

Dividend Policy

We have never paid a cash dividend on our common stock and do not anticipate the payment of cash dividends in the foreseeable future. We intend to retain any earnings for use in the development and expansion of our business. We are required to pay a 5% dividend on our Series C Preferred Stock on the last day of each quarter. We are current on our dividend payments.

Applicable provisions of the Delaware General Corporation Law may affect our ability to declare and pay dividends on our common stock as well as on our 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 our net assets over capital. Capital is defined to be the aggregate par value of shares issued unless otherwise established by the Board of Directors.

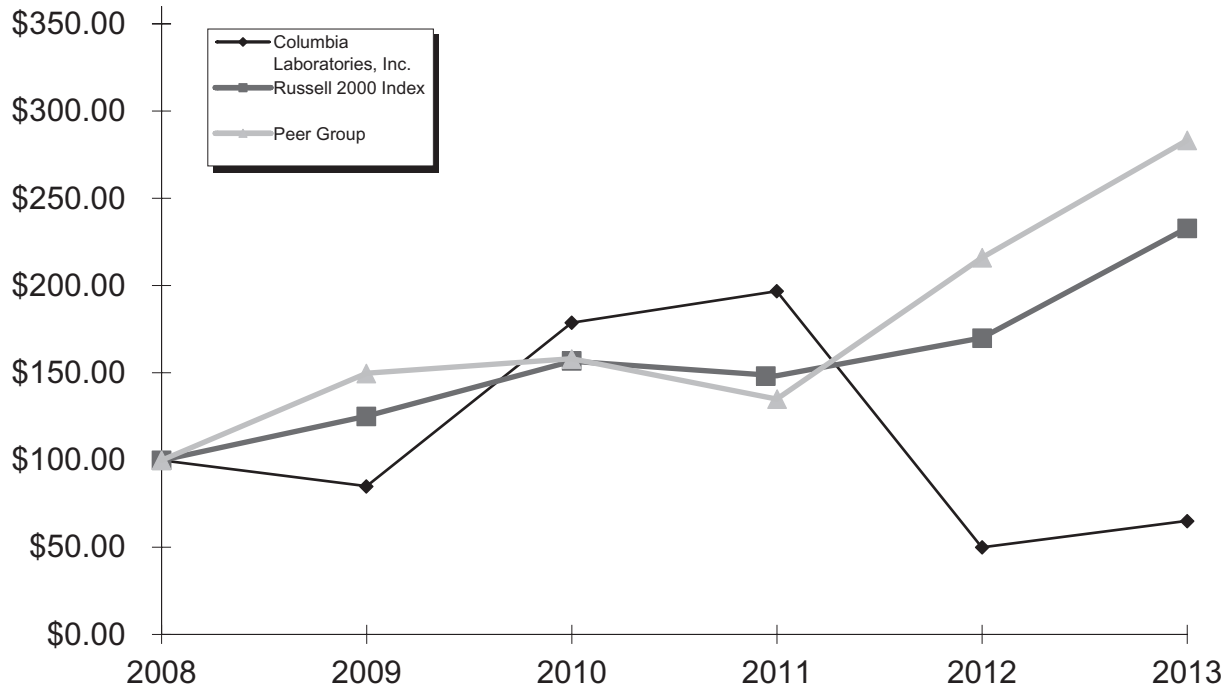
Equity Compensation Plan Information

See Part III, Item 12 for information regarding securities authorized for issuance under our equity compensation plans.

Stock Performance Graph

The table below shows the cumulative total stockholder return of an investment of \$100 on December 31, 2008 in our common stock, the Russell 2000 Index, and Peer Group. Our stock price performance shown in the table below is not indicative of future stock price performance.

**Comparison of Five-Year Cumulative Total Return
Columbia Laboratories, Inc., Russell 2000 Index and Peer Group*
(Performance Results Through 12/31/2013)**



	December 31,				
	2009	2010	2011	2012	2013
Columbia Laboratories, Inc.	\$ 85.04	\$178.74	\$196.85	\$ 50.04	\$ 65.06
Russell 2000 Index	\$125.22	\$156.90	\$148.35	\$170.06	\$232.98
Peer Group	\$149.74	\$158.10	\$135.02	\$216.08	\$283.36

* Peer Group Companies are ANI Pharmaceuticals, Inc., Elite Pharmaceuticals, Inc., Antares Pharma, Inc., BioDelivery Sciences International, Inc., Albany Molecular Research, Inc., POZEN Inc., Pain Therapeutics Inc.

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

Item 6. Selected Financial Data

The following selected financial data are derived from the Company's audited consolidated 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 consolidated statement of operations data for the years ended December 31, 2013, 2012, 2011, 2010, and 2009 and consolidated balance sheet data as of December 31, 2013, 2012, 2011, 2010, and 2009 have been derived from audited consolidated financial statements. The historical results are not necessarily indicative of the results to be expected for any future period.

	Year Ended December 31,				
	2013	2012	2011	2010	2009
Consolidated Statement of Operations Data:					
(000's except per share data)					
Revenues	\$29,226	\$25,828	\$43,062	\$ 45,676	\$ 32,196
Gross profit	15,976	13,040	31,371	36,655	23,002
Operating expenses	10,101	10,231	8,442	35,482	36,165
Interest expense	25	—	12	4,838	8,851
Net income (loss)	\$ 6,704	\$ 9,917	\$20,527	\$(21,831)	\$(21,870)
Income (loss) per common share-basic and diluted					
Basic	\$ 0.59	\$ 0.91	\$ 1.90	\$ (2.38)	\$ (3.10)
Diluted	\$ 0.52	\$ 0.26	\$ 1.73	\$ (2.38)	\$ (3.10)
Weighted average number of common shares outstanding:					
Basic	11,259	10,914	10,791	9,183	7,045
Diluted	11,273	11,063	11,569	9,183	7,045
Consolidated Balance Sheet Data:					
(000's)					
Working capital	\$25,930	\$32,157	\$27,500	\$ 1,997	\$ 14,256
Total assets	60,092	36,869	36,083	29,859	43,757
Notes payable	3,995	—	—	—	32,966
Long-term portion of financing agreements	—	—	—	—	15,234
Contingently redeemable series C preferred stock	550	550	600	600	600
Shareholders' equity (deficiency)	46,878	31,365	20,631	(20,514)	(17,824)

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial data included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review Item 1A of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Company Overview

We have historically been in the business of developing, licensing, manufacturing and selling to our marketing partner’s pharmaceutical products that utilize proprietary drug delivery technologies to treat various medical conditions. Presently, our focus is on the supply of CRINONE to our marketing partner and in providing pharmaceutical development, clinical trial manufacturing, and advanced analytical and consulting services to the pharmaceutical industry through our newly acquired wholly-owned subsidiary, Molecular Profiles Limited (“Molecular Profiles”).

On September 12, 2013, we acquired all of the outstanding capital stock of Molecular Profiles, a U.K.-based pharmaceutical development services company. The main service lines that have been added to our portfolio as a result of the acquisition include:

- Pharmaceutical Development Services – Preformulation and Chemistry Manufacturing and Controls (“CMC”), solid state form optimization and formulation development.
- Clinical Trial Manufacturing Services – Manufacturing of tablets, capsules, topicals, dry powder inhaled products (“DPI’s”) and liquids.
- Advanced Analytical and Consulting Services – Detailed analytical characterization to support pharmaceutical development, troubleshooting process issues, materials characterization, and testing and consultancy relating to intellectual property.

The acquisition expands our business model and customer base while diversifying our revenue stream. With the addition of Molecular Profiles, we have broadened our technical expertise in the field of pharmaceutical development and analytical services. As a result of the transaction, former Molecular Profiles stockholders, in the aggregate, received as consideration for their shares of Molecular Profiles common stock \$16.7 million in cash and 1,051,323 shares of our common stock. The total consideration is valued at \$24.0 million, based upon the closing price of our common stock adjusted for a discount for lack of marketability on September 12, 2013. This transaction was considered a business acquisition for accounting purposes and all operating activities have been transferred to the Nottingham, United Kingdom location.

We have a history of developing and marketing products: five bioadhesive vaginal gel products that provide patient friendly solutions for infertility, pregnancy support, amenorrhea, and other women’s health conditions, and a testosterone bioadhesive buccal system for male hypogonadism. Our primary product is CRINONE 8% (progesterone gel). We have licensed CRINONE to Merck Serono, internationally, and sold the rights to CRINONE to Actavis, Inc. in the United States.

Currently, we sell CRINONE 8% to Merck Serono at a price determined on a country-by-country basis that is the greater of (i) thirty percent (30%) of the net selling price in the country, or (ii) our direct manufacturing cost plus 20%. Certain quantity discounts apply to annual purchases over 10 million, 20 million, and 30 million units.

On April 4, 2013, our license and supply agreement with Merck Serono for the sale of CRINONE 8% outside the U.S. was renewed for an additional five year term, extending the expiration date from May 19, 2015 to May 19, 2020.

Under the terms of the amended license and supply agreement, we will continue to sell CRINONE to Merck Serono on a country-by-country basis at the greater of (i) cost plus 20% or (ii) a percentage of Merck Serono's net selling price. From 2014 through 2020, the percentage of net selling price will be determined based on a tiered structure. As sales volumes increase our percentage of incremental sales will decrease. These thresholds have been agreed to in order to incentivize Merck Serono to continue to develop existing markets and to enter new markets. Additionally, the parties will jointly cooperate to evaluate and implement manufacturing cost reduction measures, with both parties sharing any reductions realized from these initiatives. If, at the end of the supply term, the parties cannot agree upon mutually acceptable terms for renewal of the supply arrangement, Merck Serono may elect to retain a license to the product and will have an irrevocable fully paid up license to the product.

From July 2010 to November 2013 we manufactured and sold products to Actavis at our cost plus 10%; the revenues generated from these sales were recorded within product revenues from a related party. Due to a build-up of inventory by Actavis in advance of filing for FDA approval of 8% progesterone gel for use in the prevention of preterm birth in women with premature cervical shortening, and Actavis' decision, in light of the FDA's denial of our application and Actavis' subsequent appeal, not to continue development of the proposed indication, Actavis had sufficient inventories of CRINONE; therefore, there were no orders in 2013. In November 2013, we entered into an early termination of our exclusive supply agreement with Actavis. The early termination of the agreement, which would have otherwise terminated in May 2015, provided for us to receive a one-time payment as a termination fee as well as payment for all raw materials purchased by us to meet forecast requirements. Pursuant to the Purchase and Collaboration Agreement, we will continue to be eligible to receive royalties until July 2, 2020 equal to a minimum of 10% of annual net sales by Actavis for annual net sales up to \$150 million, 15% for sales above \$150 million but less than \$250 million; and 20% for annual net sales of \$250 million and over.

Future recurring revenues will be derived from product sales to Merck Serono, royalty streams from Actavis and from pharmaceutical development contracts and analytical and consulting services provided through our wholly-owned subsidiary Molecular Profiles. 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. Because products shipped to Merck Serono occur only in full batches, quarterly sales can vary widely and affect comparisons with prior periods and may not correlate to our customers' in-market sales. Likewise, our revenues from Molecular Profiles are driven by obtaining and retaining our customer contracts and may vary widely from quarter to quarter.

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 us, in the case of the products supplied for resale in the United States. Because our foreign subsidiaries recognize these sales and are reduced only by our product manufacturing costs, we have historically shown a profit from our foreign operations.

Workforce Reduction and Corporate Office Relocation

On March 1, 2012, we announced a 42% workforce reduction from 24 employees at December 31, 2011 to 14 employees. We recorded a severance charge of approximately \$1.4 million for the year ended December 31, 2012. The reduction impacted research and development and general and administrative positions.

During the year ended December 31, 2013, we relocated our corporate facilities from Livingston, New Jersey to Boston, Massachusetts. On March 15, 2013, we entered into a lease agreement for our new location in Boston. This lease has provided a significant cost saving compared to the lease for our corporate facilities in

Livingston, which expired in October 2013. We have completed our process of hiring employees for the staff of our Boston office, which is comprised of accounting and finance and other administrative staff. We incurred a charge of \$0.7 million for the year ended December 31, 2013, related to severance and other relocation costs associated with the elimination of certain positions at the Livingston location. With the relocation now complete, going forward we expect reduced personnel and other related costs associated with our headquarters.

Revenues

We generate revenues primarily from sales of our products and services and from a royalty stream and certain other revenues. During the year ended December 31, 2013, we derived approximately 73% of our revenues from sales of our products, 12% from the sales of our services and 15% from our royalty stream and certain other revenues. During the year ended December 31, 2012, we derived approximately 86% of our revenues from the sale of our products and 14% of our revenues from royalty stream and certain other revenues. During the year ended December 31, 2011, we derived approximately 42% of our revenues from the sale of our products and 58% of our revenues from royalty stream and certain other revenues. Generally, we recognize revenues from the sales of our products upon delivery to our customers and revenues from service as the work is performed.

We sell our products directly through our partner Merck Serono and use a sales force to sell our services worldwide. During the years ended December 31, 2013, 2012 and 2011, we derived 81%, 67% and 34% of our total revenues, respectively, from sales outside North America. As of December 31, 2013, we had 7 sales employees covering territories worldwide based in the United Kingdom.

Cost of Product Revenues

Our cost of product revenues consists primarily of material, labor, consulting, manufacturing overhead expenses, cost of components and subassemblies supplied by third party suppliers. Cost of revenues also includes depreciation expense for certain equipment used for the manufacturing of our products.

Cost of Service Revenues

Our cost of service revenues consists primarily of labor, consulting, overhead expenses and personnel costs associated with the production and service projects being undertaken by technicians and laboratory employees. Cost of service revenues also includes depreciation expense for certain equipment and facilities used for the manufacturing and laboratory space of our products and services as well as amortization expense for the developed technology, an intangible asset identified as a part of the Molecular Profiles acquisition.

Sales and Marketing Expenses

In 2013, sales and marketing expenses are attributable to the sales activities of our newly acquired subsidiary, Molecular Profiles, acquired on September 12, 2013. These costs include personnel and other administrative costs associated with employees directly attributable to sales and marketing functions. There were no selling and marketing costs in 2012 as a result of the elimination of this function in 2011. In 2011, these expenses represented selling and distribution costs related to our STRIANT product. We expect our selling and marketing expenses to increase in 2014 as a result of incorporating a full year of operations from Molecular Profiles.

Research and Development Expenses

Historically research and development expenses have included costs for product development, clinical development and regulatory fees, which were a combination of internal and third-party costs. There were no research and development expenses in 2013 because we eliminated our research and development activities. Currently we have not committed to any research and development expenditures in 2014.

Acquisition Related Expenses

Our acquisition related expenses for 2013 were costs associated with the September 12, 2013 acquisition of Molecular Profiles and a failed transaction in the first quarter of 2013.

General and Administrative Expenses

General and administrative costs include payroll, employee benefits, equity compensation, and other personnel-related costs associated with administrative and support staff, as well as legal costs and other administrative fees. In 2012, general and administrative expenses also includes the one-time charge of \$0.9 million for the write-down of certain assets due to the determination that certain capacity was no longer needed at our contract manufacturer in Switzerland, Maropack. As a result of our acquisition of Molecular Profiles in September 2013, we expect our general and administrative expenses to increase in absolute dollars but remain consistent as a percentage of revenues in 2014.

Net Gain on U.S. Sale of STRIANT

We recorded a one-time gain of \$2.5 million on the U.S. sale of STRIANT to Auxilium in 2011.

Interest Income (Expense), net

Historically interest income consists primarily of interest earned on our short-term marketable securities consisting of U.S. Treasury and agency securities. In 2013, the company sold its short-term marketable securities. Subsequent interest income is derived from interest bearing bank accounts. Interest expense consists of interest payments associated with the debt assumed as a part of the acquisition of Molecular Profiles. The debt assumed is a mortgage on the facilities that we own in Nottingham.

Change in the Fair Value of Common Stock Warrants

We account for our warrants in accordance with “EITF Issue No. 00- 19” Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in a Company’s Own Stock” (“ASC 815-40”) which requires warrants to be classified as permanent equity, temporary equity or as assets or liabilities. Our warrants are classified as liabilities because they include a provision that specifies that we must deliver freely tradable shares upon exercise by the warrant holder. Because there are circumstances, irrespective of likelihood that may not be within our control, that could prevent delivery of registered shares, EITF 00-19 requires the warrants be recorded as a liability at fair value, with subsequent changes in fair value recorded as income or expense in our Consolidated Statements of Operations. The fair value of our warrants is determined using a Black-Scholes option pricing model, and is affected by changes in inputs to that model including our stock price, expected stock price volatility and contractual term.

Other Income (Expense), net

Other income (expense), net consists primarily of foreign currency re-measurement gains or losses and other miscellaneous income and expense items.

Provision for Income Taxes

The Company operates in multiple countries and the need for a valuation allowance is evaluated on an individual jurisdiction basis. As of December 31, 2013, we continue to maintain a full valuation allowance on all net domestic deferred tax assets. The utilization of deferred tax assets in the United Kingdom was determined to be more likely than not and a net deferred tax asset of \$0.6 million has been recorded as of December 31, 2013.

Valuation allowances are provided if, based on the weight of available evidence, it is more-likely-than-not that some or all of the deferred tax assets will not be realized. We will continue to monitor the need for valuation allowances in each jurisdiction, and may adjust our positions in the future based on actual results.

Results of Operations

Years Ended December 31, 2013 and 2012

The following tables contain selected statement of operations information, which serves as the basis of the discussion surrounding our results of operations for the years ended December 31, 2013 and 2012:

	Year Ended December 31,		Year Ended December 31,		\$ Change	% Change
	2013		2012			
	Amount	As a % of Total Revenues	Amount	As a % of Total Revenues		
Product revenues	\$21,336,458	73%	\$22,230,473	86%	\$ (894,015)	(4)%
Service revenues	3,640,453	13	—	—	3,640,453	100
Royalties	3,830,664	13	3,459,852	13	370,812	11
Other revenues	418,877	1	138,052	1	280,825	203
Total revenues	29,226,452	100	25,828,377	100	3,398,075	13
Cost of product revenues	10,903,459	37	12,788,264	50	(1,884,805)	(15)
Cost of service revenues	2,347,426	8	—	—	2,347,426	100
Total cost of revenues	13,250,885	45	12,788,264	50	462,621	4
Gross profit	15,975,567	55	13,040,113	50	2,935,454	23
Operating expenses:						
Sales and marketing	438,950	2	—	—	438,950	100
Research and development (net of reimbursement from related party: 2012 – \$435,199)	—	—	770,642	3	(770,642)	(100)
Acquisition related expenses	1,623,368	6	—	—	1,623,368	100
General and administrative	8,038,283	28	9,459,963	37	(1,421,680)	(15)
Total operating expenses	10,100,601	35	10,230,605	40	(130,004)	(1)
Income from operations	5,874,966	20	2,809,508	11	3,065,458	109
Interest income, net	71,279	—	238,033	1	(166,754)	(70)
Change in fair value of common stock warrants	794,280	3	6,995,099	27	(6,200,819)	(89)
Other expense, net	(14,187)	—	(122,660)	—	108,473	88
Income before income taxes	6,726,338	23	9,919,980	38	(3,193,642)	(32)
Provision for income taxes	22,564	—	2,707	—	19,857	734
Net income	\$ 6,703,774	23%	\$ 9,917,273	38%	\$(3,213,499)	(32)%

Revenues

	Year Ended December 31,		\$ Change	% Change
	2013	2012		
Product revenues	\$21,336,458	\$22,230,473	\$ (894,015)	(4)%
Service revenues	3,640,453	—	3,640,453	100
Royalties	3,830,664	3,459,852	370,812	11
Other revenues	418,877	138,052	280,825	203
Total revenues	<u>\$29,226,452</u>	<u>\$25,828,377</u>	<u>\$3,398,075</u>	<u>13%</u>

Revenues for the year ended December 31, 2013 increased by \$3.4 million, or 13%, as compared to the year ended December 31, 2012. The increase was primarily attributable to the following factors:

- Revenues from the sale of products decreased by approximately \$0.9 million, or 4%, from the 2012 period primarily due to the absence of product revenues from Actavis in the year ended December 31, 2013 as compared with \$4.3 million in the year ended December 31, 2012 due to sufficient inventory on hand at Actavis in 2013 and the termination of the supply agreement in the fourth quarter of 2013. This was offset by higher revenues from Merck Serono in the year ended December 31, 2013 as compared with the year ended December 30, 2012. Higher revenues from Merck Serono are a result of a 24% increase in volume year-over-year.
- Service revenues of \$3.6 million in the 2013 period were from the pharmaceutical development, consulting and analytic services offered by our wholly-owned subsidiary Molecular Profiles, which was acquired in September 2013.
- Royalty revenues increased \$0.4 million, or 11%, for the year ended December 31, 2013 as compared to the year ended December 31, 2012 driven by higher sales of progesterone products by Actavis.
- Other revenues in the year ended December 31, 2013, increased by \$0.3 million primarily due to a one-time payment associated with the termination of the supply agreement with Actavis in the fourth quarter of 2013.

