



Delivering on the promise

2009 Annual Report



Products in Late-Stage Development

Poised for the Market

#### FIRST DRUG FOR LUPUS TO ACHIEVE POSITIVE RESULTS IN PHASE 3 TRIALS

In July and November 2009, HGS and GlaxoSmithKline announced that BENLYSTA™ (belimumab) met the primary efficacy endpoints in BLISS-52 and BLISS-76—thus becoming the first drug for lupus ever to achieve positive results in Phase 3 trials.

The Phase 3 data showed that BENLYSTA plus standard of care achieved a clinically and statistically significant improvement in patient response rate compared with placebo plus standard of care. BLISS study results also showed that belimumab was generally well tolerated, with rates of overall adverse events comparable to placebo.

HGS and GSK plan to submit marketing applications for BENLYSTA to regulatory authorities in the United States and Europe in the second quarter of 2010, and it has the potential to receive regulatory approval in the U.S. in the fourth quarter of 2010.

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It is estimated that 170 million people worldwide are infected with the hepatitis C virus, including four million people in the United States.

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#### \$180 MILLION IN 2009 REVENUE FROM DELIVERIES TO THE U.S. STRATEGIC NATIONAL STOCKPILE

In the first half of 2009, HGS achieved its first product sales and recognized \$162.5 million in revenue by delivering 20,000 doses of raxibacumab to the U.S. Strategic National Stockpile for emergency use in treating inhalation anthrax.

In July 2009, the U.S. Government exercised its option to purchase 45,000 additional doses to be delivered over a three-year period. HGS recognized \$17.7 million in 2009 revenue from the delivery of approximately 5,600 doses under the second order—and expects to deliver an additional 15,000 doses to the Stockpile in 2010.

HGS submitted a Biologics License Application to the FDA for raxibacumab for the treatment of inhalation anthrax in May 2009, received a Complete Response Letter in November 2009, and is working closely with the FDA to obtain approval.





HGS believes BENLYSTA  
has the potential to  
become the first drug  
for lupus approved  
in more than 50 years.

**Benlysta**<sup>®</sup>  
(belimumab)

#### ZALBIN™ PENDING REGULATORY REVIEW IN THE UNITED STATES AND EUROPE

HGS and Novartis have completed Phase 3 development of ZALBIN dosed every two weeks in patients with chronic hepatitis C.

In November 2009, HGS submitted a Biologics License Application to the FDA in the United States for ZALBIN dosed every two weeks and has received confirmation that its submission was accepted for filing with a PDUFA target date of October 4, 2010.

In December 2009, Novartis submitted a Marketing Authorization Application to the European Medicines Agency (EMA) in Europe for the same dosing regimen under the brand name JOULFERON®.

In both Phase 3 studies, ZALBIN, with half the injections, achieved sustained virologic response comparable to that achieved by Pegasys. The rates of serious and/or severe adverse events were also comparable in these studies.

 **Zalbin**<sup>™</sup>  
albinterferon alfa-2b



Raxibacumab represents  
a new way to address  
the anthrax threat.

**Raxibacumab**

**Raxibacumab** Serie  
34 mL Single-Use Vial  
1700 mg/34 mL (50 mg/mL)  
For Intravenous Infusion Only  
  
Rx only  
Manufactured for  
Human Genome Sciences, Inc.  
Rockville, MD 20850



“We are grateful to Human Genome Sciences and GlaxoSmithKline for their pioneering efforts to develop a new, safe, effective and tolerable treatment for lupus, to the physicians who have passionately committed to researching this disease, to the companies who continue to invest in finding new treatments, and to the thousands of people with lupus who have volunteered and participated in clinical studies over the years so discoveries such as this one could be possible.”

**SANDRA RAYMOND**

*President and Chief Executive Officer,  
Lupus Foundation of America  
July 20, 2009*

“This is a pivotal moment in lupus research. It demonstrates the power of innovative science to drive discovery and achieve solid clinical results in the complex autoimmune disease of lupus. Benlysta represents new hope for the 1.5 million Americans with lupus and millions more worldwide who have suffered without a safe and effective treatment for more than 50 years.”