Cost of revenues

	Year Ended December 31,		\$ Change	% Change
	2013	2012		
Cost of product revenues	\$10,903,459	\$12,788,264	\$(1,884,805)	(15)%
Cost of service revenues	2,347,426	—	2,347,426	100
Total cost of revenues	<u>\$13,250,885</u>	<u>\$12,788,264</u>	<u>\$ 462,621</u>	<u>4%</u>
Total cost of revenues (as a percentage of total revenues)	45%	50%		

Total cost of revenues were \$13.3 million and \$12.8 million for the years ended December 31, 2013 and 2012, respectively. Cost of product revenues decreased due to a more favorable sales mix. This was offset by cost of service revenues primarily made up of technician, labor and other materials purchased associated with the services offered from Molecular Profiles.

Sales and marketing

	<u>Year Ended December 31,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2013</u>	<u>2012</u>		
Sales and marketing	\$438,950	\$—	\$438,950	100%
Sales and marketing (as a percentage of total revenues)	2%	— %		

Sales and marketing expenses generated during the year ended December 31, 2013 are attributable to the sales activities of our newly acquired subsidiary, Molecular Profiles, acquired on September 12, 2013.

Research and development

	<u>Year Ended December 31,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2013</u>	<u>2012</u>		
Research and development	\$—	\$770,642	\$(770,642)	(100)%
Research and development (as a percentage of total revenues)	— %	3%		

There were no research and development expenses in the year ended December 31, 2013 because we have eliminated our research and development activities. Research and development expenses of \$0.8 million in 2012 included costs for product development, clinical development and regulatory fees, which were a combination of internal and third-party costs.

Acquisition related expenses

	<u>Year Ended December 31,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2013</u>	<u>2012</u>		
Acquisition related expenses	\$1,623,368	\$—	\$1,623,368	100%
Acquisition related expenses (as a percentage of total revenues)	6%	— %		

Total acquisition related expenses of \$1.6 million in 2013 were costs associated with the Molecular Profiles acquisition and a failed transaction in the first quarter of 2013. These costs were primarily made up of legal costs, accounting fees and other professional fees.

General and administrative

	<u>Year Ended December 31,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2013</u>	<u>2012</u>		
General and administrative	\$8,038,283	\$9,459,963	\$(1,421,680)	(15)%
General and administrative (as a percentage of total revenues)	28%	37%		

Total general and administrative expenses decreased by \$1.4 million to \$8.0 million for the year ended December 31, 2013, compared with \$9.5 million for the year ended December 31, 2012. This decrease is due to lower personnel costs associated with the workforce reduction in January 2013. In addition, the 2012 period included a one-time expense of \$0.9 million for the write-down of certain assets.

Non-operating income and expense

	Year Ended December 31,		\$ Change	% Change
	2013	2012		
Interest income, net	\$ 71,279	\$ 238,033	\$ (166,754)	(70)%
Change in fair value of common stock				
warrants	\$794,280	\$6,995,099	\$(6,200,819)	(89)%
Other expense, net	\$ (14,187)	\$ (122,660)	\$ 108,473	88%

The decrease in interest income, net primarily relates to the realized gain on the sale of our marketable securities during the 2013 period offset by interest expense associated with the debt assumed as a part of the acquisition of Molecular Profiles in September 2013. The debt assumed is a mortgage on the facilities that are owned in Nottingham, United Kingdom.

The income of \$0.8 million associated with the change in fair value of stock warrants for the year ended December 31, 2013 is related to the October 2009 stock issuance and resulted from an stabilization of the volatility rate used in our Black-Scholes model as the warrants arrive closer to their expiration date. The change in fair value of stock warrants for the year ended December 31, 2012 resulted in \$7.0 million in income associated with a decrease in our stock price during 2012.

Other expense, net, for the year ended December 31, 2013 decreased primarily due to lower net foreign currency transaction losses related to the strengthening of the euro and the British pound against the U.S. dollar in 2013 as compared with 2012.

Provision for income taxes

	Year Ended December 31,		\$ Change	% Change
	2013	2012		
Provision for income taxes	\$22,564	\$2,707	\$19,857	734%
Provision as a percentage of income before provision for income taxes	0.3%	0.03%		

The difference in our effective tax rate between the years ended December 31, 2013 and 2012 of 0.3% and 0.03%, respectively, is due to the foreign tax expense in 2013 and state true-up adjustments in 2012. The 2013 effective tax rate represents state minimum taxes owed and foreign tax expense calculated on the investment in a foreign subsidiary. All other items are offset by tax net operating loss carryforwards which are offset by a full valuation allowance.

Years Ended December 31, 2012 and 2011

The following tables contain selected statement of operations information, which serves as the basis of the discussion surrounding our results of operations for the years ended December 31, 2012 and 2011:

	Year Ended December 31,					
	2012		2011		\$ Change	% Change
	Amount	As a % of Total Revenues	Amount	As a % of Total Revenues		
Product revenues	\$22,230,473	86%	\$17,977,608	42%	\$ 4,252,865	24%
Royalties	3,459,852	13	2,970,980	7	488,872	16
Other revenues	138,052	1	22,113,433	51	(21,975,381)	(99)
Total revenues	25,828,377	100	43,062,021	100	(17,233,644)	(40)
Cost of product revenues	12,788,264	50	11,691,365	27	1,096,899	9
Gross profit	13,040,113	50	31,370,656	73	(18,330,543)	(58)
Operating expenses:						
Sales and marketing	—	—	87,669	—	(87,669)	(100)
Research and development (net of reimbursement from related party: 2012 – \$435,199; 2011 – \$3,196,601	770,642	3	2,779,058	6	(2,008,416)	(72)
General and administrative . . .	9,459,963	37	8,108,194	19	1,351,769	17
Net gain on U.S. sale of STRIANT	—	—	(2,533,127)	(6)	2,533,127	100
Total operating expenses	10,230,605	40	8,441,794	20	1,788,811	21
Income from operations	2,809,508	11	22,928,862	53	(20,119,354)	(88)
Interest income, net	238,033	1	95,146	—	142,887	150
Change in fair value of common stock warrants	6,995,099	27	(2,164,543)	(5)	9,159,642	423
Other income (expense), net	(122,660)	—	(292,991)	(1)	170,331	58
Income before income taxes	9,919,980	38	20,566,474	48	(10,646,494)	(52)
Provision for income taxes	2,707	—	39,282	—	(36,575)	(93)
Net income	\$ 9,917,273	38%	\$20,527,192	48%	\$(10,609,919)	(52)%

Revenues

	Year Ended December 31,		\$ Change	% Change
	2012	2011		
Product revenues	\$22,230,473	\$17,977,608	\$ 4,252,865	24%
Royalties	3,459,852	2,970,980	488,872	16
Other revenues	138,052	22,113,433	(21,975,381)	(99)
Total revenues	\$25,828,377	\$43,062,021	\$(17,233,644)	(40)%

Revenues for the year ended December 31 2012 decreased by \$17.2 million, or 40%, as compared to the year ended December 31, 2011. The decrease was primarily attributable to the following factors:

- Revenues from the sale of products increased by \$4.3 million, or 24%, from the 2011 period. The increase was primarily due to a 17% increase in product revenues from Merck Serono for international sales of CRINONE 8% combined with a 35% increase of product revenues from Actavis for domestic sales of CRINONE over 2011 levels.
- Royalty revenues increased by \$0.5 million, or 16%, from the 2011 period. The increase was due to higher royalty revenues from Actavis on Progesterone related sales.
- Other revenues in the year ended December 31, 2012, decreased by \$22.0 million, or 99%. The decrease was due to the recognition in 2011 of \$17.0 million in revenue related to the gain on the sale of the progesterone assets to Actavis and a \$5.0 million milestone payment from Actavis for the acceptance for filing of NDA 22-139 by the FDA.

Cost of revenues

	<u>Year Ended December 31,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2012</u>	<u>2011</u>		
Cost of product revenues	\$12,788,264	\$11,691,365	\$1,096,899	9%
Cost of product revenues (as a percentage of total revenues)	50%	27%		

Total cost of revenues were \$12.8 million and \$11.7 million for the years ended December 31, 2012 and 2011, respectively. The \$1.1 million increase was primarily attributed to higher product revenues and a less favorable product mix.

Sales and marketing

	<u>Year Ended December 31,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2012</u>	<u>2011</u>		
Sales and marketing	\$—	\$87,669	\$(87,669)	(100)%
Sales and marketing (as a percentage of total revenues) . . .	— %	— %		

There were no sales and marketing expenses in the year ended December 31, 2012 as a result of the elimination of our sales and marketing organization following the closing of the Actavis transaction in 2010 and the sale of STRIANT to Auxilium in April 2011. In 2011, these expenses represented selling and distribution costs related to STRIANT.

Research and development

	<u>Year Ended December 31,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2012</u>	<u>2011</u>		
Research and development	\$770,642	\$2,779,058	\$(2,008,416)	(72)%
Research and development (as a percentage of total revenues)	3%	6%		

Total research and development expenses decreased by \$2.0 million to \$0.8 million for the year ended December 31, 2012 as a result of the workforce reduction that took place in the first quarter of 2011.

General and administrative

	Year Ended December 31,		\$ Change	% Change
	2012	2011		
General and administrative	\$9,459,963	\$8,108,194	\$1,351,769	17%
General and administrative (as a percentage of total revenues)	37%	19%		

Total general and administrative expenses for the year ended December 31, 2012 increased by \$1.4 million or 17%, as compared to the year ended December 31, 2011. The increase was primarily due to severance costs associated with the workforce reduction of \$1.4 million and a one-time expense of \$0.9 million for the write-down of certain assets.

Net gain on U.S. sale of STRIANT

	Year Ended December 31,		\$ Change	% Change
	2012	2011		
Net gain on U.S. sale of STRIANT	\$—	\$(2,533,127)	\$2,533,127	100%
Net gain on U.S. sale of STRIANT (as a percentage of total revenues)	— %	(6)%		

On April 20, 2011, we entered into an asset purchase agreement (“Asset Purchase Agreement”) and a license agreement (“License Agreement”) with Auxilium Pharmaceuticals, LLC (“Auxilium”), Lake Forest, IL, relating to the sale of certain assets and the licensing of certain intellectual property related to STRIANT® (testosterone buccal system), (“STRIANT”) in the United States. Under the Asset Purchase Agreement, we sold to Auxilium certain assets primarily related to STRIANT in the United States, its territories, and possessions (“Territory”), including, but not limited to the STRIANT NDA and other regulatory approvals in the Territory; the STRIANT trademark, trade dress and other promotional materials used primarily to promote, market and sell STRIANT in the Territory; on-hand STRIANT inventories as of the closing; and other ancillary assets and rights. In consideration of the assets and rights acquired under the Asset Purchase Agreement, we received a one-time payment at closing of \$3.1 million from Auxilium. We recognized a gain in the second quarter of 2011 of \$2.5 million on the sale of STRIANT, net of the transfer of inventory, fixed assets related to STRIANT, and the residual prepaid FDA fees.

Non-operating income and expense

	Year Ended December 31,		\$ Change	% Change
	2012	2011		
Interest income, net	\$ 238,033	\$ 95,146	\$ 142,887	150%
Change in fair value of common stock warrants	\$6,995,099	\$(2,164,543)	\$9,159,642	423%
Other expense, net	\$ (122,660)	\$ (292,991)	\$ 170,331	58%

Interest income, net increased by \$0.1 million for the year ended December 31, 2012. The increase primarily related to an increase in both interest bearing cash and cash equivalents and short term investments.

Change in fair value of stock warrants for the year ended December 31, 2012 was due to \$7.0 million of income associated with the fair value of the warrants issued in conjunction with the October 2009 stock issuance and resulted from a decrease in our stock price during the period.

Change in fair value of stock warrants for the year ended December 31, 2011 included \$2.2 million of expense related to the recognition of the change in fair value of the redeemable warrants issued in conjunction with the July 2010 convertible note retirement, resulting from an increase in our stock price during 2011.

Other expense, net decreased by \$0.2 million for the year ended December 31, 2012. The decrease was primarily due to a result of lower net foreign currency re-measurement losses related to the strengthening of the euro and the British pound against the U.S. dollar in the 2012 period as compared with the 2011 period.

Provision for income taxes

	Year Ended December 31,		\$ Change	% Change
	2012	2011		
Provision for income taxes	\$2,707	\$39,282	\$(36,575)	(93)%
Provision as a percentage of income before provision for income taxes	0.03%	0.2%		

The difference in the effective tax rate between the years ended December 31, 2011 and 2012 of 0.03% and 0.2% respectively, was due to state tax adjustments in 2011 and 2012. The 2012 effective tax rate represented state minimum taxes owed. All other items are offset by tax net operating loss carryforwards which are offset by a full valuation allowance.

Impact of Restatement on Quarterly Results of Operations.

During the first quarter of 2014, we determined that our previously issued consolidated financial statements for the three and nine month periods ended September 30, 2013 should be restated to revise conclusions regarding the calculation of our common stock warrant expense.

The Restatement resulted in a \$4.9 million adjustment to the value of the common stock warrant liability, resulting in a gain being recorded for the change in fair value of stock warrants of \$0.4 million and \$0.5 million for the three and nine month periods ending September 30, 2013. A restatement of our previously reported net loss for the three month period ended September 30, 2013, resulted in net income of \$1.7 million, for such period. A Restatement of our previously reported net income for the nine month period ended September 30, 2013, resulted in net income of \$5.6 million, for such period. We have determined that this Restatement described only affects the three and nine month periods ending September 30, 2013 as described and has no impact on any other previously issued unaudited interim consolidated financial statements. The restatement did not affect liquidity or capital resources for any interim period. (see Note 15 “Restatement of Unaudited Interim Consolidated Financial Statements”).

Liquidity and Capital Resources

We require cash to pay our operating expenses, fund working capital needs, make capital expenditures and fund acquisitions. Historically, we have funded our operations through cash generated from our operations.

On September 12, 2013, we acquired all of the outstanding capital stock of Molecular Profiles. As a result of the transaction, former Molecular Profiles stockholders, in the aggregate, received as consideration for their shares of Molecular Profiles common stock \$16.7 million in cash and 1,051,323 shares of our common stock. The total consideration is valued at \$24.0 million, based upon the closing price of our common stock adjusted for a discount for lack of marketability on September 12, 2013.

At December 31, 2013, our cash and cash equivalents were \$20.7 million. Our cash and cash equivalents are highly liquid investments with original maturities of 90 days or less at date of purchase and consist of cash in operating accounts.

Our future capital requirements depend on a number of factors, including the rate of market acceptance of our current and future products and the resources we devote to developing and supporting our products.

Excluding the \$12.0 million of property and equipment acquired as part of our acquisition of Molecular Profiles, our capital expenditures decreased for the year ended December 31, 2013, as compared to the year ended December 31, 2012, primarily as a result of completing, during 2012, the addition of increased manufacturing capacity to ensure our ability to meet Actavis' forecasts for the anticipated launch of progesterone vaginal gel 8% for preterm birth in women with premature cervical shortening and facility improvements to ensure compliant manufacturing operations. We expect our capital expenditures to increase in the year ended December 31, 2014 as compared to the year ended December 31, 2013 primarily due to investments made within our Nottingham United Kingdom location.

As of December 31, 2013, we had 279,198 exercisable options, and 1,236,682 exercisable warrants outstanding that, if exercised, would result in approximately \$17.7 million of additional capital and would cause the number of shares outstanding to increase; provided, however, that the cashless exercise feature of certain warrants will result in no cash to us. There can be no assurance that any such options or warrants will be exercised. The intrinsic value of exercisable options at December 31, 2013 was \$17,000. There was no intrinsic value associated with the warrants outstanding at December 31, 2013.

On August 9, 2013, the Company effected a 1-for-8 reverse stock split, which was previously approved by the Board of Directors on July 26, 2013. Our reverse stock split was approved by our stockholders at our annual meeting of stockholders on May 1, 2013. All share and per share amounts relating to the common stock, stock options and warrants included in the financial statements and accompanying footnotes have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an equal amount to the reduction in par value of common stock to additional paid-in capital. The reverse stock split did not result in a retroactive adjustment to the share amounts for any of the classes of our preferred stock.

We believe that our current cash and cash equivalents, as well as cash generated from operations, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for the foreseeable future.

Cash Flows

Net cash provided by operating activities for the year ended December 31, 2013 was \$7.1 million and resulted primarily from \$6.7 million of net income for the period, increased by approximately \$1.4 million in depreciation and amortization and stock-based compensation expense, partially offset by \$0.8 million from the change in fair value of stock warrants. Net changes in working capital items reduced cash from operating activities by approximately \$0.3 million, primarily due to an increase in accounts receivable of \$2.4 million associated with increased product shipments and a decrease in accrued expense of \$0.8 million, offset by a decrease in amounts due from related party totaling \$1.3 million primarily related to the absence of product shipments to Actavis and a decrease in prepaid expenses and other current assets of \$1.4 million. Net cash provided by investing activities was \$0.3 million for the year ended December 31, 2013, which resulted primarily from the proceeds from the sale of short-term investments totaling \$15.4 million partially offset by the net cash paid for the Molecular Profiles acquisition of \$14.5 million and the purchase of property and equipment of \$0.5 million. Net cash used in financing activities was \$0.1 million for the year ended December 31, 2013, primarily due to \$0.1 million of principal payments on notes payable.

Net cash provided by operating activities for the year ended December 31, 2012 was \$4.3 million and resulted primarily from \$9.9 million of net income for the period, increased by approximately \$1.3 million in depreciation and amortization and stock-based compensation expense as well as \$1.0 million related to the write-off of certain inventories and \$0.9 million for write-down of impaired assets, and decreased by \$7.0 million for the change in fair value of stock warrants and \$0.6 million from the increase in provision for sales returns. Net changes in working capital items reduced cash from operating activities by \$1.1 million, primarily relating to a decrease in accounts payable and accrued expense of \$2.7 million and an increase of prepaid expenses and other

current assets of \$0.6 million partially offset by a decrease of accounts receivable of \$1.8 million and other non-current assets of \$0.4 million. Net cash used in investing activities for the year ended December 31, 2012 was \$1.2 million resulting from the purchase of property and equipment of \$1.0 million and the purchase of short-term investments of \$0.2 million. Net cash used in financing activities was \$0.1 million for the year ended December 31, 2012, due to \$0.1 million associated with the redemption of series C convertible preferred stock.

Contractual Obligations

In July 2010, we terminated the STRIANT Agreement with PharmaBio. PharmaBio retains the warrant to purchase 112,500 shares of common stock at \$9.20 per share, which expires on November 22, 2014.

In October 2009, we raised approximately \$11.8 million in gross proceeds from the issuance and sale of 1,362,500 shares of our common stock at a price of \$8.64 per share and warrants to purchase 681,275 shares of our common stock with an exercise price of \$12.16 per share in a registered offering. The warrants became exercisable on April 30, 2010, and expire on April 30, 2015, unless earlier exercised or terminated.

In July 2010, we purchased approximately \$40 million in aggregate principal amount of our outstanding Notes. The aggregate purchase price for the Notes was approximately \$26 million in cash (plus accrued and unpaid interest through but excluding the date of the closing of the Note purchases), warrants to purchase 968,750 shares of common stock with an exercise price of \$10.80 per share and 925,925 shares of our common stock. The warrants issued under the Note Purchase Agreements are exercisable, subject to the limitations set forth therein, until July 2, 2015, unless earlier exercised or terminated as provided in such warrants.

Our significant outstanding contractual obligations relate to operating leases for our facilities that are not owned and debt assumed as a result of the acquisition of Molecular Profiles on September 12, 2013. Our facility leases are non-cancellable and contain renewal options. Our future contractual obligations include the following:

	<u>Total</u>	<u>1 year or less</u>	<u>1-3 years</u>	<u>3-5 years</u>	<u>More than 5 years</u>
Operating lease obligations	\$ 249,278	\$104,785	\$144,493	\$ —	\$ —
Loan agreements	3,995,437	250,162	522,594	554,689	2,667,992
Total	<u>\$4,244,715</u>	<u>\$354,947</u>	<u>\$667,087</u>	<u>\$554,689</u>	<u>\$2,667,992</u>

As part of the acquisition of Molecular Profiles, we assumed a \$2.5 million obligation under a grant arrangement with the Regional Growth Fund on behalf of the Secretary of State for Business, Innovation, and Skills in the United Kingdom. Molecular Profiles used this grant to fund the building of their second facility, which includes analytical labs, office space, and a manufacturing facility. As a part of the arrangement, Molecular Profiles is required to create and maintain certain full-time equivalent personnel levels through October 2017. As of December 31, 2013, Molecular Profiles is in compliance with the covenants of the arrangement.

The income from the Regional Growth Fund will be recognized on a decelerated basis over the next four years. As of December 31, 2013, the obligation is valued at \$2.6 million due to foreign currency revaluation and is recorded as deferred revenue on the consolidated balance sheets. The amount of other income on the obligation that will be recognized provided Molecular Profiles remains in compliance with the covenants will be the following:

<u>Year</u>	<u>Total</u>
2014	\$ 329,820
2015	593,676
2016	857,532
2017	791,568
Total	<u>\$2,572,596</u>

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations set forth above are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates and judgments, including those described below. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities, and the reported amounts of revenues and expenses, that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies require significant judgment and estimates by us in the preparation of our financial statements.

Revenue Recognition

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. In addition, revenue recognition determines the timing of certain expenses. Because products shipped to our one major customer occurs only in full batches and because services provided by our services business are primarily provided under discrete short-term contracts, quarterly sales can vary widely and affect quarter to quarter comparisons and may not correlate to our customers' in-market sales.

Revenues from the sale of products are recorded at the time goods were shipped to customers. The Company believes it has not made any shipments in excess of its customers' ordinary course of business inventory levels.

Revenues from our pharmaceutical drug services business are recorded as multiple-element arrangements and are evaluated in accordance with the principles of Accounting Standards update ("ASU") 2009-13, (*Revenue Recognition Topic – Multiple Element Arrangements*) and we allocate revenue among the elements based upon each element's relative fair value. These amounts are recognized as revenue as the service for each element is performed.

Amounts paid but not yet earned on a project are recorded as deferred revenue until such time as performance is rendered or the obligation to perform the service is completed.

When a sale includes performance of multiple services, we allocate revenue derived from each such service to a unit of accounting based on its relative selling price, and recognize revenue for each such unit of accounting when the revenue recognition criteria for such unit have been met. The Company follows the selling price hierarchy as outlined in the guidance Revenue Recognition (ASC Topic 605) – Multiple-Deliverable Revenue Arrangements. The guidance provides a hierarchy to determine the selling price to be used for allocating revenue to deliverables: (i) vendor-specific objective evidence ("VSOE"), (ii) third-party evidence ("TPE"), if available, and when VSOE is not available, and (iii) best estimate of the selling price ("BESP"), if neither VSOE nor TPE is available. We use BESP to determine the standalone selling price for our services. We have a process for developing BESP, which incorporates, pricing practices, historical selling prices, the effect of market conditions as well as entity-specific factors. Estimated selling price is monitored and evaluated on a regular basis to ensure that changes in circumstances are accounted for in a timely manner.

Royalty revenues, based on sales by licensees, are recorded as revenues as those sales are made by the licensees.

Deferred revenue recognized as a result of the Actavis transaction was amortized over the remaining research and development period for the PREGNANT study, including the Company's filing with, and the FDA's acceptance of, NDA 22-139 in June 2011. Other deferred revenue is amortized over the life of the underlying agreement.

License fees are recorded over the life of the license.

Inventories and Allowance for Excess and Obsolescence

We state all inventories at the lower of cost or market value, determined on a first-in, first-out method. We monitor standard costs on a monthly basis and update them annually and as necessary to reflect changes in raw material costs and labor and overhead rates. Our inventory balance was \$2.6 million for both the December 31, 2013 and 2012 periods.

We provide inventory allowances when conditions indicate that the selling price could be less than cost due to physical deterioration, usage, obsolescence, reductions in estimated future demand and reductions in selling prices. We balance the need to maintain strategic inventory levels with the risk of obsolescence due to changing technology and customer demand levels. Unfavorable changes in market conditions may result in a need for additional inventory reserves that could adversely impact our gross margins. Conversely, favorable changes in demand could result in higher gross margins when we sell products. Our inventory allowance as of December 31, 2013 was \$0.2 million and as of December 31, 2012 was \$1.1 million.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed in a business combination. We do not amortize our goodwill, but instead test for impairment annually and more frequently whenever events or changes in circumstances indicate that the fair value of the asset may be less than its carrying value of the asset. Our annual test for impairment occurs on the first day in the fourth quarter.

We have adopted ASU 2011-08, *Intangibles—Goodwill and Other*, an amendment to ASC 350, which updates how an entity will evaluate its goodwill for impairment. The guidance provides entities an option to perform a "qualitative" assessment to determine whether further impairment testing is necessary. If further testing is required, the test for impairment continues with the two step process. The first step compares the carrying amount of the reporting unit to its estimated fair value (Step 1). To the extent that the carrying value of the reporting unit exceeds its estimated fair value, a second step is performed, wherein the reporting unit's carrying value is compared to the implied fair value (Step 2). To the extent that the carrying value exceeds the implied fair value, impairment exists and must be recognized.

We have concluded that our business represents one reporting unit for goodwill impairment testing. We have performed our annual test for impairment on the first day of the fourth quarter beginning in 2013. We have determined that our goodwill is not impaired as of December 31, 2013.

Intangible Assets

We capitalize and include in intangible assets the costs of developed technology, customer relationships and trade names. Intangible assets are recorded at fair value and stated net of accumulated amortization and impairments. We amortize our intangible assets that have finite lives using either the straight-line or accelerated

method, based on the useful life of the asset over which it is expected to be consumed utilizing expected undiscounted future cash flows. Amortization is recorded over the estimated useful lives ranging from 3 to 7 years. We evaluate the realizability of our definite lived intangible assets whenever events or changes in circumstances or business conditions indicate that the carrying value of these assets may not be recoverable based on expectations of future undiscounted cash flows for each asset group. If the carrying value of an asset or asset group exceeds its undiscounted cash flows, we estimate the fair value of the assets, generally utilizing a discounted cash flow analysis based on the present value of estimated future cash flows to be generated by the assets using a risk adjusted discount rate. To estimate the fair value of the assets, we use market participant assumptions pursuant to ASC 820, *Fair Value Measurements*. If the estimate of an intangible asset's remaining useful life is changed, we will amortize the remaining carrying value of the intangible asset prospectively over the revised useful life.

Sales Returns

We are only responsible for sales returns for CRINONE and PROCHIEVE products sold prior to the Actavis transaction on July 2, 2010, and for STRIANT sold prior to the sale of the product to Auxilium in April 2011. We are not responsible for returns for international sales. Our policy for sales to the trade made prior to the Actavis and Auxilium transactions 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 assume that our customers are using the first-in, first-out method in filling orders so that the oldest saleable product is used first. We record a provision for returns on a quarterly basis using an estimated rate and adjust the provision when necessary.

Accounting for Fair Value for Common Stock Warrant Liabilities

The estimated fair value of the common stock warrant liability is determined by using the Black-Scholes option pricing model which is based on our stock price at measurement date, exercise price of this warrant, risk-free rate and historical volatility, and are classified as a Level 2 measurement.

Share-Based Compensation

We recognize compensation expense in accordance with ASC 718, "*Share Based Payment*" ("ASC 718"), for all stock-based awards made to employees and directors including employee stock options based on estimated fair values. ASC 718 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 our Consolidated Statements of Operations.

Recent Accounting Pronouncements

None that apply.

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

Market Rate Risk

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.

Foreign Currency Exchange

A significant portion of our operations is conducted through operations in countries other than the United States. Revenues from our international operations that were recorded in U.S. dollars represented approximately 85% of our total international revenues during the year ended December 31, 2013. The remaining 15% of our revenues were in British pounds. Since we conduct our business in U.S. dollars, our main exposure, if any, results from changes in the exchange rate between the British pound and the U.S. dollar. Our functional currency is the U.S. dollar. Our policy is to reduce exposure to exchange rate fluctuations by having most of our assets and liabilities, as well as most of our revenues and expenditures, designated in U.S. dollars, or U.S. dollar linked. We have not historically engaged in hedging activities relating to our non-U.S. dollar operations. We may be exposed to exchange rate fluctuations that occur from certain intercompany transactions with our subsidiaries, which we recognize as unrealized gains and losses in our statements of operations. Upon settlement of these payments, we may record realized foreign exchange gains and losses. We may incur negative foreign currency translation charges as a result of changes in currency exchange rates.

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 on Form 10-K.

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

Not Applicable.

Item 9A. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

In connection with the Restatement described elsewhere in this Annual Report on Form 10-K, management, under the supervision of and with the participation of the Chief Executive Officer and Chief Financial Officer, reevaluated the effectiveness of the Company’s disclosure controls and procedures and has determined that the Company’s disclosure controls and procedures, were not effective as of December 31, 2013.

Management’s Annual Report on Internal Control over Financial Reporting

The Company’s management is responsible for establishing and maintaining adequate system of internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). 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.

The Company's management is responsible for establishing and maintaining an adequate system of internal control over financial reporting and for its assessment of the effectiveness 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.

In connection with the Restatement described elsewhere in this Annual Report on Form 10-K, management, under the supervision of and with the participation of the Chief Executive Officer and Chief Financial Officer, reevaluated the effectiveness, as of December 31, 2013, of the Company's internal control over financial reporting based on the COSO Framework and concluded that, because a material weakness, as discussed below, existed as of December 31, 2013, the Company's internal control over financial reporting was not effective as of December 31, 2013.

A "material weakness," as defined by Rule 12b-2 of the Exchange Act and PCAOB Auditing Standard No. 5, Paragraph A.7, is a deficiency, or 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 material weakness in internal control over financial reporting identified by management relates to our evaluation of warrant accounting during the third quarter of 2013. Specifically, management determined that there was a calculation error with the number of warrants remaining within a manual spreadsheet. The subsequent review process failed to detect and correct the error.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting identified in connection with the evaluation described above that occurred during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management's Remediation Initiatives

Management has commenced steps to remediate the material weakness identified above and to implement an enhanced process to review and approve, among other things, the complex calculations associated with the measurement of the fair value of the Company's outstanding stock warrants, which process will involve more significant staffing of Company personnel.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item with respect to our directors and executive officers will be contained in our 2014 Proxy Statement under the caption “Board of Directors and Corporate Governance – The Board in General” and “– Executive Officers” and is incorporated in this report by reference.

The information required by this item with respect to Section 16(a) beneficial ownership reporting compliance will be contained in our 2014 Proxy Statement under the caption “Ownership of the Company – Section 16(a) Beneficial Owner Reporting Compliance” and is incorporated in this report by reference.

The information required by this item with respect to audit committee matters will be contained in our 2014 Proxy Statement under the caption “Board of Directors and Corporate Governance – Audit Committee” and is incorporated in this report by reference.

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 (“www.columbialabs.com”), under the investor relations tab. We will provide an electronic or paper copy of this document free of charge upon request. If amendments to the Code of Business Conduct and Ethics are executed, or if waivers are granted with respect to the Company’s Chief Executive Officer, Chief Financial Officer, Controller or persons performing similar functions, 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.

Item 11. Executive Compensation

The information required by Item 11 will be contained in our 2014 Proxy Statement under the caption “Compensation Discussion and Analysis” and “Executive and Director Compensation” and is incorporated by reference.

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

The information required by Item 12 will be contained in our 2014 Proxy Statement under the caption “Ownership of the Company – Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” and is incorporated by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by Item 13 will be contained in our 2014 Proxy Statement under the caption “Board of Directors and Corporate Governance – Certain Relationships and Related Party Transactions” and “– Director Independence” and is incorporated by reference.

Item 14. Principal Accountant Fees and Services

The information required by Item 14 will be contained in our 2014 under the caption “Relationship With Independent Registered Public Accounting Firm”.

PART IV

Item 15. *Exhibits and Financial Statement Schedule* (a)(1)(2) **Financial Statements and Financial Statement Schedules**

Exhibit	Index Description of Exhibit
2.1	Purchase and Collaboration Agreement by and between Columbia Laboratories, Inc. and Coventry Acquisition, Inc. dated March 3, 2010 (19)
2.2	Share Purchase Agreement dated September 2013 between the Sellers, Columbia Laboratories, Inc. and Molecular Profiles Limited (38)
3.1	Restated Certificate of Incorporation of the Company, as amended (8)
3.2	Certificate of Amendment of Restated Certificate of Incorporation of the Company (22)
3.3	Certificate of Amendment of Restated Certificate of Incorporation of the Company (37)
3.4	Amended and Restated By-laws of Company (28)
4.1	Certificate of Designations, Preferences and Rights of Series C Convertible Preferred Stock of the Company, dated as of January 7, 1999 (2)
4.2	Certificate of Designations of Series E Convertible Preferred Stock, filed May 10, 2005 with the Delaware Secretary of State (7)
4.3*	Form of Restricted Stock Agreement (9)
4.4*	Form of Option Agreement (13)
4.5	Form of Warrant (22)
4.6	Amended and Restated Rights Agreement by and between Columbia Laboratories, Inc. and American Stock Transfer & Trust Company, LLC dated November 29, 2010 (24)
4.7	Amendment No. 1, dated as of September 20, 2011, to the Amended and Restated Rights Agreement, dated as of November 29, 2010, by and between Columbia Laboratories, Inc. and American Stock Transfer & Trust Company, LLC. (29)
4.8	Amendment No. 2, dated as of March 5, 2013, to the Amended and Restated Rights Agreement, dated as of November 29, 2010, by and between Columbia Laboratories, Inc. and American Stock Transfer & Trust Company, LLC. (34)
4.9*	Form of Award Agreement under the Amended and Restated 2008 Long-term Incentive Plan of Columbia Laboratories, Inc. (35)
10.1*	1996 Long-term Performance Plan, as amended, of the Company (1)
10.2	License Agreement dated April 18, 2000, between the Company and Lil' Drug Store Products, Inc. (3)
10.3†	Semi-Exclusive Supply Agreement dated May 7, 2002 between the Company and Mipharm S.p.A. (4)
10.4*	Form of Indemnification Agreement for Officers and Directors (5)
10.5†	Asset Purchase Agreement dated June 29, 2004, between the Company and Lil' Drug Store Products, Inc. (6)
10.6*	Separation Agreement by and between Columbia Laboratories, Inc. and David L. Weinberg effective as of December 12, 2006 (9)
10.7	Lease Agreement between Allwood Associates I and Columbia Laboratories, Inc., dated July 6, 2007 (10)

Exhibit	Index Description of Exhibit
10.8	Packaging Agreement between Columbia Laboratories (Ireland) Ltd. and Maropack AG, dated October 28, 1993 (11)
10.9*	Columbia Laboratories, Inc., 2008 Long-Term Incentive Plan (12)
10.10*	Columbia Laboratories, Inc., Amended and Restated Incentive Plan (13)
10.11*	Form of Executive Change of Control Severance Agreement (13)
10.12*	Amended and Restated Employment Agreement by and between Columbia Laboratories, Inc. and Michael McGrane dated March 11, 2009 (15)
10.13*	Employment Agreement by and between Columbia Laboratories, Inc. and Lawrence Gyenes dated July 15, 2009 (14)
10.14*	Columbia Laboratories Stock Ownership Guidelines for Officers and Directors (16)
10.15	Manufacturing and Supply Agreement between Fleet Laboratories and Columbia Laboratories (Bermuda), Ltd., dated December 8, 2009 (17)
10.16	Note Purchase and Amendment Agreement by and between Columbia Laboratories, Inc. and holders listed on Schedule I thereto dated March 3, 2010 (19).
10.17*	Amended and Restated Employment Agreement by and between Columbia Laboratories, Inc. and Frank C. Condella, Jr., dated May 4, 2010 (20)
10.18	Second Amended and Restated License and Supply Agreement dated May 14, 2010 between Columbia Laboratories, Inc. and Ares Trading S.A. (21)
10.19	Investor's Rights Agreement by and between Columbia Laboratories, Inc. and Coventry Acquisition, Inc. dated July 2, 2010 (22)
10.20	Supply Agreement by and between Columbia Laboratories, Inc. and Coventry Acquisition, Inc. dated July 2, 2010 (22)
10.21	License Agreement by and between Columbia Laboratories, Inc. and Coventry Acquisition, Inc. dated July 2, 2010 (22)
10.22	Securities Purchase Agreement by and between Columbia Laboratories, Inc. and holders listed on Schedule I thereto dated August 9, 2010 (23)
10.23	Settlement Agreement and Release by and between Bio-Mimetics, Inc. and Columbia Laboratories, Inc. dated December 3, 2010 (25)
10.24*	Addendum to Amended and Restated Employment Agreement by and between Columbia Laboratories, Inc., and Frank C. Condella, Jr., dated March 1, 2011 (26)
10.25	Asset Purchase Agreement dated April 20, 2011, between Actient Pharmaceuticals LLC, and Columbia Laboratories, Inc. (27)
10.26	License Agreement dated April 20, 2011, between Actient Pharmaceuticals LLC, and Columbia Laboratories, Inc. (27)
10.27	U.S. Supply Agreement Assignment dated April 20, 2011, between Mipharm S.p.A., and Columbia Laboratories (Bermuda), Ltd. (27)
10.28	Agreement dated February 10, 2012, between Columbia Laboratories, Inc., and Coventry Acquisition, LLC, to Waive Conditions Precedent to Second Closing of March 3, 2010 Purchase and Collaboration Agreement (30)

Exhibit	Index Description of Exhibit
10.29*	Description of the Registrant's Compensation and Reimbursement Practices for Non-employee Directors. (31)
10.30	License Agreement dated July 24, 2012, between Columbia Laboratories, Inc., and Scientelle LLC (32)
10.31*	Employment Agreement by and between Columbia Laboratories, Inc., and Jonathan B. Lloyd Jones dated January 15, 2013 (33)
10.32	Amendment No. 1 to the Second Amended and Restated License and Supply Agreement dated April 4, 2013, between Columbia Laboratories, Inc. and Ares Trading S.A. (36)
10.33	Parent Guarantee of Columbia Laboratories, Inc., dated September 12, 2013 (38)
10.34*	Employment Agreement dated September 12, 2013, between Dr. Nikin Patel and Columbia Laboratories, Inc. (38)
10.35	Bank Loan Agreement between Molecular Profiles Limited and Lloyds TSB Bank plc, dated January 6, 2012 (39)
10.36	Amendment letter between Molecular Profiles Limited and Lloyds TSB Bank plc, dated September 16, 2013 (39)
10.37	Amendment to Manufacturing and Supply Agreement, effective as of December 31, 2013, between Columbia Laboratories (Bermuda) Ltd., and Fleet Laboratories Limited (40)
14	Code of Ethics of the Company (5)
21	Subsidiaries of the Company (41)
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm (41)
31(i).1	Certification of Chief Executive Officer of the Company (41)
31(i).2	Certification of Chief Financial Officer of the Company (41)
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 (41)
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 (41)
101††	XBRL data file (41)

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

†† Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended (the "Securities Act"), are deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise not subject to liability under those sections. This exhibit shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Registrant specifically incorporates this exhibit by reference.