**MARGARET G. DOWD**

*President  
Lupus Research Institute  
November 2, 2009*

On the cover (clockwise from upper left), three members of the Belimumab Steering Committee: Roger A. Levy, M.D., Ph.D., Adjunct Professor of Rheumatology, The State University of Rio de Janeiro, Brazil. Ronald F. van Hollenhoven, M.D., Ph.D., Associate Professor of Rheumatology, Karolinska Institute, and Chief, Clinical Trial Unit, Karolinska University Hospital, Stockholm, Sweden. Michelle A. Petri, M.D., M.P.H., Professor, Division of Rheumatology, Department of Medicine, The Johns Hopkins University, Baltimore, Maryland.

A photograph of a female doctor with short dark hair, smiling warmly at a patient. She is wearing a white lab coat over a purple top and a pearl necklace. A red stethoscope is draped around her neck. Her lab coat has a name tag that reads "SANDRA V. NAVARRA, M.D." and "RHEUMATOLOGY". She is holding a clipboard and a pen. The patient, seen from the back, is wearing a blue and white plaid shirt. They are standing in front of a large window with a view of greenery outside.

# No new lupus drug approved in 50 years

Professor Sandra V. Navarra, M.D.,  
member of the Belimumab Steering  
Committee, and Head of Rheumatology,  
University of Santo Tomas, Manila,  
The Philippines



# One Woman's Story: Living with Lupus



My name is Lynne Kinney and I live in Lakewood, Colorado. I am 49 years old and have had lupus since I was 23 years old. However, I was not formally diagnosed until the age of 46, when I became so ill it became apparent what was wrong. I am no different from any other lupus patient. We all worry about our vital organs, we all hate that we have lost the best years of our lives due to a terrible disease, and we all panic when we get sick, hoping we will get over whatever bug or virus has found us and that we won't end up in the hospital due to a compromised immune system.

Some of us have never known the joy of becoming a mother or carrying a baby. Some of us have lived for years while lupus was undiagnosed and our vital organs were being attacked and damaged.

What has 50 years without a new lupus drug done to me? Every day that I have been alive has been one day that a new lupus drug hasn't been found.

Why do we have to borrow drugs from other diseases? My dad died of an autoimmune disease and, ironically, he was on the same drugs I take for lupus. That just isn't right. My niece has type 1 diabetes and she has insulin and a pump to boot. Her organs will be spared. I know of people with MS and they have their daily injections of beta interferons. What do lupus patients have? We still only have drugs that were developed for other diseases. That is just not right.

Many people ask me what lupus is—I always try to use the analogy when describing lupus that type 1 diabetes attacks your pancreas, arthritis affects your joints, MS attacks your myelin sheath. Lupus can and does affect every part of your body and vital organs. It's the mother lode of autoimmune diseases.

Fifty years means trying to explain to someone why you are so exhausted you cannot do something on the spur of the moment, why it's difficult to make long-term plans and having to explain to someone that, yes, you really are sick, even though you look and act just fine.

When people find out I have lupus, two simple things tell me everything I need to know. Those that know nothing of lupus always say, "Oh really." Those that know of lupus and have known someone with lupus respond, "I am so sorry. How can I help and how are you?" Even without words you know what they are saying and thinking by the look on their faces. Only a sick person can understand this.

Fifty years without a new drug means I may live a normal life span, but it's a life span with incredible health complications and no light at the end of the tunnel.

But it also means I have an inner strength I didn't know I have. It means never, ever taking anything for granted, and it also means I can never explain to anyone what it means to have lupus.

Lynne Kinney  
Lakewood, Colorado





BENLYSTA (belimumab) is the first in a new class of drugs called BLYS-specific inhibitors. BLYS®, or B-lymphocyte stimulator, is a naturally occurring protein discovered by HGS in 1997. BENLYSTA is being developed by HGS and GSK under a co-development and commercialization agreement entered into in 2006.