* Management contract or compensatory plans or arrangements

1/ Incorporated by reference to the Registrant's Proxy Statement, dated May 10, 2000

2/ Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998

3/ Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000

- 4/ Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, dated August 14, 2002
- 5/ Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003
- 6/ Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, dated August 4, 2004
- 7/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated May 12, 2005
- 8/ Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005
- 9/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated December 15, 2006
- 10/ Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, dated August 8, 2007
- 11/ Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2007
- 12/ Incorporated by reference to the Registrant's Proxy Statement, dated April 8, 2008
- 13/ Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2008
- 14/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated July 15, 2009
- 15/ Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, dated August 6, 2009
- 16/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated November 17, 2009
- 17/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated December 8, 2009
- 18/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated December 14, 2009
- 19/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated March 4, 2010
- 20/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated May 5, 2010
- 21/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated May 18, 2010
- 22/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated July 6, 2010
- 23/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated August 10, 2010
- 24/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated November 30, 2010
- 25/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated December 6, 2010
- 26/ Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2010
- 27/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated April 20, 2011
- 28/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated July 15, 2011
- 29/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated September 16, 2011
- 30/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated February 10, 2012
- 31/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated June 7, 2012
- 32/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated July 26, 2012
- 33/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated January 15, 2013
- 34/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated March 1, 2013
- 35/ Incorporated by reference to the Registrant's Registration Statement on Form S-8, dated May 16, 2013
- 36/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated April 4, 2013
- 37/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated August 8, 2013
- 38/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated September 18, 2013
- 39/ Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, dated November 6, 2013
- 40/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated February 6, 2014
- 41/ 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 5, 2014

By: /s/ Jonathan B. Lloyd Jones
Jonathan B. Lloyd Jones
Vice President, Chief Financial Officer and
Treasurer

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>/s/ Frank C. Condella, Jr.</u> Frank C. Condella, Jr.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 5, 2014
<u>/s/ Jonathan B. Lloyd Jones</u> Jonathan B. Lloyd Jones	Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 5, 2014
<u>/s/ Nikin Patel</u> Nikin Patel	Chief Executive Officer and Director (Molecular Profiles)	March 5, 2014
<u>/s/ Valerie L. Andrews</u> Valerie L. Andrews	Director	March 5, 2014
<u>/s/ Frank Armstrong</u> Frank Armstrong	Director	March 5, 2014
<u>/s/ Edward A. Blechschmidt</u> Edward A. Blechschmidt	Director	March 5, 2014
<u>/s/ Cristina Csimma</u> Cristina Csimma	Director	March 5, 2014
<u>/s/ Donald H. Hunter</u> Donald H. Hunter	Director	March 5, 2014
<u>/s/ Stephen G. Kasnet</u> Stephen G. Kasnet	Chairman of the Board of Directors	March 5, 2014
<u>/s/ G. Frederick Wilkinson</u> G. Frederick Wilkinson	Director	March 5, 2014

COLUMBIA LABORATORIES, INC.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Columbia Laboratories, Inc.
Boston, MA

We have audited the accompanying consolidated balance sheets of Columbia Laboratories, Inc. as of December 31, 2013 and 2012 and the related consolidated statements of operations, comprehensive income, shareholders' equity (deficiency), and cash flows for each of the three years in the period ended December 31, 2013. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Columbia Laboratories, Inc. at December 31, 2013 and 2012, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP
Boston, Massachusetts
March 5, 2014

Columbia Laboratories, Inc.
Consolidated Balance Sheets

	December 31,	
	2013	2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 20,715,414	\$ 13,204,067
Short-term investments	—	15,433,967
Accounts receivable, net	7,197,032	1,159,145
Amounts due from related parties	900,000	2,194,491
Inventories	2,583,455	2,626,606
Prepaid expenses and other current assets	831,138	1,284,279
Total current assets	32,227,039	35,902,555
Property and equipment, net	13,226,330	927,227
Intangible assets, net	2,828,451	—
Goodwill	11,151,925	—
Deferred tax assets	570,033	—
Other assets	88,682	38,882
Total assets	\$ 60,092,460	\$ 36,868,664
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,805,112	\$ 1,435,660
Accrued expenses	2,488,096	2,216,524
Deferred revenue	753,979	93,750
Notes payable	250,162	—
Total current liabilities	6,297,349	3,745,934
Deferred revenue, net of current portion	2,242,746	33,526
Notes payable, net of current portion	3,745,275	—
Common stock warrant liability	379,468	1,173,747
Total liabilities	12,664,838	4,953,207
Commitments and contingencies		
Contingently redeemable series C preferred stock, 550 shares issued and outstanding (liquidation preference of \$550,000)	550,000	550,000
Shareholders' equity:		
Preferred stock, \$.01 par value; 1,000,000 shares authorized		
Series B convertible preferred stock, 130 shares issued and outstanding (liquidation preference of \$13,000)	1	1
Series E convertible preferred stock, 22,740 shares issued and outstanding in 2012 (liquidation preference of \$2,274,000)	—	227
Common stock \$.01 par value; 150,000,000 shares authorized; 12,151,670 and 10,942,973 shares issued in 2013 and 2012, respectively	121,517	109,430
Additional paid-in capital	287,047,939	279,463,439
Treasury stock (at cost), 4,556 shares in 2012	—	(125,381)
Accumulated deficit	(241,661,706)	(248,365,480)
Accumulated other comprehensive income	1,369,871	283,221
Total shareholders' equity	46,877,622	31,365,457
Total liabilities and shareholders' equity	\$ 60,092,460	\$ 36,868,664

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

Columbia Laboratories, Inc.
Consolidated Statements of Operations

	Year Ended December 31,		
	2013	2012	2011
Revenues			
Product revenues	\$21,336,458	\$17,925,954	\$14,776,144
Product revenues from related party	—	4,304,519	3,201,464
Service revenues	3,640,453	—	—
Royalties	394,491	380,473	320,149
Royalties from related party	3,436,173	3,079,379	2,650,831
Other revenues	119,059	138,052	139,050
Other revenues from related party	299,818	—	21,974,383
Total revenues	<u>29,226,452</u>	<u>25,828,377</u>	<u>43,062,021</u>
Cost of product revenues	10,903,459	8,875,065	8,816,492
Cost of product revenues from related party	—	3,913,199	2,874,873
Cost of service revenues	2,347,426	—	—
Total cost of revenues	<u>13,250,885</u>	<u>12,788,264</u>	<u>11,691,365</u>
Gross profit	15,975,567	13,040,113	31,370,656
Operating expenses			
Sales and marketing	438,950	—	87,669
Research and development (net of reimbursement from related party: 2012 – \$435,199; 2011 – \$3,196,601)	—	770,642	2,779,058
Acquisition related expenses	1,623,368	—	—
General and administrative	8,038,283	9,459,963	8,108,194
Net gain on U.S. sale of STRIANT	—	—	(2,533,127)
Total operating expenses	<u>10,100,601</u>	<u>10,230,605</u>	<u>8,441,794</u>
Income from operations	5,874,966	2,809,508	22,928,862
Interest income, net	71,279	238,033	95,146
Change in fair value of common stock warrants	794,280	6,995,099	(2,164,543)
Other expense, net	(14,187)	(122,660)	(292,991)
Income before income taxes	<u>6,726,338</u>	<u>9,919,980</u>	<u>20,566,474</u>
Provision for income taxes	22,564	2,707	39,282
Net income	<u>\$ 6,703,774</u>	<u>\$ 9,917,273</u>	<u>\$20,527,192</u>
Basic net income per common share	<u>\$ 0.59</u>	<u>\$ 0.91</u>	<u>\$ 1.90</u>
Diluted net income per common share	<u>\$ 0.52</u>	<u>\$ 0.26</u>	<u>\$ 1.73</u>
Basic weighted average common shares outstanding	<u>11,259,347</u>	<u>10,914,476</u>	<u>10,790,669</u>
Diluted weighted average common shares outstanding	<u>11,273,456</u>	<u>11,063,034</u>	<u>11,568,644</u>

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

Columbia Laboratories, Inc.
Consolidated Statements of Comprehensive Income

	Year Ended December 31,		
	2013	2012	2011
Net income	\$6,703,774	\$ 9,917,273	\$20,527,192
Other comprehensive income components:			
Foreign currency translation	1,183,870	3,118	(13,721)
Unrealized (loss) gain on short term investments	(80,223)	175,201	(77,981)
Reclassification adjustment for gains included in net income ...	(16,997)	—	—
Total other comprehensive income (loss)	1,086,650	178,319	(91,702)
Comprehensive income	<u>\$7,790,424</u>	<u>\$10,095,592</u>	<u>\$20,435,490</u>

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

Columbia Laboratories, Inc.

Consolidated Statements of Shareholders' Equity (Deficiency)

	Series B Convertible Preferred Stock		Series E Convertible Preferred Stock		Common Stock		Treasury Stock			Accumulated Other Comprehensive Income	Total	
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Treasury Stock	Accumulated Deficit			
Balance, January 2011	130	\$ 1	59,000	\$ 590	10,554,326	\$105,543	\$261,339,791	(432,766)	\$(3,346,090)	\$(278,809,945)	\$ 196,604	\$(20,513,506)
Options exercised	—	—	—	—	86,244	862	1,679,374	124,383	961,714	—	—	2,641,950
Conversion of series E Preferred Stock	—	—	(36,260)	(363)	167,475	1,675	(458,653)	59,150	457,341	—	—	—
Warrants exercised	—	—	—	—	108,509	1,085	(713,423)	249,233	1,927,035	—	—	1,214,697
Share based compensation expense	—	—	—	—	4,360	44	814,476	—	—	—	—	814,520
Purchase of treasury stock	—	—	—	—	—	—	—	(4,556)	(125,381)	—	—	(125,381)
Dividends on preferred stock	—	—	—	—	—	—	(30,000)	—	—	—	—	(30,000)
Reclassification of redeemable warrants	—	—	—	—	—	—	16,193,037	—	—	—	—	16,193,037
Translation adjustment	—	—	—	—	—	—	—	—	—	—	(13,721)	(13,721)
Unrealized loss on short term investments	—	—	—	—	—	—	—	—	—	—	(77,981)	(77,981)
Net income	—	—	—	—	—	—	—	—	—	20,527,192	—	20,527,192
Balance, December 31, 2011	130	\$ 1	22,740	\$ 227	10,920,914	\$109,209	\$278,824,602	(4,556)	\$(125,381)	\$(258,282,753)	\$ 104,902	\$ 20,630,807
Share based compensation expense	—	—	—	—	22,059	221	668,171	—	—	—	—	668,392
Dividends on preferred stock	—	—	—	—	—	—	(29,334)	—	—	—	—	(29,334)
Translation adjustment	—	—	—	—	—	—	—	—	—	—	3,118	3,118
Unrealized gain on short term investments	—	—	—	—	—	—	—	—	—	—	175,201	175,201
Net income	—	—	—	—	—	—	—	—	—	9,917,273	—	9,917,273
Balance, December 31, 2012	130	\$ 1	22,740	\$ 227	10,942,973	\$109,430	\$279,463,439	(4,556)	\$(125,381)	\$(248,365,480)	\$ 283,221	\$ 31,365,457
Options exercised	—	—	—	—	2,030	20	10,698	—	—	—	—	10,718
Issuance of common stock in connection with the acquisition of Molecular Profiles LTD	—	—	—	—	1,051,323	10,513	7,284,617	—	—	—	—	7,295,130
Conversion of series E preferred stock	—	—	(22,740)	(227)	131,328	1,312	(157,922)	10,897	156,837	—	—	—
Purchase of treasury stock	—	—	—	—	—	—	—	(6,341)	(31,456)	—	—	(31,456)
Share based compensation expense	—	—	—	—	24,193	242	475,061	—	—	—	—	475,303
Dividends on preferred stock	—	—	—	—	—	—	(27,500)	—	—	—	—	(27,500)
Reverse stock split – cash in lieu	—	—	—	—	(77)	—	(454)	—	—	—	—	(454)
Translation adjustment	—	—	—	—	—	—	—	—	—	—	1,183,870	1,183,870
Unrealized loss on short term investments	—	—	—	—	—	—	—	—	—	—	(80,223)	(80,223)
Reclassification adjustment for gains included in net income	—	—	—	—	—	—	—	—	—	—	(16,997)	(16,997)
Net income	—	—	—	—	—	—	—	—	—	6,703,774	—	6,703,774
Balance, December 31, 2013	130	\$ 1	—	\$ —	12,151,770	\$121,517	\$287,047,939	—	\$ —	\$(241,661,706)	\$1,369,871	\$ 46,877,622

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

Columbia Laboratories, Inc.
Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2013	2012	2011
Operating activities:			
Net income	\$ 6,703,774	\$ 9,917,273	\$ 20,527,192
Reconciliation of net income to net cash provided by (used in) operating activities:			
Depreciation and amortization	919,097	642,358	166,990
Gain on sale of STRIANT	—	—	(2,533,127)
Change in fair value of common stock warrants	(794,280)	(6,995,099)	2,164,543
Recognition of deferred provision for sales returns	—	—	(17,113,404)
Provision for sales returns	(26,120)	(625,452)	358,287
Write-off of inventories	—	970,419	58,612
Write-off of accounts receivable	—	—	7,616
Stock-based compensation expense	475,303	668,392	814,520
Gain on sale of short-term investments	(16,997)	—	—
Deferred income taxes	57,456	—	—
Write-down of impaired assets	—	889,869	—
Loss on disposal of fixed assets	36,900	7,547	3,780
Changes in operating assets and liabilities:			
Accounts receivable	(2,346,954)	1,775,961	(902,857)
Due from related party	1,294,491	(68,458)	568,735
Inventories	46,470	38,705	(1,396,167)
Prepaid expenses and other current assets	1,438,558	(616,352)	(275,017)
Other non-current assets	(49,791)	425,404	19,855
Accounts payable	314,757	(2,456,240)	(2,095,673)
Accrued expenses	(830,466)	(217,572)	(1,838,756)
Deferred revenue	(149,603)	(12,890)	125,000
Net cash provided by (used in) operating activities	7,072,595	4,343,865	(1,339,871)
Investing activities:			
Purchase of property and equipment	(522,352)	(985,930)	(1,307,103)
Additions to short-term investments	—	(234,767)	(15,101,980)
Cash paid for acquisition, net of cash received	(14,516,297)	—	—
Proceeds from the sale of short-term investments	15,353,744	—	—
Proceeds from the sale of STRIANT	—	—	3,100,000
Net cash provided by (used in) investing activities	315,095	(1,220,697)	(13,309,083)
Financing activities:			
Redemption of series C convertible preferred stock	—	(50,000)	—
Proceeds from exercise of stock options	10,718	—	2,641,950
Proceeds from exercise of warrants	—	—	653,299
Principal payments on notes payable	(72,278)	—	—
Payments for the purchase of treasury stock	—	—	(125,381)
Dividends paid	(27,500)	(29,334)	(30,000)
Net cash (used in) provided by financing activities	(89,060)	(79,334)	3,139,868
Effect of exchange rate changes on cash and cash equivalents	212,717	46,070	(7,730)
Net increase (decrease) in cash and cash equivalents	7,511,347	3,089,904	(11,516,816)
Cash and cash equivalents, beginning of period	13,204,067	10,114,163	21,630,979
Cash and cash equivalents, end of period	\$ 20,715,414	\$13,204,067	\$ 10,114,163
Supplemental cash flow information			
Cash paid for interest	\$ 24,887	\$ —	\$ —
Cash paid for income taxes	\$ 3,047	\$ —	\$ 220,042
Supplemental noncash financing activities			
Common stock issued in connection with the acquisition of Molecular Profiles	\$ 7,295,130	\$ —	\$ —
Conversion of series E convertible preferred stock into common stock	\$ 158,149	\$ —	\$ —

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

Columbia Laboratories, Inc.
Notes to Consolidated Financial Statements

1. Organization

Columbia Laboratories, Inc. (the “Company” or “Columbia”) was incorporated as a Delaware corporation in December 1986. The Company has historically been in the business of developing, licensing, manufacturing and selling to its marketing partner’s pharmaceutical products that utilize proprietary drug delivery technologies to treat various medical conditions. Presently, the Company’s focus is on the supply of CRINONE to our marketing partner and in providing pharmaceutical development, clinical trial manufacturing, and advanced analytical and consulting services to the pharmaceutical industry through its newly acquired wholly-owned subsidiary, Molecular Profiles Limited (“Molecular Profiles”).

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries; Columbia Laboratories Bermuda Ltd., Columbia Laboratories France SA , Columbia Laboratories UK Ltd, and Molecular Profiles Limited. All significant intercompany balances and transactions have been eliminated in consolidation.

Reclassifications

For comparability purposes, certain prior year amounts in the consolidated financial statements have been reclassified to conform to the current year’s presentation within the consolidated balance sheets, consolidated statements of operations and consolidated statements of cash flows.

Basis of Presentation

On July 26, 2013, Columbia’s Board of Directors set a ratio of 1-for-8 for its previously approved reverse stock split which took effect on August 9, 2013. The reverse stock split was approved by Columbia’s shareholders at its annual meeting of shareholders on May 1, 2013. All share and per share amounts relating to the common stock, stock options and common stock warrants included in the financial statements and accompanying footnotes have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an equal amount to the reduction in par value of common stock to additional paid-in capital. The reverse stock split did not result in a retroactive adjustment to the share amounts for any of the classes of the Company’s preferred stock.

Segments

The Company currently operates in one segment; the development and analysis of pharmaceuticals, clinical trial manufacturing of pharmaceutical products for its pharmaceutical company customers and the potential development of pharmaceutical products for its behalf. In certain foreign countries, these products may be classified as medical devices or cosmetics by those countries’ regulatory agencies. See Note 13 for information on foreign operations.

The Company acquired Molecular Profiles, Ltd, a UK-based provider of pharmaceutical development, clinical trial manufacturing, and advanced analytical and consulting services to the pharmaceutical industry, on September, 12, 2013. The Company views the manufacturing of clinical trial drug supplies for its pharmaceutical company clients and the manufacture of CRINONE for our license partner to be seamless activities and have therefore sought to capture synergies by transferring all operational activities related to its historic business to

Molecular Profiles. These activities, including management of CRINONE manufacturing, quality assurance and logistics and, management of our intellectual property estate are now fully integrated into and managed out of its Nottingham, U.K. facility.

Prior to the Company's acquisition of Molecular Profiles, the Company had invested heavily in an approximate quadrupling of its capacity. This capacity expansion necessarily has increased the overall cost-base of the Nottingham operations. As such the Chief Executive Officer, Chief Operating Decision Maker (CODM), currently focuses his decision making attention on the expansion of the Company's revenue base.

Management Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures at the date of the financial statements during the reporting period. Significant estimates are used for, but are not limited to revenue recognition, sales return reserves, allowance for doubtful accounts, inventory reserve, impairment analysis of goodwill and intangibles including their useful lives, deferred tax assets, liabilities and valuation allowances, common stock warrant valuations, and fair value of stock options. On an ongoing basis, management evaluates its estimates. Actual results could differ from those estimates.

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. The functional currency of Columbia's foreign subsidiaries is considered to be the local currency for each entity and, accordingly, translation adjustments for these subsidiaries are included in accumulated other comprehensive income within stockholders' equity. Certain intercompany and third party foreign currency-denominated transactions generated foreign currency re-measurement losses of approximately \$47,000, \$0.1 million and \$0.3 million during the years ended December 31, 2013, 2012 and 2011, respectively, which are included in other expense, net in the consolidated statements of operations.

Cash Equivalents

The Company considers all investments purchased with an original maturity of three months or less to be cash equivalents.

Short Term Investments

Investments consist of U.S. Treasury and agency securities. The Company's investments are classified as available-for-sale and are recorded at fair value, based upon quoted market prices. Unrealized temporary adjustments to fair value are included on the balance sheet in a separate component of stockholders' equity as unrealized gains and losses and reported as a component of accumulated other comprehensive income. No gains or losses on investments are realized until shares are sold or a decline in fair value is determined to be other-than-temporary. If a decline in fair value is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis in the investment is established.

Fair Value of Financial Instruments

U.S. GAAP establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined as the amount that would be received for an asset or paid to transfer a liability (i.e., an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the

measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes the following fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

Level 1: Quoted prices in active markets for identical assets and liabilities.

Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The fair value of short term investments are determined based on quoted market prices on the balance sheet date and are classified as a level 1 investment. At December 31, 2012, short-term investments totaled \$15.4 million. There were no short-term investments at December 31, 2013.

The estimated fair value of the common stock warrant liability resulting from the October 2009 registered direct offering of 1,362,500 shares of the common stock and warrants to purchase 681,275 shares of common stock was \$0.4 million and \$1.2 million as of December 31, 2013 and 2012, respectively. These values were determined by using the Black-Scholes option pricing model which is based on the Company's stock price at measurement date, exercise price of this common stock warrant, risk-free rate and historical volatility, and are classified as a Level 2 measurement. During the years ended December 31, 2013, 2012 and 2011, the Company recorded income of \$0.8 million, \$7.0 million and expense of \$2.2 million, respectively, to adjust the value of the common stock warrant liability to market.

	<u>2013</u>	<u>2012</u>	<u>2011</u>
Stock Price	\$ 6.61	\$ 5.12	\$ 20.00
Exercise Price	\$ 12.16	\$ 12.16	\$ 12.16
Risk free interest rate	0.20%	0.25%	0.36%
Expected term	1.25 years	2.25 years	3.25 years
Dividend yield	—	—	—
Expected volatility	61.32%	103.10%	83.24%

The fair value of accounts receivable and accounts payable approximate their carrying amount. The Company's long-term debt is carried at amortized cost which approximates fair value based on current market pricing of similar debt instruments and is categorized as a Level 2 measurement.

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>2013</u>	<u>2012</u>
Raw materials	\$ 770,523	\$ 685,578
Work in process	774,578	1,308,399
Finished goods	<u>1,038,354</u>	<u>632,629</u>
Total	<u>\$2,583,455</u>	<u>\$2,626,606</u>

Reserves for excess and obsolete inventory were \$0.2 million and \$1.1 million at December 31, 2013 and 2012, respectively.

Columbia's excess and obsolescence reserve policy is to establish inventory reserves when conditions exist which suggest that the inventory may be in excess of anticipated demand or is obsolete based upon assumptions about future demand for products and market conditions. Columbia only manufactures products to customer orders. Columbia regularly evaluates the ability to realize the value of inventory based upon a combination of factors. Assumptions used in determining management's estimates of future product demand may prove to be incorrect, in which case the provision required for excess and obsolete inventory would have to be adjusted in the future.

Columbia purchases raw material components from sole source suppliers. A delay in the production capabilities of these vendors could cause a delay in Columbia's manufacturing, and a possible loss or revenues, which would adversely affect operating results.

Accounts Receivable and Allowance for Doubtful Accounts

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 uncollectable.

Accounts receivable allowance activity consisted of the following for the years ended December 31:

	<u>2013</u>	<u>2012</u>	<u>2011</u>
Balance at beginning of year	\$100,000	\$100,000	\$100,000
Additions	12,174	—	—
Deductions	—	—	—
Balance at end of year	<u>\$112,174</u>	<u>\$100,000</u>	<u>\$100,000</u>

Columbia's accounts receivable balance, net of allowance for doubtful accounts, was \$7.2 million as of December 31, 2013, compared with \$1.2 million as of December 31, 2012. Included in the accounts receivable balance at December 31, 2013 were \$2.8 million of unbilled accounts receivable. There is no unbilled accounts receivable as of December 31, 2012. Columbia's unbilled accounts receivable is derived from the milestones completed on the pharmaceutical development service contracts as of the balance sheet date.

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 leases. Depreciation is computed on the straight-line basis over the estimated useful lives of the respective assets, as follows:

	<u>Years</u>
Machinery and equipment	3-10
Furniture and fixtures	3-5
Computer equipment and software	3
Buildings and leasehold improvements	Up to 39
Land	Indefinite

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.

Columbia continually evaluates whether events or circumstances have occurred that indicate that the remaining useful life of its long-lived assets may warrant revision or that the carrying value of these assets may be impaired. Columbia evaluates the realizability of its long-lived assets based on profitability and cash flow expectations for the related asset. Any write-downs are treated as permanent reductions in the carrying amount of the assets. Based on this evaluation, Columbia believes, as of each balance sheet date presented, none of Columbia's long-lived assets were impaired.

In the fourth quarter of 2012, the Company recorded an impairment charge on the net carrying value of certain machinery and equipment that was acquired in anticipation of increased capacity requirements for Progesterone production in anticipation of the approval of the preterm birth indication. The company recorded a loss of \$0.9 million which was recorded in general and administrative expense in the consolidated statements of operations.

Concentration of Risk

The Company has two major customers – Actavis and Merck Serono. See Note 13 for customer and product concentrations.

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

Goodwill

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed in a business combination. The Company does not amortize its goodwill, but instead tests for impairment annually and more frequently whenever events or changes in circumstances indicate that the fair value of the asset may be less than its carrying value of the asset.

The Company has adopted ASU 2011-08, *Intangibles—Goodwill and Other*, and amendment to ASC 350, which updates how an entity will evaluate its goodwill for impairment. The guidance provides entities an option to perform a “qualitative” assessment to determine whether further impairment testing is necessary. If further testing is required, the test for impairment continues with the two step process. The first step compares the carrying amount of the reporting unit to its estimated fair value (Step 1). To the extent that the carrying value of the reporting unit exceeds its estimated fair value, a second step is performed, wherein the reporting unit's carrying value is compared to the implied fair value (Step 2). To the extent that the carrying value exceeds the implied fair value, impairment exists and must be recognized.

The Company has concluded that its business represents one reporting unit for goodwill impairment testing. The Company has performed its annual test for impairment on the first day of the fourth quarter beginning in 2013. The Company has determined that its goodwill is not impaired as of December 31, 2013.

Intangible Assets

The Company capitalizes and includes in intangible assets the costs of trademark, developed technology and customer relationships. Intangible assets are recorded at fair value and stated net of accumulated amortization. The Company amortizes its intangible assets that have finite lives using either the straight-line or accelerated method, based on the useful life of the asset over which it is expected to be consumed utilizing expected undiscounted future cash flows. Amortization is recorded over the estimated useful lives ranging from 3 to 7 years. The Company evaluates the realizability of its definite lived intangible assets whenever events or changes

in circumstances or business conditions indicate that the carrying value of these assets may not be recoverable based on expectations of future undiscounted cash flows for each asset group. If the carrying value of an asset or asset group exceeds its undiscounted cash flows, the Company estimates the fair value of the assets, generally utilizing a discounted cash flow analysis based on the present value of estimated future cash flows to be generated by the assets using a risk-adjusted discount rate. To estimate the fair value of the assets, the Company uses market participant assumptions pursuant to ASC 820, *Fair Value Measurements*. If the estimate of an intangible asset's remaining useful life is changed, the Company will amortize the remaining carrying value of the intangible asset prospectively over the revised useful life.

Income Taxes

Deferred tax assets or liabilities are determined based on timing differences between when income and expense items are recognized for financial statement purposes versus when they're recognized for tax purposes, as measured by enacted tax rates. A valuation allowance is provided against deferred tax assets in circumstances where management believes it is more likely than not that all or a portion of the assets will not be realized. The Company has provided a full valuation allowance against its net domestic deferred tax assets as of December 31, 2013 and 2012.

Accumulated Other Comprehensive (Loss) Income

Changes to accumulated other comprehensive (loss) income during the year ended December 31, 2013 were as follows:

	<u>Unrealized Gain on Marketable Securities, net of tax</u>	<u>Translation Adjustment</u>	<u>Accumulated Other Comprehensive (Loss) Income</u>
Balance – December 31, 2012	\$ 97,220	\$ 186,001	\$ 283,221
Current period other comprehensive (loss) income	(80,223)	1,183,870	1,103,647
Amounts reclassified from accumulated other comprehensive (loss) income	<u>(16,997)</u>	<u>—</u>	<u>(16,997)</u>
Balance – December 31, 2013	<u>\$ —</u>	<u>\$1,369,871</u>	<u>\$1,369,871</u>

Revenue Recognition and Sales Returns Reserves

Revenues include product revenues, which primarily consist of sales of CRINONE to Merck Serono, royalty revenues, which primarily consist of royalty revenues from Actavis on sales of CRINONE, service revenues, which primarily consist of analytical and consulting services, pharmaceutical development services and clinical trial drug manufacturing services and other revenues.

Revenues from the Company's pharmaceutical drug service line are recorded as multiple-element arrangements and are evaluated in accordance with the principles of Accounting Standards update ("ASU") 2009-13, (*Revenue Recognition Topic – Multiple Element Arrangements*) and Columbia allocates revenue among the elements based upon each element's relative fair value. These elements are recognized as revenue as the service for each element is performed.

Amounts paid but not yet earned on a project are recorded as deferred revenue until such time as performance is rendered or the obligation to perform the service is completed.

When a sale combines multiple elements upon performance of multiple services, the Company allocates revenue for transactions that include multiple elements to each unit of accounting based on its relative selling price, and recognizes revenue for each unit of accounting when the revenue recognition criteria have been met.

The Company follows the selling price hierarchy as outlined in the guidance Revenue Recognition (ASC Topic 605) – Multiple-Deliverable Revenue Arrangements. The guidance provides a hierarchy to determine the selling price to be used for allocating revenue to deliverables: (i) vendor-specific objective evidence (“VSOE”), (ii) third-party evidence (“TPE”) if available and when VSOE is not available, and (iii) best estimate of the selling price (“BESP”) if neither VSOE nor TPE is available. The Company uses BESP to determine the standalone selling price for such deliverables. The Company has a process for developing BESP, which incorporates, pricing practices, historical selling prices, the effect of market conditions as well as entity-specific factors. Estimated selling price is monitored and evaluated on a regular basis to ensure that changes in circumstances are accounted for in a timely manner.

Revenues from the sale of products are recorded at the time goods are shipped to customers, except in the case of product shipments to Actavis, which are recognized when received at Actavis’ warehouse. Sales to Merck Serono for CRINONE (progesterone gel) are determined on a country-by-country basis and are the greater of (i) thirty percent (30%) of the net selling price in the country, or (ii) Columbia’s direct manufacturing cost plus 20%. Columbia estimates net selling prices based on historical experience and other current information from Merck Serono; the amounts are reconciled on a quarterly basis when information is received from Merck Serono. Certain quantity discounts apply to annual purchases over 10 million, 20 million, and 30 million units. Columbia accrues an estimated volume discount on a quarterly basis and reconciles it on an annual basis.

Royalty revenues, based on sales by licensees, are recorded as revenues as those sales are made by the licensees.

Revenues from the sales of consulting services are recognized on a straight-line basis over the contract period as services are provided. Payments received by Columbia in advance of performance for services are deferred until earned.

License fees revenues are recognized and recorded as revenues over the estimated development period.

In accordance with the provisions of ASC 605-45, *Revenue Recognitions Topic – Principal Agent Considerations*, Columbia records shipping and handling costs billed to its customers as a component of revenue, and the underlying expense as a component of cost of revenue.

Columbia collects value added tax from its customers for revenues generated out of the United Kingdom for which the customer is not tax exempt and remits such taxes to the appropriate governmental authorities. Columbia presents its value added tax on a net basis; therefore, these taxes are excluded from revenues.

Columbia is not responsible for returns on international sales. Sales adjustments for international sales are estimated to recognize changes in foreign exchange rates and changes in market prices that may fluctuate within a year. Columbia is responsible for sales returns for products sold to domestic customers prior to both the Actavis Transactions and the sale in April 2011 of STRIANT[®] (testosterone buccal system) to Auxilium Pharmaceuticals LLC (“Auxilium”). Revenues from the sale of products to domestic customers were recorded at the time goods were shipped to customers. Except for sales to licensees, Columbia’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. Products sold to Merck Serono and Actavis are not returnable to Columbia. Provisions for returns on sales to wholesalers, distributors and retail chain stores were estimated based on a percentage of sales, using such factors as historical sales information, distributor inventory levels and product prescription data, and were recorded as a reduction to sales in the same period as the related sales were recognized. Columbia evaluates its remaining provision for returns on a quarterly basis based on the rate of returns processed and adjusts the provision if its analysis indicates that the provision needs to be adjusted.

An analysis of the reserve for sales returns at December 31, 2012 and 2013 is as follows:

	<u>Total</u>
Balance – December 31, 2011	\$1,429,597
Provision:	
Related to current period sales	—
Related to prior period sales	<u>(625,452)</u>
	<u>(625,452)</u>
Returns:	
Related to prior period sales	<u>(320,280)</u>
	<u>(320,280)</u>
Balance – December 31, 2012	\$ 483,865
Provision:	
Related to current period sales	—
Related to prior period sales	<u>(26,120)</u>
	<u>(26,120)</u>
Returns:	
Related to prior period sales	<u>(319,817)</u>
	<u>(319,817)</u>
Balance – December 31, 2013	<u>\$ 137,928</u>

Deferred Revenue

As part of the acquisition of Molecular Profiles, Columbia assumed a \$2.5 million obligation under a grant arrangement with the Regional Growth Fund on behalf of the Secretary of State for Business, Innovation, and Skills in the United Kingdom. Molecular Profiles used this grant to fund the building of its second facility, which includes analytical labs, office space, and a manufacturing facility. As a part of the arrangement, Molecular Profiles is required to create and maintain certain full-time equivalent personnel levels through October 2017. As of December 31, 2013, Molecular Profiles is in compliance with the covenants of the arrangement.

The income from the Regional Growth Fund will be recognized on a decelerated basis through September 30, 2017. As of December 31, 2013, the obligation is valued at \$2.6 million due to foreign currency revaluation and is recorded in deferred revenue on the consolidated balance sheets.

Amounts paid but not yet earned on a product are recorded as deferred revenue until such time as performance is rendered or the obligation to perform the service is completed.

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. 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.

Research and Development Costs

Research and development consist of salaries and other personnel related expenses including stock-based compensation of employees primarily engaged in research and development activities and materials used and other overhead expenses incurred in connection with conducting the PREGNANT study.

Columbia entered into an agreement with Actavis to collaborate on the development of Progesterone Products, specifically the PREGNANT study. The PREGNANT study expenses consisted of fees for preparation, filing and approval process of the related drug application. Under the terms of the agreement, Columbia performed certain research and development activities, the cost of which was partially funded by Actavis. Columbia recorded \$0.4 million and \$3.2 million of reimbursements from Actavis as a reduction to research and development expenses in the years ended December 31, 2012 and 2011, respectively. All research and development costs are expensed as incurred.

In 2013, there were no research and development expenses or reimbursements from Actavis as the Company eliminated its research and development activities in 2012.

Stock-based compensation

Columbia follows the fair value recognition provisions of ASC 718, *Stock Compensation Topic* (ASC 718). Columbia expenses the fair value of stock options over the service period. Columbia records its stock-based compensation expense without a forfeiture rate. Accordingly, Columbia reviews its actual forfeiture rates and aligns its stock compensation expense with the options that are vesting. In December 2012, \$0.2 million was credited to stock compensation related to the forfeiture of unvested options.

Columbia recorded stock-based compensation expense of \$0.5 million, \$0.7 million and \$0.8 million for the years ended December 31, 2013, 2012 and 2011, respectively.

Total stock-based compensation expense was recorded to cost of revenues, and operating expenses based upon the functional responsibilities of the individuals holding the respective options as follows:

	Years Ended December 31,		
	2013	2012	2011
Cost of revenues	\$ 14,558	\$ 22,804	\$ 12,227
General and administrative	460,745	605,349	723,034
Research and development	—	40,239	79,259
Total employee stock-based compensation	<u>\$475,303</u>	<u>\$668,392</u>	<u>\$814,520</u>

As of December 31, 2013, total unamortized share-based compensation cost related to non-vested stock options was \$0.5 million which is expected to be recognized on a straight-line basis over a weighted average period of 2.2 years.

Cash received from option exercises was \$11,000 and \$2.6 million during the years ending December 31, 2013 and 2011, respectively. There were no option exercises in the year ended December 31, 2012.

Columbia granted 88,749, 104,375 and 129,375 stock options during the years ended December 31, 2013, 2012 and 2011, respectively.

Stock based compensation for consultants amounted to \$0.1 million for both years ending December 31, 2012 and 2011, respectively. There was no stock-based compensation expense recorded for consultants in the year ended December 31, 2013. No tax benefit has been recognized due to the net tax losses during the periods presented.