In lupus and certain other autoimmune diseases, elevated levels of BLYS are believed to contribute to the production of autoantibodies—antibodies that attack and destroy the body's own healthy tissues. The presence of autoantibodies appears to correlate with disease activity in patients with systemic lupus erythematosus.


BENLYSTA acts by specifically inhibiting the biological activity of BLYS and restoring the potential for autoantibody-producing B cells to undergo the normal process of apoptosis or programmed cell death. Preclinical and clinical studies have shown that BENLYSTA can reduce autoantibody levels in patients with systemic lupus.

Approximately five million people worldwide suffer from various forms of lupus, including an estimated 1.5 million in the United States. Systemic lupus is both chronic and life-threatening. It can occur at any age, but appears most often in young women ages 15 to 45. The symptoms may include extreme fatigue, painful and swollen joints, unexplained fever, skin rash and kidney problems. Flares, or periods of increased disease activity, can be severely debilitating in patients with systemic lupus. Flares can cumulatively cause irreversible damage to major organs, including the kidneys, heart, lungs and nervous system.

BENLYSTA has successfully met its primary efficacy endpoint in two pivotal Phase 3 trials in patients with systemic lupus erythematosus. Based on the results of these studies, known as BLISS-52 and BLISS-76, BENLYSTA has the potential to become the first new approved drug in more than 50 years for people living with lupus.



► BENLYSTA is the first in a new class of drugs called BLYS-specific inhibitors that recognize and inhibit the biological activity of B-lymphocyte stimulator, or BLYS®, which was discovered by HGS in 1997.

A middle-aged man with glasses, wearing a white lab coat over a blue shirt and a red patterned tie, is seated and looking towards a woman whose back is to the camera. He is holding a large, thick folder or book. The background is a clinical setting with medical equipment, including a blue and white device on a stand and various tubes and monitors.

Richard A. Furie, M.D., member of the Belimumab Steering Committee; Chief, Division of Rheumatology and Allergy—Clinical Immunology, North Shore Long Island Jewish Health System, Lake Success, New York; and Professor of Medicine, Albert Einstein College of Medicine

## First lupus drug with positive Phase 3 results





# Could become an important treatment for hepatitis C

Stefan Zeuzem, M.D., member of the Albinterferon Alfa-2b Steering Committee, Professor of Medicine and Chief, Department of Medicine, J.W. Goethe University Hospital, Frankfurt, Germany





ZALBIN (albinterferon alfa-2b) is a long-acting investigational treatment for chronic hepatitis C. Known as JOULFERON® outside the United States, ZALBIN was created by HGS using its proprietary albumin-fusion technology, and is being developed as a treatment for chronic hepatitis C by HGS and Novartis under an exclusive worldwide co-development and commercialization agreement entered into in 2006.

Human albumin is the most prevalent naturally occurring blood protein in the human circulatory system, persisting in circulation in the body for approximately 19 days. Research has shown that genetic fusion of therapeutic proteins to albumin decreases clearance and prolongs the half-life of the therapeutic proteins. ZALBIN results from the genetic fusion of human albumin and interferon alfa, and induces a biological effect similar to that induced by currently available recombinant interferon alfa treatments.

Hepatitis C is an inflammation of the liver caused by the hepatitis C virus. It is the most common chronic blood-borne infection in the developed world. It is estimated that approximately 170 million people worldwide are infected with the hepatitis C virus, including approximately four million people in the United States. The hepatitis C virus can cause serious liver disease, leading to cirrhosis, primary liver cancer and even death.

Data from two pivotal Phase 3 trials, ACHIEVE 1 and ACHIEVE 2/3, showed that ZALBIN met its primary endpoint of non-inferiority to Pegasys (peginterferon alfa-2a). With half the injections, ZALBIN achieved a rate of sustained virologic response comparable to Pegasys in these studies; rates of serious and/or severe adverse events were also comparable.