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for stock-based awards. The weighted-average fair value of the options granted during the years ended December 31, 2013, 2012 and 2011 was \$3.52, \$3.68 and \$10.56, respectively using the following assumptions:

	Years Ended December 31,		
	2013	2012	2011
Risk free interest rate	0.71%-0.76%	0.82%	2.11%
Expected term	4.75 years	4.75 years	4.75 years
Dividend yield	—	—	—
Expected volatility	96.52%-97.02%	93.57%	92.72%

Option-pricing models require the input of various subjective assumptions, including the option's expected life and the price volatility of the underlying stock. Columbia's estimated expected stock price volatility is based on its own historical volatility. Columbia's expected term of options granted in the years ended December 31, 2013, 2012 and 2011 was derived from the simplified method. The risk-free rate for the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

Net Income Per Common Share

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

	Years Ended December 31,		
	2013	2012	2011
Basic net income per common share			
Net income	\$ 6,703,774	\$ 9,917,273	\$20,527,192
Less: Preferred stock dividends	(27,500)	(29,334)	(30,000)
Net income applicable to common stock	<u>\$ 6,676,274</u>	<u>\$ 9,887,939</u>	<u>\$20,497,192</u>
Basic weighted average number of common shares outstanding	<u>11,259,347</u>	<u>10,914,476</u>	<u>10,790,669</u>
Basic net income per common share	<u>\$ 0.59</u>	<u>\$ 0.91</u>	<u>\$ 1.90</u>
Diluted net income per common share			
Net income applicable to common stock	\$ 6,676,274	\$ 9,887,939	\$20,497,192
Add: Preferred stock dividends	27,500	29,334	30,000
Less: Fair value of stock warrants for dilutive warrants	(794,280)	(6,995,099)	(556,662)
Net income applicable to dilutive common stock	<u>\$ 5,909,494</u>	<u>\$ 2,922,174</u>	<u>\$19,970,530</u>
Basic weighted average number of common shares outstanding	11,259,347	10,914,476	10,790,669
Effect of dilutive securities			
Dilutive stock awards	13,784	6,108	169,714
Dilutive warrants	—	—	356,981
Dilutive preferred share conversions	325	142,450	251,280
	<u>14,109</u>	<u>148,558</u>	<u>777,975</u>
Diluted weighted average number of common shares outstanding	<u>11,273,456</u>	<u>11,063,034</u>	<u>11,568,644</u>
Diluted net income per common share	<u>\$ 0.52</u>	<u>\$ 0.26</u>	<u>\$ 1.73</u>

Basic income per common share is computed by dividing the net income, plus preferred dividends by the weighted-average number of shares of common stock outstanding during a period. The diluted earnings per common share calculation gives effect to dilutive options, warrants, convertible notes, convertible preferred stock,

and other potential dilutive common stock including selected restricted shares of common stock outstanding during the period. Diluted income per share is based on the treasury stock method and includes the effect from potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options, assuming the exercise of all in-the-money stock options. Common share equivalents have been excluded where their inclusion would be anti-dilutive.

Shares to be issued upon the exercise of the outstanding options and warrants, convertible preferred stock and selected restricted shares of common stock excluded from the income per share calculation amounted to 1,599,551, 1,841,857 and 769,757 for the years ended December 31, 2013, 2012 and 2011, respectively, because the awards were anti-dilutive.

Acquisition Related Expenses

The Company's acquisition related expenses for 2013 were costs associated with the September 12, 2013 acquisition of Molecular Profiles and a failed transaction in the first quarter of 2013.

3. *Acquisition of Molecular Profiles Limited*

On September 12, 2013, Columbia acquired all of the outstanding capital stock of Molecular Profiles, a U.K.-based pharmaceutical development services company. The main service lines that have been added to the Company's portfolio as a result of the acquisition include:

- Pharmaceutical Development Services – Preformulation and Chemistry Manufacturing and Controls (“CMC”), solid state form optimization and formulation development.
- Clinical Trial Manufacturing Services – Manufacturing of tablets, capsules, topicals, dry powder inhaled products (“DPI’s”) and liquids.
- Advanced Analytical and Consulting Services – Detailed analytical characterization to support pharmaceutical development, troubleshooting process issues, materials characterization, and testing and consultancy relating to intellectual property.

The acquisition expands Columbia's service offerings and customer base while diversifying the Company's revenue streams. With the addition of Molecular Profiles, the Company now supplies analytical and consultancy services for drug development, preformulation and formulation development, clinical trial drug manufacturing services to a broad range of pharmaceutical customers and commercial drug manufacturing and supply to Merck Serono. As a result of the transaction, former Molecular Profiles stockholders, in the aggregate received for their shares of Molecular Profiles common stock \$16.7 million in cash and 1,051,323 unregistered shares of Columbia common stock. The total consideration is valued at \$24.0 million, based upon the closing price of Columbia's common stock adjusted for a discount for lack of marketability on September 12, 2013. The goodwill recognized is attributable to expected synergies as the formulation, clinical trial manufacturing and consulting business lines are integrated into Columbia's business model. Columbia accounted for this transaction using the acquisition method under the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 805, *Business Combinations*.

Columbia has allocated the purchase price to the net tangible assets and intangible assets based upon their fair values at September 12, 2013. The difference between the aggregate purchase price and the fair value of assets acquired and liabilities assumed is allocated to goodwill, none of which is deductible for tax purposes. Columbia acquired \$25.7 million of net assets, including \$2.9 million of identifiable intangible assets and goodwill of \$10.7 million. The identifiable assets include \$0.3 million of trade names, \$1.4 million of developed technology and \$1.2 million of customer relationships.

The following table summarizes the purchase consideration paid for Molecular Profiles and the fair values of the assets acquired and liabilities assumed at the date of acquisition:

Purchase consideration:	
Cash and stock paid	\$24,041,941
Cash acquired	(2,230,514)
Debt assumed	<u>3,889,486</u>
Fair value of consideration transferred	<u>\$25,700,913</u>
Recognized amounts of identifiable assets acquired and liabilities assumed:	
Accounts receivable	\$ 3,522,281
Prepaid expenses and other current assets	970,376
Property and equipment	11,967,176
Deferred tax assets	605,009
Identifiable intangible assets	2,910,000
Goodwill	10,660,296
Accounts payable	(999,539)
Accrued expenses	(1,045,309)
Deferred revenue	<u>(2,889,377)</u>
Total	<u>\$25,700,913</u>

The above fair values of the assets acquired and liabilities assumed are based on information that was available as of the acquisition date to estimate the fair value of assets acquired and liabilities assumed. As of December 31, 2013, the Company's measurement period adjustments are complete.

Revenue related to Molecular Profiles operations was \$3.6 million following the September 12, 2013 acquisition date, and is included in Columbia's consolidated statements of operations for the year ended December 31, 2013 as service revenues. As a result of the integration of the operations of Molecular Profiles into Columbia's operations, disclosure of earnings included in the accompanying consolidated statements of operations since the acquisition date is not practicable.

The following unaudited pro forma condensed consolidated operating results for the years ended December 31, 2013 and 2012 summarize the combined results of operations for Columbia and Molecular Profiles. The unaudited pro forma consolidated operating results include the business combination accounting effects as if the acquisition had been completed as of January 1, 2012 (for both the 2013 and 2012 period results). These pro forma amounts are for informational purposes only and are not indicative of the operating results that would have occurred if the transaction had occurred on such date. No effect has been given for synergies, if any, that may be realized through the acquisition.

	Year Ended December 31,	
	2013	2012
Revenues	\$36,074,941	\$30,965,698
Pre-tax income	\$ 6,251,894	\$ 7,600,216
Basic net income per share	\$ 0.52	\$ 0.63
Diluted net income per share	\$ 0.45	\$ 0.05

For the year ended December 31, 2013, Columbia recorded \$1.1 million in costs associated with the acquisition of Molecular Profiles. These amounts and \$0.5 million in costs associated with a failed transaction are recorded as acquisition related expenses within operating expenses on the consolidated statements of operations. These costs consist of legal, accounting and other professional service fees.

4. *Goodwill and Other Intangible Assets*

Changes to goodwill during the year ended December 31, 2013 were as follows:

	<u>Total</u>
Balance – December 31, 2012	\$ —
Molecular Profiles acquisition	10,660,296
Translation adjustment	491,629
Balance – December 31, 2013	<u>\$11,151,925</u>

Other intangible assets consist of the following at December 31, 2013:

	<u>Trademark</u>	<u>Developed Technology</u>	<u>Customer Relationships</u>	<u>Total</u>
Cost	\$300,000	\$1,370,000	\$1,240,000	\$2,910,000
Translation adjustment	13,402	61,947	55,733	131,082
Accumulated amortization	(36,093)	(90,585)	(85,953)	(212,631)
Balance—December 31, 2013	<u>\$277,309</u>	<u>\$1,341,362</u>	<u>\$1,209,780</u>	<u>\$2,828,451</u>

Amortization expense related to the developed technology is classified as a component of cost of service revenues in the consolidated statements of operations. Amortization expense related to trademark and customer relationships is classified as a component of general and administrative expenses in the consolidated statements of operations.

Acquired intangible assets subject to amortization are amortized over their estimated useful lives based on either the pattern in which the economic benefits of the intangible asset are consumed or on a straight-line method. The estimated useful life represents the anticipated term of the acquired intangible assets. The estimated useful lives for the trademark, developed technology and customer relationships are 3 years, 7 years and 7 years, respectively. The weighted average amortization period in total is 5.9 years.

Amortization expense for the years ended December 31, 2013, was \$0.2 million. As of December 31, 2013, amortization expense on existing intangible assets for the next five years and beyond is as follows:

<u>Year</u>	<u>Total</u>
2014	\$ 512,181
2015	535,450
2016	485,676
2017	385,586
2018 and thereafter	909,558
Total	<u>\$2,828,451</u>

5. *Debt and other Contractual Obligations*

As a part of the Molecular Profiles acquisition, Columbia assumed debt of \$3.9 million that Molecular Profiles had entered into to fund the completion and building of a second facility in the United Kingdom. Molecular Profiles entered into a Business Loan Agreement (“Loan Agreement”) covering three loan facilities with Lloyds TSB Bank (“Lloyds”), as administrative agent. Molecular Profiles had withdrawn \$3.9 million and as of December 31, 2013 owes \$4.0 million due to foreign currency revaluation. The three loan facilities are each repayable by monthly installments, one started repayment in February 2013 and the remaining two commenced in October 2013. All facilities are due for repayment over 15 years from the date of drawdown. Two of the

facilities bear interest at the Bank of England’s base rate plus 1.95% and 2.55%, respectively. The interest rate at December 31, 2013 for these two facilities was 2.45% and 3.05%, respectively. The third facility is a fixed rate agreement bearing interest at 3.52% per annum. The weighted average interest rate for the period from September 12, 2013 to December 31, 2013 was 3.08%. The Loan Agreement is secured by the mortgaged property and an unlimited lien on the other assets of Molecular Profiles. The Loan Agreement contains financial covenants that limit the amount of indebtedness Molecular Profiles may incur, requires Molecular Profiles to maintain certain levels of net worth, and restricts Molecular Profile’s ability to materially alter the character of its business. Molecular Profiles is currently in compliance with all of the covenants under the Loan Agreement.

The Company’s significant outstanding contractual obligations relate to operating leases for the Company’s facilities and loan agreements assumed as a result of the acquisition of Molecular Profiles on September 12, 2013. The Company’s facility leases are non-cancellable and contain renewal options. The Company’s future contractual obligations include the following:

	<u>Total</u>	<u>2014</u>	<u>2015</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>	<u>Thereafter</u>
Operating lease obligations	\$ 249,278	\$104,785	\$108,094	\$ 36,399	\$ —	\$ —	\$ —
Loan agreements	3,995,437	250,162	257,407	265,187	273,209	281,480	2,667,992
Total	<u>\$4,244,715</u>	<u>\$354,947</u>	<u>\$365,501</u>	<u>\$301,586</u>	<u>\$273,209</u>	<u>\$281,480</u>	<u>\$2,667,992</u>

Rent expense was \$0.3 million for each of the years ended December 31, 2013, 2012 and 2011, respectively.

As part of the acquisition of Molecular Profiles, Columbia assumed a \$2.5 million obligation under a grant arrangement with the Regional Growth Fund on behalf of the Secretary of State for Business, Innovation, and Skills in the United Kingdom. Molecular Profiles used this grant to fund the building of its second facility, which includes analytical labs, office space, and a manufacturing facility. As a part of the arrangement, Molecular Profiles is required to create and maintain certain full-time equivalent personnel levels through October 2017. As of December 31, 2013, Molecular Profiles is in compliance with the covenants of the arrangement.

The income from the Regional Growth Fund will be recognized on a decelerated basis over the next four years. As of December 31, 2013, the obligation is valued at \$2.6 million due to foreign currency revaluation and is recorded in deferred revenue on the consolidated balance sheets. The amount of other income on the obligation that will be recognized provided Molecular Profiles remains in compliance with the covenants will be the following:

<u>Year</u>	<u>Total</u>
2014	\$ 329,820
2015	593,676
2016	857,532
2017	791,568
Total	<u>\$2,572,596</u>

6. STRIANT Asset Purchase Agreement

On April 20, 2011, the Company entered into an asset purchase agreement (“Asset Purchase Agreement”) and a license agreement (“License Agreement”) with Auxilium Pharmaceuticals, Inc. (“Auxilium”, formerly Actient, Inc.), relating to the sale of certain assets and the licensing of certain intellectual property related to STRIANT® (testosterone buccal system), (“STRIANT”) in the United States.

Under the Asset Purchase Agreement, the Company sold to Auxilium certain assets primarily related to STRIANT in the United States, its territories, and possessions (“Territory”), including, but not limited to the

STRIANT NDA and other regulatory approvals in the Territory; the STRIANT trademark, trade dress and other promotional materials used primarily to promote, market and sell STRIANT in the Territory; on-hand STRIANT inventories as of the closing; and other ancillary assets and rights.

In consideration of the assets and rights acquired under the Asset Purchase Agreement, Auxilium made a one-time payment at closing to Columbia of \$3.1 million. Columbia recognized a gain in the second quarter of 2011 of \$2.5 million on the sale of STRIANT, net of the transfer of inventory, fixed assets related to STRIANT, and the residual prepaid FDA fees.

Under the License Agreement, Columbia has granted to Auxilium an exclusive (even as to Columbia) irrevocable, perpetual and transferable license in the Territory to the intellectual property primarily related to STRIANT, including a license relating to Columbia's progressive hydration technology used in STRIANT, for use in the treatment of hypogonadism and other indications related to low testosterone levels in men.

In consideration of the rights granted under the License Agreement, Auxilium will pay Columbia a royalty on Auxilium's net sales of STRIANT in the Territory. No royalty is payable on net sales less than \$10.0 million annually. A 7% royalty is payable on sales \$10.0 million and \$20.0 million annually. A 10% royalty is due on sales in excess of \$20.0 million annually. The royalty is reduced by 50% upon the expiration or other termination of the STRIANT patent and eliminated in the event of the launch of a generic product to STRIANT after the expiration or other termination of the STRIANT patent. No royalty is due after ten years from closing. No royalties have been earned to date.

7. Balance Sheet Accounts

Property and Equipment

Property and equipment consists of the following:

	Estimated Useful Life (Years)	December 31,	
		2013 Cost	2012 Cost
Machinery and equipment	3-10	\$ 4,287,940	\$ 1,901,190
Furniture and fixtures	3-5	1,010,038	1,112,732
Computer equipment and software	3	183,563	1,055,964
Buildings and leasehold improvements	Up to 39	9,615,904	57,296
Land	Indefinite	626,649	—
Construction in-process		104,016	—
		15,828,110	4,127,182
Less: Accumulated depreciation		(2,601,780)	(3,199,955)
Total		<u>\$13,226,330</u>	<u>\$ 927,227</u>

Depreciation expense for the years ended December 31, 2013, 2012, and 2011 was \$0.7 million, \$0.6 million and \$0.2 million, respectively.

The net book value of property and equipment subject to lien is \$7.9 million as of December 31, 2013.

Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2013	2012
Sales returns	\$ 137,928	\$ 483,865
Payroll	1,011,888	328,503
Severance costs	—	905,872
Professional fees	892,032	253,987
Other	446,248	244,297
Total	<u>\$2,488,096</u>	<u>\$2,216,524</u>

8. Income Taxes

Effective January 1, 2007, the Company adopted the provisions of FASB ASC 740, “Accounting for Uncertainty in Income Taxes—An Interpretation of FASB No. 109.” FASB ASC 740 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 FASB ASC 740 and in subsequent periods. Columbia 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, 2013. As a result of the acquisition of Molecular Profiles, a U.K. deferred tax asset of \$2.8 million and a deferred tax liability of \$2.2 million were recorded. No valuation allowance has been recorded in the U.K. as the Company believes that the full utilization of the deferred tax attributes in this jurisdiction is more likely than not.

(Loss) income before income taxes consists of the following:

	Year Ended December 31,		
	2013	2012	2011
Domestic	\$ (4,090,619)	\$3,462,225	\$15,356,922
Foreign	10,816,957	6,457,755	5,209,552
Income before income taxes	<u>\$ 6,726,338</u>	<u>\$9,919,980</u>	<u>\$20,566,474</u>

The Company is evaluating its plan to re-invest its foreign earnings. As of December 31, 2013, the liability for repatriating foreign earnings is deemed to be immaterial.

The components of the provision (benefit) for income taxes are as follows:

	Year Ended December 31,		
	2013	2012	2011
Current:			
Federal	\$(19,812)	\$ —	\$ —
State	(1,872)	2,707	39,282
Foreign	—	—	—
Total current	(21,684)	2,707	39,282
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	44,248	—	—
Total deferred	44,248	—	—
Provision for income taxes	<u>\$ 22,564</u>	<u>\$2,707</u>	<u>\$39,282</u>

The reconciliation of the federal statutory rate to Columbia's effective tax rate is as follows:

	<u>2013</u>	<u>2012</u>	<u>2011</u>
Federal income tax rate	34.0%	34.0%	34.0%
Foreign rate differential	(53.9)%	(22.1)%	(8.6)%
State tax, net of federal benefit	17.8	0.2	1.4
Permanent Items:			
Change in fair value of redeemable warrants	—	—	4.5
Change in fair market value of stock warrants	(4.0)	(24.0)	(0.9)
Incentive stock options	—	—	(2.6)
Subpart F inclusion	8.9	—	—
Acquisition costs capitalized	3.3	—	—
Amortization of technical rights	(5.2)	(3.5)	(1.7)
Deferred adjustments	(6.0)	—	—
Other	<u>1.1</u>	<u>3.9</u>	<u>1.0</u>
Effect of permanent differences	(1.9)	(23.6)	0.3
Rate Change	<u>(9.3)</u>	<u>(19.9)</u>	—
Effective income tax rate	(13.3)	(31.4)	27.1
Change in valuation allowance	<u>13.6</u>	<u>31.4</u>	<u>(26.9)</u>
Effective income tax rate	<u><u>0.3%</u></u>	<u><u>0.0%</u></u>	<u><u>0.2%</u></u>

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax-planning strategies in making this assessment. Management believes it is more likely than not that the results of future operations for Columbia U.S. will not generate sufficient taxable income in the future to realize the full benefits of its deferred tax assets.

As of December 31, 2013, the Company has U.S. tax net operating loss carryforwards of approximately \$160 million which expire through 2034. The Company also has unused tax credits of approximately \$2.0 million, which expire at various dates through 2031. Utilization of the tax net operating loss carryforwards may be limited in any year due to limitations in the Internal Revenue Code. U.S. net operating loss carryforwards include no excess tax benefits from the exercise of share based awards due to the full valuation allowance that remains on the net domestic deferred tax assets.

As of December 31, 2013, Molecular Profiles has U.K. tax net operating loss carryforwards of approximately \$11 million, which will not expire.

The components of Columbia's net deferred tax assets and liabilities are as follows:

	<u>December 31,</u> <u>2013</u>	<u>2012</u>
Share Based awards compensation	\$ 1,127,692	\$ 1,033,720
Allowance for returns	56,080	215,143
Inventory reserve	8,930	27,218
Book accumulated depreciation net of tax	(1,655,073)	(10,471)
Other deferred revenue	447,670	37,463
Patents	1,334,999	1,260,191
Federal net operating loss	54,571,823	52,679,076
State net operating loss	4,321,666	4,911,560
Foreign losses	2,269,322	—
Unused R&D credit	1,740,567	1,957,337
Write-up of intangibles	(589,018)	—
Other	113,623	149,924
Net deferred tax assets	63,748,281	62,261,161
Less: valuation allowance:		
Federal	(63,178,248)	(62,261,161)
Deferred tax asset	<u>\$ 570,033</u>	<u>\$ —</u>

The Company files federal income tax returns as well as multiple state, local and foreign jurisdiction tax returns. Tax years ended December 31, 2010 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, 2009 or later.

As of December 31, 2013, the Company's open tax years subject to audit are 2011, 2012 and 2013. The Internal Revenue Service is currently auditing tax years 2010 and 2011.

9. Shareholders' Equity

Preferred Stock

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

Each share of Series B Preferred Stock is convertible into 20 shares of common stock. At December 31, 2013, only 130 shares remain outstanding. 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.

The Series C Preferred Stock 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) \$28.00 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 294,045 shares). The Series C Preferred Stock pays a 5% dividend, payable quarterly in arrears on the last day of the quarter. In 2012, 50 shares of Series C Preferred Stock were redeemed for cash. 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.

On September 24, 2012, a holder of 50 shares of the Company's contingently redeemable Series C Convertible Preferred Stock redeemed those shares pursuant to Section 6.5 of the Certificate of Designations for

the Series C Preferred (“Certificate of Designations”), which provides that following a “Triggering Event,” as defined therein, the holders of the Company’s shares of Series C Preferred have the right to require us to redeem their shares in cash plus all accrued and unpaid dividends thereon on the date such redemption is demanded. The Actavis Transactions were a Triggering Event. There is no deadline following a Triggering Event by which a holder is required to make a redemption request. As a result, the Company redeemed the 50 shares for \$50,000 (the “Mandatory Redemption Price” as defined in the Certificate of Designations) plus accrued and unpaid dividends. Five hundred fifty (550) shares of Series C Convertible Preferred Stock remain outstanding.

The Series E Preferred Stock has a stated value of \$100 per share. On November 14, 2013, 22,740 shares of Series E Preferred Stock were converted into 142,125 shares of common stock. As of December 31, 2013 there are no shares outstanding.

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 a specified amount (the “Specified Amount”) (originally 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 the Specified Amount or more of the Company’s voting stock. 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 the Specified Amount 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 the Specified Amount or more of the Company’s voting stock, subject to certain exceptions.

On November 29, 2010, the Board of Directors of the Company adopted an amendment and restatement (the “Amendment”) of the Rights Agreement, dated as of March 13, 2002 (the “Original Rights Agreement”), between the Company and American Stock Transfer & Trust Company, LLC, as successor rights agent (as amended, the “Rights Plan”). In general, the Amendment leaves the Original Rights Agreement unchanged in all material respects, other than changing the trigger for the Rights becoming exercisable from 15% to 4.99% of the outstanding Voting Rights (as defined in the Rights Plan), expanding the concept of “beneficial ownership” to include shares owned (including those owned indirectly and constructively) under Section 382 of the Code and modifying the provisions relating to the exchange of Rights for common stock.

The Company adopted the Amendment to preserve the value of the Company’s net operating loss carry forwards (the “Tax Benefits”), because its ability to fully use the Tax Benefits on an annual basis to offset future income may be substantially limited if the Company experiences an “ownership change” for purposes of Section 382 of the Internal Revenue Code of 1986 (the “Code”). Generally, the Company would experience an “ownership change” under Section 382 of the Code if a greater than 50 percentage point change in ownership of the Voting Stock (as defined in the Rights Plan and described below) by stockholders who beneficially own (or who are deemed to own) 5% or more of the Company’s Voting Stock occurs over a rolling three year period.

On September 20, 2011, the Company and American Stock Transfer and Trust Company, LLC, as rights agent, further amended the Rights Plan to extend the expiration date of the rights from March 12, 2012 to July 3, 2013. On March 1, 2013, the Company further amended the Rights Plan to extend the expiration date from July 3, 2013, to July 3, 2016. Except for the extension of the expiration date, the Rights Plan otherwise remained unmodified. The extension was made to preserve the value of the Tax Benefits.

The Rights Plan is designed to reduce the likelihood that the Company will experience an ownership change by discouraging any person (together with such person's affiliates and associates), without the approval of the Board, (i) from acquiring 4.99% or more of the outstanding Voting Stock and (ii) that currently beneficially owns 4.99% or more of the outstanding Voting Stock from acquiring more shares of Voting Stock, other than by exercise or conversion of currently existing warrants, convertible securities or other equity-linked securities. There is no guarantee that the Rights Plan will prevent the Company from experiencing an ownership change.

Common Stock

The Company granted 28,083 shares of restricted stock to the Company's independent Directors during the year ended December 31, 2013. On September 12, 2013, as part of the total consideration paid for the acquisition of Molecular Profiles, the Company issued 1,051,323 shares of common stock.

During the second quarter of 2012, the Company granted 22,059 shares of restricted stock to the Company's independent Directors.

During the year ended December 31, 2011, the Company granted 4,360 shares of restricted stock to the Company's independent Directors and redeemed 4,556 shares into treasury stock for payment of taxes.

Warrants

As of December 31, 2013, the Company had warrants outstanding for the purchase shares of common stock. Information on outstanding warrants is as follows:

<u>Weighted Average Exercise Price</u>	<u>Warrants</u>	<u>Expiration Date</u>
\$9.20	112,500	07/22/2014
\$10.80	502,907	07/02/2015
\$12.16	621,275	04/30/2015
<u>\$11.34</u>	<u>1,236,682</u>	

During the years ended December 31, 2013 and 2012, there were no warrants issued or exercised.

During the year ended December 31, 2011, 465,825 warrants with an exercise price of \$10.80 were exercised through either an exchange of cash or a cashless exercise in exchange for 301,417 shares of common stock and 59,975 warrants were exercised with an exercise price of \$12.16 through either an exchange of cash or a cashless exercise in exchange for 56,325 shares of common stock.

10. Stock-based Compensation

Stock Option Plans

In May of 2008, the Company adopted the 2008 Long-term Incentive Plan ("2008 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 Committee of the Board of Directors. 750,000 shares of common stock have been reserved for issuance under the 2008 Plan.

The Company's stock options have a maximum term of ten years from the date of grant. Options granted prior to 2006 have a ten year term. Since 2006, the Company has been granting 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 2008 annual grant vests over 4 years. The Company's general policy is to issue new shares upon the exercise of stock options. The Company's current policy is to utilize shares held in treasury to settle option exercises and issue new shares for restricted stock grants.

A summary of the status of the Company's stock option plans as of December 31, 2013 is as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Vested	301,384	\$17.34		\$ —
Unvested	192,515	11.85		—
Outstanding, December 31, 2012	493,899	15.22	3.24 years	—
Granted	88,749	4.97		
Exercised	(2,030)	5.28		4,380
Forfeited	(301,420)	16.09		
Outstanding, December 31, 2013	279,198	\$11.09	4.53 years	\$212,386
Vested	119,561	15.07	3.27 years	16,622
Unvested	159,637	8.11		195,764
Vested or expected to vest, December 31, 2013	279,198	\$11.09	4.53 years	\$212,386
Exercisable, December 31, 2013	119,561	\$15.07	3.27 years	\$ 16,622

The intrinsic value of options exercised in 2013, 2012, and 2011, respectively, were \$4,380, \$0, and \$2.5 million.

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 except annual grants to independent Directors which vest at the next annual meeting of stockholders. The fair 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 the year ended December 31, 2013 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Unvested, December 31, 2012	22,059	\$5.44
Granted	28,083	\$5.34
Vested	(22,059)	\$5.44
Forfeited	—	\$ —
Unvested, December 31, 2013	28,083	\$5.34

As of December 31, 2013, there was \$0.1 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 0.46 years. The total fair value of shares vested during the year ended December 31, 2013 was \$0.1 million.

11. Related Party Transactions

From July 2010 to November 2013 the Company manufactured and sold products to Actavis at Columbia's cost plus 10%; the revenues generated from these sales were recorded within product revenues from related party. Pursuant to the Purchase and Collaboration Agreement, Columbia receive royalties equal to a minimum of 10% of annual net sales of CRINONE by Actavis for annual net sales up to \$150 million, 15% for sales above \$150 million but less than \$250 million; and 20% for annual net sales of \$250 million and over. At December 31, 2013, Actavis owned 11.5% of the Company's outstanding common stock.

The table below presents the transactions between the Company and Actavis for the years ended, December 31, 2013, 2012 and 2011:

	<u>2013</u>	<u>2012</u>	<u>2011</u>
Revenues:			
Product revenues	\$ —	\$4,304,519	\$ 3,201,464
Royalties	3,436,173	3,079,379	2,650,831
Other revenues	299,818	—	21,974,383
Total revenues	<u>3,735,991</u>	<u>7,383,898</u>	<u>27,826,678</u>
Cost of Product Revenues:			
Cost of product revenues	—	3,913,199	2,874,873
Gross profit	<u>\$3,735,991</u>	<u>\$3,470,699</u>	<u>\$24,951,805</u>

As of December 31, 2013 and December 31, 2012, amounts due from related party for these sales were \$0.9 million and \$2.2 million, respectively. There were no amounts due to Actavis as of December 30, 2013 and December 31, 2012.

Other revenues for the year ended December 31, 2013, consisted of a \$0.3 million one-time payment associated with the termination of the supply agreement with Actavis in fourth quarter of 2013.

Other revenues for the year ended December 31, 2011 of \$22.0 million, consisted of the recognition in 2011 of \$17.0 million in revenue related to the gain on the sale of the progesterone assets to Actavis and a \$5.0 million milestone payment from Actavis for the acceptance for filing of NDA 22-139 by the FDA.

In the years ended December 31, 2012 and 2011, Actavis reimbursed Columbia \$0.4 million and \$3.2 million, respectively, for research and development expenses pursuant to the purchase agreement. There are no further research and development expenses to be reimbursed by Actavis related to the purchase agreement.

12. Legal Proceedings

Claims and lawsuits are filed against the Company from time to time. Although the results of pending claims are always uncertain, 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 coverage in the event of any unfavorable outcome resulting from these actions.

Between February 1, 2012 and February 6, 2012, two putative securities class action complaints were filed against Columbia and certain of its officers and directors in the United States District Court for the District of New Jersey. These actions were filed under the captions *Wright v. Columbia Laboratories, Inc., et al.*, and *Shu v. Columbia Laboratories, Inc., et al* and asserted claims under sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated under the Exchange Act on behalf of an alleged class of purchasers of the common stock during the period from December 6, 2010 through January 20, 2012. Both actions were consolidated into a single proceeding entitled *In re Columbia Laboratories, Inc., Securities Litigation*, under which Actavis, Inc., and three of its officers have been added as defendants. The Consolidated Amended Complaint alleged that

Columbia and two of its officers, one of whom is a director, omitted to state material facts that they were under a duty to disclose, and made materially false and misleading statements that related to the results of Columbia's PREGNANT study and the likelihood of approval by the U.S. Food and Drug Administration ("FDA") of a New Drug Application ("NDA") to market progesterone vaginal gel 8% for the prevention of preterm birth in women with premature cervical shortening. According to the amended complaint, these alleged omissions and misleading statements had the effect of artificially inflating the market price of the common stock. The plaintiffs sought unspecified damages on behalf of the putative class and an award of costs and expenses, including attorney's fees. On June 11, 2013, the Court dismissed the amended complaint for failure to state a claim upon which relief could be granted, holding that the plaintiffs did not adequately plead facts supporting an inference of an intent to deceive investors. The Court permitted the plaintiffs to file a second amended complaint, and they did so on July 11, 2013. Columbia moved to dismiss the second amended complaint. On October 21, 2013, the Court dismissed the second amended complaint. The Court ruled that changes the plaintiffs made to their first amended complaint "still do not create a strong inference that Columbia acted with an intent to deceive, manipulate or defraud." The Court ordered that if the plaintiffs sought to attempt to plead a cognizable action in a third amended complaint, they must do so within thirty days and specifically address why the attempt would not be futile. The plaintiffs chose not to file any further amendments and, on December 20, 2013, appealed the dismissals to the United States Court of Appeals for the Third Circuit. The Third Circuit will consider the matter after briefing is completed. Columbia believes that the appealed action is without merit, and intends to defend it vigorously. At this time, it is not possible to determine the likely outcome of, or estimate the liability related to this action, and Columbia has not made any provision for losses in connection with it.

13. *Geographic Information and Customer Concentration*

Geographic Information

The Company and its subsidiaries are engaged in one line of business: the development, licensing, manufacturing, advanced analysis, consulting services and sale of pharmaceutical products. The Company has consolidated and runs all of its operational functions in one location in Nottingham, United Kingdom. The Company owns certain plant and equipment physically located at third party contractor facilities in the United Kingdom and Switzerland. The Company conducts its advanced formulation, analytical and consulting services through its newly acquired subsidiary, Molecular Profiles.

The Company's largest customer, Merck Serono, utilizes a Switzerland-based subsidiary to acquire product from us which it then sells throughout the world excluding the U.S. The Company's primary domestic customer, Actavis, is responsible for the commercialization and sale of Progesterone Products in the United States. The following tables show selected information by geographic area:

Revenues:

	Year Ended December, 31		
	2013	2012	2011
United States	\$ 5,463,761	\$ 8,566,725	\$28,420,480
Switzerland	21,728,434	17,261,652	14,641,541
Other countries	2,034,257	—	—
Subtotal international	<u>23,762,691</u>	<u>17,261,652</u>	<u>14,641,541</u>
Total	<u>\$29,226,452</u>	<u>\$25,828,377</u>	<u>\$43,062,021</u>

Total assets:

	December 31,	
	2013	2012
United States	\$20,277,756	\$31,898,401
Switzerland	3,063,023	1,189,183
United Kingdom	36,486,686	3,538,446
Other countries	264,995	242,634
Total	<u>\$60,092,460</u>	<u>\$36,868,664</u>

Long-lived assets:

	December 31,	
	2013	2012
United States	\$ 306,543	\$171,167
Switzerland	21,556	59,582
United Kingdom	12,986,737	734,280
Other countries	176	1,080
Total	<u>\$13,315,012</u>	<u>\$966,109</u>

The increase in the amount of total assets is due primarily to the Molecular Profiles acquisition. The increase in the amount of long-lived assets is due to the tangible net assets acquired in the Molecular Profiles acquisition.

Customer Concentration

The following table presents information about Columbia's revenues by customer, including product sales, royalty and license revenue and service revenues for each customer accounting for 10% or more of consolidated revenues in any of the three years ended December 31:

	Year Ended December, 31		
	2013	2012	2011
Merck Serono	\$21,336,458	\$17,215,126	\$14,627,491
Actavis	3,735,991	8,061,253	27,826,678
All others	4,154,003	551,998	607,852
Total	<u>\$29,226,452</u>	<u>\$25,828,377</u>	<u>\$43,062,021</u>

Revenue by Product

The following table sets forth the breakdown of the Company's consolidated revenues, including product sales, royalty and license revenue and service revenues, by revenue source for each revenue source accounting for 10% or more of consolidated revenues in any of the three years ended December 31:

	2013	2012	2011
CRINONE product sales	\$21,336,458	\$22,045,871	\$17,807,014
CRINONE Royalties	3,436,173	3,079,379	2,650,831
Service	3,640,453	—	—
Other including license fees	813,368	703,127	22,604,176
Total	<u>\$29,226,452</u>	<u>\$25,828,377</u>	<u>\$43,062,021</u>

14. Quarterly Financial Information (Unaudited)

The following table summarizes selected quarterly data for the years ended December 31, 2013 and 2012:

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
2013				
Revenues	\$ 6,315,724	\$7,977,818	\$ 7,125,692	\$7,807,218
Gross profit	3,473,985	5,147,222	3,887,477	3,466,883
Operating expenses	2,460,563	2,319,594	2,620,202	2,700,242
Income from operations	1,013,422	2,827,628	1,267,275	766,641
Change in fair value of common stock				
warrants	204,772	(154,746)	427,656	316,598
Net income	1,241,640	2,656,879	1,718,143	1,087,112
Income per common share:				
Basic	\$ 0.11	\$ 0.24	\$ 0.15	\$ 0.09
Diluted	\$ 0.09	\$ 0.24	\$ 0.11	\$ 0.06
2012				
Revenues	\$ 3,833,541	\$8,230,536	\$ 6,673,038	\$7,091,262
Gross profit	1,830,555	3,764,690	3,486,246	3,958,622
Operating expenses	3,105,003	2,082,428	2,045,675	2,997,499
Income (loss) from operations	(1,274,448)	1,682,262	1,440,571	961,123
Change in fair value of common stock				
warrants	6,259,367	205,700	(1,065,498)	1,595,530
Net income	4,954,393	1,942,810	388,729	2,631,341
Income (loss) per common share:				
Basic	\$ 0.45	\$ 0.18	\$ 0.04	\$ 0.24
Diluted	\$ (0.12)	\$ 0.16	\$ 0.04	\$ 0.09

The explanations for major variances from the fourth quarters for the years ended December 31, 2013 and 2012 are:

1. In the fourth quarter of 2013, the Company recorded other revenues of \$0.3 million for the termination of the supply agreement with Actavis.
2. In the fourth quarter of 2012, the Company recorded severance expenses of \$0.9 million in operating expenses related to the departure of two executive officers.
3. In the fourth quarter of 2012, the Company recorded an expense for the impairment of long-lived assets of \$0.9 million.

The third quarter of 2013 has been previously restated. Refer to Footnote 15 for further details.

15. Restatement of Unaudited Interim Consolidated Financial Statements

The Company's Board of Directors, based on the recommendation of the Audit Committee of the Company's Board of Directors and consultation with management, concluded that the previously issued interim consolidated financial statements contained in Form 10-Q for the quarterly period ended September 30, 2013 should no longer be relied upon and must be restated to correct an error related to the valuation of the Company's common stock warrant liability as of September 30, 2013.

As of September 30, 2013, there were 621,275 warrants outstanding with an exercise price of \$12.16 and an expiration date of April 30, 2015 that are classified as liability instruments in the Company's consolidated balance sheet and are remeasured at fair value each reporting period. Management estimates the fair value of the common stock warrant liability each reporting period using the Black-Scholes option pricing model and input assumptions such as: the Company's common stock price on the applicable measurement date; the exercise price of the common stock warrants; remaining contractual term; risk-free interest rate; and historical volatility.