HGS has submitted a Biologics License Application to the FDA in the United States for ZALBIN dosed every two weeks and has received confirmation that its submission was accepted for filing with a PDUFA target date of October 4, 2010. Novartis has submitted a Marketing Authorization Application to the European Medicines Agency in Europe for the same dosing regimen under the brand name JOULFERON®. Assuming licensure by the FDA and other regulatory agencies, HGS believes that ZALBIN could become an important treatment for chronic hepatitis C.



ZALBIN is a genetic fusion of human albumin and interferon alfa, and was created using proprietary HGS albumin-fusion technology.



“Over the past several years, we have moved HGS step by step toward our goal of becoming a fully commercial biopharmaceutical company with important products on the market and multiple opportunities to drive future growth. We made important strides toward this goal in 2009.”

#### TO OUR SHAREHOLDERS:

In last year's letter to shareholders, we spoke of our belief that 2009 would be a pivotal year for Human Genome Sciences. The year more than lived up to our expectations; 2009 was a transformational year for HGS.

Over the past several years, we have moved HGS step by step toward our goal of becoming a fully commercial biopharmaceutical company with important products on the market and multiple opportunities to drive future growth. We made important strides toward this goal in 2009.

We expect to continue our transformation in 2010 as we work with our partners to bring our first major products through regulatory review and to the patients who need them.

**BENLYSTA™** In July and November 2009, we and GlaxoSmithKline (GSK) announced that BENLYSTA met the primary efficacy endpoints in BLISS-52 and BLISS-76, the largest late-stage clinical trials ever conducted in lupus patients. In these BLISS studies, BENLYSTA was also generally well tolerated, with rates of adverse events, infections and discontinuations due to adverse events comparable between BENLYSTA and placebo treatment groups.

The BLISS studies are the only two large-scale late-stage clinical trials ever conducted in which a drug for lupus met the primary efficacy endpoint.

We and GSK are developing BENLYSTA under a co-development and commercialization agreement entered into in 2006. We expect to submit the U.S. marketing application for BENLYSTA to the FDA in the United States in the second quarter of 2010, and it could receive regulatory approval in the U.S. as early as the fourth quarter of this year. We expect GSK to submit the European marketing application to regulatory authorities soon after the U.S. submission.

Based on the Phase 3 data, we believe BENLYSTA could become the first new drug approved for the treatment of lupus in more than 50 years.

**ZALBIN™** In March 2009, we and Novartis successfully completed the Phase 3 development of ZALBIN (albinterferon alfa-2b) in patients with chronic hepatitis C. We and Novartis are developing ZALBIN under an exclusive worldwide co-development and commercialization agreement entered into in 2006.



H. Thomas Watkins  
President and Chief Executive Officer



Argeris (Jerry) N. Karabelas, Ph.D.  
Chairman of the Board

In the fourth quarter of 2009, HGS submitted a Biologics License Application (BLA) to the FDA in the United States for ZALBIN, and Novartis submitted a Marketing Authorization Application under the brand name JOULFERON® to the European Medicines Agency (EMA) in Europe. We have received confirmation that the ZALBIN U.S. submission was accepted for filing with a PDUFA target date of October 4, 2010.

The regulatory submissions include the results of two pivotal Phase 3 clinical trials, known as ACHIEVE 1 and ACHIEVE 2/3, showing that 900-mcg ZALBIN dosed every two weeks met its primary endpoint of non-inferiority to Pegasys (peginterferon alfa-2a) dosed once each week. In both studies, ZALBIN, with half the injections, achieved sustained virologic response comparable to that achieved by Pegasys. The rates of serious and/or severe adverse events were also comparable in these studies. Assuming approval by regulatory agencies in the United States, Europe and other regions, HGS believes ZALBIN could become an important treatment for chronic hepatitis C.