Following a review of the Original Financial Statements, the Company discovered a calculation error related to the valuation of the common stock warrant liability as of September 30, 2013 that was previously reported. This error resulted in the overstatement of the common stock warrant liability recorded in the consolidated balance sheet as of September 30, 2013 and overstatement of the associated expense recognized in the consolidated statements of operations for the change in the fair value of the common stock warrant liability recognized for the three and nine month periods ended September 30, 2013.

As a result, the Company has restated its consolidated balance sheet to reflect the corrected value of the common stock warrant liability as of September 30, 2013 and its consolidated statements of operations to correct the amounts recognized for the change in fair value of common stock warrants for the three and nine month periods ended September 30, 2013. The Company also restated its consolidated statements of comprehensive income (loss) for the three and nine month periods ended September 30, 2013 and the consolidated statement of cash flows for the nine month period ended September 30, 2013 to conform to the changes made in the consolidated balance sheet and statements of operations. As a result of this misstatement, net income was understated by \$4.9 million for the three and nine month periods ended September 30, 2013.

This restatement has resulted in certain adjustments to our financial statements which are illustrated in detail below.

	September 30, 2013		
	As Previously Reported	Adjustment	As Restated
Consolidated Balance Sheet:			
Common stock warrant liability	\$ 5,568,525	\$(4,872,460)(1)	\$ 696,065
Total liabilities	18,180,455	(4,872,460)	13,307,995
Accumulated deficit	(247,621,276)	4,872,460	(242,748,816)
Total shareholders' equity	41,050,241	4,872,460	45,922,701
Three Months Ended September 30, 2013			
	As Previously Reported	Adjustment	As Restated
Consolidated Statement of Operations:			
Change in fair value of common stock warrants	\$ (4,444,804)	\$4,872,460	\$ 427,656
(Loss) income before income taxes	(3,151,693)	4,872,460	1,720,767
Net (loss) income	(3,154,317)	4,872,460	1,718,143
Basic net (loss) income per common share . . .	\$ (0.28)	\$ 0.43	\$ 0.15
Diluted net (loss) income per common share	\$ (0.28)	\$ 0.39	\$ 0.11
Basic weighted average common shares outstanding	11,137,780	—	11,137,780
Diluted weighted average common shares outstanding	11,137,780	155,249 ⁽²⁾	11,293,029
Consolidated Statement of Comprehensive (Loss) Income:			
Net (loss) income	\$ (3,154,317)	\$4,872,460	\$ 1,718,143
Comprehensive (loss) income	(2,516,607)	4,872,460	2,355,853

Nine Months Ended September 30, 2013

	As Previously Reported	Adjustment	As Restated
<u>Consolidated Statement of Operations:</u>			
Change in fair value of common stock			
warrants	\$ (4,394,778)	\$ 4,872,460	\$ 477,682
Income before income taxes	752,378	4,872,460	5,624,838
Net income	744,204	4,872,460	5,616,664
Basic net income per common share	\$ 0.07	\$ 0.44	\$ 0.51
Diluted net income per common share	\$ 0.07	\$ 0.39	\$ 0.46
Basic weighted average common shares			
outstanding	10,994,382	—	10,994,382
Diluted weighted average common shares			
outstanding	11,148,275	—	11,148,275
<u>Consolidated Statement of Comprehensive</u>			
<u>Income:</u>			
Net income	\$ 744,204	\$ 4,872,460	\$ 5,616,664
Comprehensive income	1,282,762	4,872,460	6,155,222
<u>Consolidated Statement of Cash Flows:</u>			
Net income	\$ 744,204	\$ 4,872,460	\$ 5,616,664
Change in fair value of common stock			
warrants	4,394,778	(4,872,460)	(477,682)

- (1) Represents the warrant liability adjustment as of September 30, 2013.
- (2) Represents the effect of dilutive securities change to the diluted weighted average common shares outstanding due to the three months ended September 30, 2013 results changing from a net (loss) to net income.

EXHIBIT INDEX

Exhibit	Index Description of Exhibit
2.1	Purchase and Collaboration Agreement by and between Columbia Laboratories, Inc. and Coventry Acquisition, Inc. dated March 3, 2010 (19)
2.2	Share Purchase Agreement dated September 2013 between the Sellers, Columbia Laboratories, Inc. and Molecular Profiles Limited (38)
3.1	Restated Certificate of Incorporation of the Company, as amended (8)
3.2	Certificate of Amendment of Restated Certificate of Incorporation of the Company (22)
3.3	Certificate of Amendment of Restated Certificate of Incorporation of the Company (37)
3.4	Amended and Restated By-laws of Company (28)
4.1	Certificate of Designations, Preferences and Rights of Series C Convertible Preferred Stock of the Company, dated as of January 7, 1999 (2)
4.2	Certificate of Designations of Series E Convertible Preferred Stock, filed May 10, 2005 with the Delaware Secretary of State (7)
4.3*	Form of Restricted Stock Agreement (9)
4.4*	Form of Option Agreement (13)
4.5	Form of Warrant (22)
4.6	Amended and Restated Rights Agreement by and between Columbia Laboratories, Inc. and American Stock Transfer & Trust Company, LLC dated November 29, 2010 (24)
4.7	Amendment No. 1, dated as of September 20, 2011, to the Amended and Restated Rights Agreement, dated as of November 29, 2010, by and between Columbia Laboratories, Inc. and American Stock Transfer & Trust Company, LLC. (29)
4.8	Amendment No. 2, dated as of March 5, 2013, to the Amended and Restated Rights Agreement, dated as of November 29, 2010, by and between Columbia Laboratories, Inc. and American Stock Transfer & Trust Company, LLC. (34)
4.9*	Form of Award Agreement under the Amended and Restated 2008 Long-term Incentive Plan of Columbia Laboratories, Inc. (35)
10.1*	1996 Long-term Performance Plan, as amended, of the Company (1)
10.2	License Agreement dated April 18, 2000, between the Company and Lil' Drug Store Products, Inc. (3)
10.3†	Semi-Exclusive Supply Agreement dated May 7, 2002 between the Company and Mipharm S.p.A. (4)
10.4*	Form of Indemnification Agreement for Officers and Directors (5)
10.5†	Asset Purchase Agreement dated June 29, 2004, between the Company and Lil' Drug Store Products, Inc. (6)
10.6*	Separation Agreement by and between Columbia Laboratories, Inc. and David L. Weinberg effective as of December 12, 2006 (9)
10.7	Lease Agreement between Allwood Associates I and Columbia Laboratories, Inc., dated July 6, 2007 (10)
10.8	Packaging Agreement between Columbia Laboratories (Ireland) Ltd. and Maropack AG, dated October 28, 1993 (11)
10.9*	Columbia Laboratories, Inc., 2008 Long-Term Incentive Plan (12)

- 10.10* Columbia Laboratories, Inc., Amended and Restated Incentive Plan (13)
- 10.11* Form of Executive Change of Control Severance Agreement (13)
- 10.12* Amended and Restated Employment Agreement by and between Columbia Laboratories, Inc. and Michael McGrane dated March 11, 2009 (15)
- 10.13* Employment Agreement by and between Columbia Laboratories, Inc. and Lawrence Gyenes dated July 15, 2009 (14)
- 10.14* Columbia Laboratories Stock Ownership Guidelines for Officers and Directors (16)
- 10.15 Manufacturing and Supply Agreement between Fleet Laboratories and Columbia Laboratories (Bermuda), Ltd., dated December 8, 2009 (17)
- 10.16 Note Purchase and Amendment Agreement by and between Columbia Laboratories, Inc. and holders listed on Schedule I thereto dated March 3, 2010 (19).
- 10.17* Amended and Restated Employment Agreement by and between Columbia Laboratories, Inc. and Frank C. Condella, Jr., dated May 4, 2010 (20)
- 10.18 Second Amended and Restated License and Supply Agreement dated May 14, 2010 between Columbia Laboratories, Inc. and Ares Trading S.A. (21)
- 10.19 Investor's Rights Agreement by and between Columbia Laboratories, Inc. and Coventry Acquisition, Inc. dated July 2, 2010 (22)
- 10.20 Supply Agreement by and between Columbia Laboratories, Inc. and Coventry Acquisition, Inc. dated July 2, 2010 (22)
- 10.21 License Agreement by and between Columbia Laboratories, Inc. and Coventry Acquisition, Inc. dated July 2, 2010 (22)
- 10.22 Securities Purchase Agreement by and between Columbia Laboratories, Inc. and holders listed on Schedule I thereto dated August 9, 2010 (23)
- 10.23 Settlement Agreement and Release by and between Bio-Mimetics, Inc. and Columbia Laboratories, Inc. dated December 3, 2010 (25)
- 10.24* Addendum to Amended and Restated Employment Agreement by and between Columbia Laboratories, Inc., and Frank C. Condella, Jr., dated March 1, 2011 (26)
- 10.25 Asset Purchase Agreement dated April 20, 2011, between Actient Pharmaceuticals LLC, and Columbia Laboratories, Inc. (27)
- 10.26 License Agreement dated April 20, 2011, between Actient Pharmaceuticals LLC, and Columbia Laboratories, Inc. (27)
- 10.27 U.S. Supply Agreement Assignment dated April 20, 2011, between Mipharm S.p.A., and Columbia Laboratories (Bermuda), Ltd. (27)
- 10.28 Agreement dated February 10, 2012, between Columbia Laboratories, Inc., and Coventry Acquisition, LLC, to Waive Conditions Precedent to Second Closing of March 3, 2010 Purchase and Collaboration Agreement (30)
- 10.29* Description of the Registrant's Compensation and Reimbursement Practices for Non-employee Directors. (31)
- 10.30 License Agreement dated July 24, 2012, between Columbia Laboratories, Inc., and Scientelle LLC (32)
- 10.31* Employment Agreement by and between Columbia Laboratories, Inc., and Jonathan B. Lloyd Jones dated January 15, 2013 (33)

- 10.32 Amendment No. 1 to the Second Amended and Restated License and Supply Agreement dated April 4, 2013, between Columbia Laboratories, Inc. and Ares Trading S.A. (36)
- 10.33 Parent Guarantee of Columbia Laboratories, Inc., dated September 12, 2013 (38)
- 10.34* Employment Agreement dated September 12, 2013, between Dr. Nikin Patel and Columbia Laboratories, Inc. (38)
- 10.35 Bank Loan Agreement between Molecular Profiles Limited and Lloyds TSB Bank plc, dated January 6, 2012 (39)
- 10.36 Amendment letter between Molecular Profiles Limited and Lloyds TSB Bank plc, dated September 16, 2013 (39)
- 10.37 Amendment to Manufacturing and Supply Agreement, effective as of December 31, 2013, between Columbia Laboratories (Bermuda) Ltd., and Fleet Laboratories Limited (40)
- 14 Code of Ethics of the Company (5)
- 21 Subsidiaries of the Company (41)
- 23.1 Consent of BDO USA, LLP, Independent Registered Public Accounting Firm (41)
- 31(i).1 Certification of Chief Executive Officer of the Company (41)
- 31(i).2 Certification of Chief Financial Officer of the Company (41)
- 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 (41)
- 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 (41)
- 101†† XBRL data file (41)
- † Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.
- †† Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended (the “Securities Act”), are deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise not subject to liability under those sections. This exhibit shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Registrant specifically incorporates this exhibit by reference.
- * Management contract or compensatory plans or arrangements
- 1/ Incorporated by reference to the Registrant’s Proxy Statement, dated May 10, 2000
- 2/ Incorporated by reference to the Registrant’s Annual Report on Form 10-K for the year ended December 31, 1998
- 3/ Incorporated by reference to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2000
- 4/ Incorporated by reference to the Registrant’s Quarterly Report on Form 10-Q, dated August 14, 2002
- 5/ Incorporated by reference to the Registrant’s Annual Report on Form 10-K for the year ended December 31, 2003
- 6/ Incorporated by reference to the Registrant’s Quarterly Report on Form 10-Q, dated August 4, 2004
- 7/ Incorporated by reference to the Registrant’s Current Report on Form 8-K, dated May 12, 2005
- 8/ Incorporated by reference to the Registrant’s Annual Report on Form 10-K for the year ended December 31, 2005
- 9/ Incorporated by reference to the Registrant’s Current Report on Form 8-K, dated December 15, 2006
- 10/ Incorporated by reference to the Registrant’s Quarterly Report on Form 10-Q, dated August 8, 2007
- 11/ Incorporated by reference to the Registrant’s Annual Report on Form 10-K for the year ended December 31, 2007

- 12/ Incorporated by reference to the Registrant's Proxy Statement, dated April 8, 2008
- 13/ Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2008
- 14/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated July 15, 2009
- 15/ Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, dated August 6, 2009
- 16/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated November 17, 2009
- 17/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated December 8, 2009
- 18/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated December 14, 2009
- 19/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated March 4, 2010
- 20/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated May 5, 2010
- 21/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated May 18, 2010
- 22/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated July 6, 2010
- 23/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated August 10, 2010
- 24/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated November 30, 2010
- 25/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated December 6, 2010
- 26/ Incorporated by reference to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2010
- 27/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated April 20, 2011
- 28/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated July 15, 2011
- 29/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated September 16, 2011
- 30/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated February 10, 2012
- 31/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated June 7, 2012
- 32/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated July 26, 2012
- 33/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated January 15, 2013
- 34/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated March 1, 2013
- 35/ Incorporated by reference to the Registrant's Registration Statement on Form S-8, dated May 16, 2013
- 36/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated April 4, 2013
- 37/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated August 8, 2013
- 38/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated September 18, 2013
- 39/ Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, dated November 6, 2013
- 40/ Incorporated by reference to the Registrant's Current Report on Form 8-K, dated February 6, 2014
- 41/ Filed herewith

Subsidiaries of the Company

Columbia Laboratories (Bermuda) Ltd.

Columbia Laboratories (France) SA

Columbia Laboratories (UK) Limited

Molecular Profiles Limited

Consent of Independent Registered Public Accounting Firm

Columbia Laboratories, Inc.
Boston, MA

We hereby consent to the incorporation by reference in the Registration Statement on Forms S-3 (No. 333-169599, 333-75275, 333-125671, 333-132803, 333-140107, 333-37976, 333-38230, and 333-155530) and Forms S-8 (No. 333-34079, 333-63470, 333-116072, 333-152008, and 333-188647) of Columbia Laboratories, Inc. of our report dated March 5, 2014, relating to the consolidated financial statements which appears in this Annual Report on Form 10-K.

/s/ BDO USA, LLP
Boston, MA

March 5, 2014

**Certification Pursuant to Rule 13a-14(a)/15d-14(a)
of the Securities Exchange Act of 1934**

I, Frank C. Condella, Jr. certify that:

1. I have reviewed this quarterly report on Form 10-K of Columbia Laboratories, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement 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 periods covered by this quarterly 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 quarterly 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 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - 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.

/s/ Frank C. Condella Jr.

Frank C. Condella Jr.
President and Chief Executive Officer
DATE: March 5, 2014

**Certification Pursuant to Rule 13a-14(a)/15d-14(a)
of the Securities Exchange Act of 1934**

I, Jonathan B. Lloyd Jones, certify that:

1. I have reviewed this quarterly report on Form 10-K of Columbia Laboratories, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement 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 periods covered by this quarterly 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 quarterly 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 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - 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.

/s/ Jonathan B. Lloyd Jones

Jonathan B. Lloyd Jones
Vice President, Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)
DATE: March 5, 2014

**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, 2013 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Frank C. Condella, Jr., President and 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.

/s/ Frank C. Condella, Jr.

Frank C. Condella, Jr.
President and Chief Executive Officer
Date: March 5, 2014

**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, 2013 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Jonathan B. Lloyd Jones, Vice President, Chief Financial Officer and Treasurer 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.

/s/ Jonathan B. Lloyd Jones

Jonathan B. Lloyd Jones
Vice President, Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)
DATE: March 5, 2014

Board of Directors

Stephen G. Kasnet
Chairman of the Board

Valerie L. Andrews
*Vice President and General Counsel,
Vertex Pharmaceuticals Inc.*

Dr. Frank M. Armstrong
Director

Edward A. Blechschmidt*
Director

Frank C. Condella, Jr.
*President and Chief Executive
Officer, Columbia Laboratories, Inc.*

Cristina Csimma, PharmD
Chief Executive Officer, Cydan, Inc.

Donald H. Hunter
Principal, Donald Hunter LLC

Dr. Nikin Patel
*Chief Executive Officer, Molecular
Profiles Ltd.*

Advisor to the Board

Dr. Martyn Davies
*Professor of Biomedical Surface
Chemistry, University of Nottingham*

Corporate Officers

Frank C. Condella, Jr.
President and Chief Executive Officer

Dr. Nikin Patel
*Chief Executive Officer, Molecular
Profiles Ltd.*

Jonathan Lloyd Jones
*Vice President, Chief Financial
Officer, Treasurer and Secretary*

Corporate Headquarters

Columbia Laboratories, Inc.
4 Liberty Square
Fourth Floor
Boston, MA 02109
(617) 639-1500 (phone)
(866) 566-5636 (toll-free)

Corporate websites:
<http://www.columbialabs.com>
<http://www.molprofiles.co.uk>

Independent Auditors

BDO USA, LLP
Boston, MA 02110

Registrar and Stock Transfer

American Stock Transfer & Trust
Company, LLC
59 Maiden Lane
New York, New York 10038
(800) 937-5449 (toll-free)

Annual Meeting

The annual meeting of shareholders will be held Thursday, May 8, 2014 at 9:00 a.m. Eastern Time at the Hilton Hotel Boston Downtown/Faneuil Hall, 89 Broad Street, Boston, MA 02110. The record date for the meeting will be March 14, 2014.

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 inquiries, should be directed to Jonathan Lloyd Jones, Chief Financial Officer, at the Company's headquarters or by email at CIR@columbialabs.com.

Securities and Related Information

The Company's Common Stock is traded on the Nasdaq National 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".

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 operating and growing its business for the foreseeable future.

*Mr. Blechschmidt will not stand for re-election at the annual meeting of shareholders.

Safe Harbor Statement

This annual report contains forward-looking statements regarding Columbia's strategic direction, prospects and future results, which statements are indicated by the words "may," "will," "plans," "believes," "expects," "potential," "should," and similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to 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 14, 2014. Factors that might cause future results to differ include, but are not limited to: Actavis' and Merck Serono's success in marketing CRINONE in their respective markets; changes in timing and quantity of Merck Serono's supply orders; timely and successful renewals by Merck Serono of the license for CRINONE in major ex-U.S. markets; Merck Serono's success gaining entry to new markets for CRINONE; the successful launch by Actavis of the next-generation CRINONE for the U.S. market; our ongoing ability to retain current and attract new customers; difficulties or delays in manufacturing; the availability and pricing of third-party sourced products and materials; successful compliance with FDA, MHRA, and other governmental regulations applicable to manufacturing facilities, products and/or businesses; changes in the laws and regulations; the ability to obtain and enforce patents and other intellectual property rights; the impact of competitive products and pricing; our inability to maintain effective reporting internal controls over financial reporting; the strength of the U.S. dollar relative to international currencies, particularly the euro, the British pound and the Swiss franc; 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 SEC. Columbia does not undertake any responsibility to revise or update any forward-looking statements contained herein.

Columbia Laboratories, Inc.

(Nasdaq: CBRX)

4 Liberty Square, Fourth Floor

Boston, MA 02109

(617) 639-1500 (phone)

(866) 566-5636 (toll-free)

<http://www.columbialabs.com>

<http://www.molprofiles.co.uk>

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