In March 2010, we announced interim results from a Phase 2b dose-ranging trial conducted by Novartis to

evaluate ZALBIN dosed monthly in patients infected with genotypes 2 and 3 hepatitis C virus. The results at twelve weeks following the end of treatment suggested that the efficacy of 1500-mcg ZALBIN dosed every four weeks was comparable to the current standard of 180-mcg Pegasys dosed once weekly. The overall adverse event profile in this study was also generally comparable for ZALBIN treatment groups compared with the Pegasys treatment group. We are delighted that the monthly dosing regimen for ZALBIN merits further study.

**RAXIBACUMAB** In the first half of 2009, we achieved the first product sales in our Company's history with the delivery of 20,000 doses of raxibacumab to the U.S. Strategic National Stockpile for emergency use in treating inhalation anthrax. We are developing raxibacumab under a contract entered into in 2006 with the Biomedical Advanced Research and Development Authority (BARDA) of the U.S. Department of Health and Human Services (HHS).

Raxibacumab fills a void in the treatment of inhalation anthrax and is complementary to the vaccines and antibiotics that are currently available. It is well established



NAME	INDICATION	DEVELOPMENT STAGE			
		PHASE 1	PHASE 2	PHASE 3	TO MARKET
BENLYSTA™	Systemic Lupus				Potential for approval of our first major products in 2010
ZALBIN™	Hepatitis C				
Raxibacumab	Inhalation Anthrax				
Mapatumumab	Cancer				
HGS1029	Cancer				
BENLYSTA™	Additional Autoimmune				
Darapladib (GSK*)	Cardiovascular Disease				
Syncria® (GSK*)	Diabetes				

\*Both darapladib and Syncria® are products to which we have substantial financial rights in the GlaxoSmithKline clinical pipeline.

that antibiotics are effective in killing anthrax bacteria, but antibiotics are not effective against the anthrax toxins once the toxins have been released into the blood. In contrast to antibiotics, raxibacumab blocks the deadly effects of the anthrax toxins, and may also be effective against antibiotic-resistant strains of anthrax.

In last year's annual report, we expressed the hope that fulfillment of our initial order for raxibacumab would result in additional deliveries of raxibacumab to the Stockpile. We are pleased to report that in July 2009, the U.S. Government exercised its option to purchase 45,000 additional doses of raxibacumab for the Stockpile, to be delivered over a three-year period.

In 2009, HGS recognized \$162.5 million in revenue from deliveries to the Stockpile under our first order. We expect to receive approximately \$142 million from the second award as deliveries are completed, including \$17.7 million recognized from our initial delivery of approximately 5,600 doses in November 2009.

We submitted a BLA for raxibacumab to the FDA in May 2009. We received a Complete Response Letter in response to this submission in November 2009, and we

continue to work closely with the FDA to obtain approval for this important product.

**GSK PIPELINE** In December 2009, GSK announced the initiation of its second pivotal Phase 3 trial to evaluate whether darapladib can reduce the risk of adverse cardiovascular events such as a heart attack or stroke. With more than 27,000 patients enrolled in the two trials, the Phase 3 clinical program for darapladib is among the largest ever conducted to evaluate the safety and efficacy of any cardiovascular medication. Darapladib was discovered by GSK based on our technology. HGS will receive 10% royalties on worldwide sales if darapladib is commercialized, and has a 20% co-promotion option in North America and Europe.

In the first quarter of 2009, we received a \$9 million milestone payment following GSK's initiation of a Phase 3 program to evaluate the efficacy and safety of Syncria® (albiglutide) in the long-term treatment of type 2 diabetes mellitus. Six Phase 3 trials of Syncria are currently ongoing. Syncria was created by HGS using our proprietary albumin-fusion technology, and we licensed the product to GSK in 2004. HGS is entitled

“With more than 27,000 patients enrolled in the two trials, the Phase 3 clinical program for darapladib is among the largest ever conducted to evaluate the safety and efficacy of any cardiovascular medication.”

to fees and milestone payments that could amount to as much as \$183 million—including \$33 million received to date—in addition to single-digit net royalties on worldwide sales if Syncria is commercialized.

**ONCOLOGY PROGRAM** Although our priority focus is on advancing our late-stage products toward commercialization, we continue to invest to expand and advance our oncology portfolio, building on our leading expertise in the apoptosis, or programmed cell death, pathway. Mapatumumab (HGS-ETR1) is the most advanced of any product that targets the TRAIL apoptosis pathway.

In March 2010, we announced the results of our randomized Phase 2 trial of mapatumumab in combination with chemotherapy as first-line therapy in advanced non-small cell lung cancer (NSCLC). The results showed that mapatumumab was well tolerated in this study, but showed no difference in disease response or progression-free survival for the combination that included mapatumumab versus the control group. At present, we do not intend to study mapatumumab further for use in treating NSCLC.

We continue to view our oncology program as a high priority. Randomized Phase 2 chemotherapy combination

trials are ongoing to evaluate mapatumumab's potential in the treatment of advanced multiple myeloma and hepatocellular cancer. We expect to have progression-free survival data from the multiple myeloma study in mid-2010, and we expect to initiate the randomization stage of the hepatocellular cancer study before the end of 2010.

In November 2009, we and Aegea Therapeutics announced the initiation of a Phase 1 trial of our Company's lead IAP inhibitor, HGS1029, as monotherapy in patients with advanced lymphoid tumors. We are also studying HGS1029 as monotherapy in an ongoing Phase 1 study in patients with advanced solid tumors. The IAP inhibitors are a novel class of compounds that block the activity of IAP (inhibitor of apoptosis) proteins, allowing apoptosis to proceed and causing the cancer cells to die. When IAP proteins are over-expressed in cancer cells, they can help cancer cells resist apoptosis and resume growth and proliferation.

We will continue to pursue these opportunities by studying HGS-ETR1 and our IAP inhibitors both in combination with one another and in combination with other therapeutic agents.

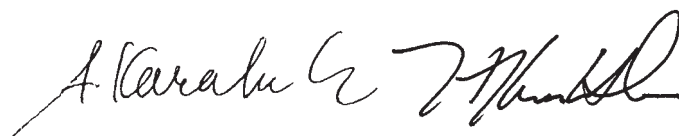
“We expect 2010 to be another year of transformation for HGS, as we continue to progress toward our goal of becoming a fully commercial biopharmaceutical company able to generate sustaining revenues to fuel growth well into the future.”

**FINANCIAL PROGRESS** We greatly strengthened our Company's financial position during 2009. With \$813 million in net proceeds from two successful public offerings of HGS common stock in the second half of 2009, our cash position is more than sufficient to take us through the filing of marketing applications and the launch of our late-stage products, and will allow us to continue to invest in our earlier-stage pipeline. We also generated net cash flow of nearly \$30 million from operations in 2009, and ended the year with \$1.2 billion in cash and investments.

**LEADERSHIP TEAM** We are delighted to welcome David P. Southwell to our senior leadership team in his new role as Executive Vice President and Chief Financial Officer and a member of the HGS Management Committee. David served as a member of our Company's Board of Directors from July 2008 until resigning from the Board to accept his new position. David brings more than 25 years of experience to HGS, including serving as Executive Vice President and Chief Financial Officer of Sepracor, a leading publicly held specialty pharmaceutical company.

We expect 2010 to be another year of transformation for HGS, as we continue to progress toward our goal of becoming a fully commercial biopharmaceutical company able to generate sustaining revenues to fuel growth well into the future. We have the potential to receive U.S. regulatory approvals for our first products in the last quarter of this year. We are ramping up our commercial organization and pre-launch manufacturing in preparation for these historic milestones. We and our partners are ready to bring BENLYSTA and ZALBIN to market, and our employees are passionately engaged in our mission to deliver innovative and life-changing therapies to patients who need them.

We thank you for your continued support.



Argeris (Jerry) N. Karabelas, Ph.D.  
*Chairman of the Board*

H. Thomas Watkins  
*President and Chief Executive Officer*



Form 10-K



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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, 2009

Commission File Number 001-14169

**HUMAN GENOME SCIENCES, INC.**

(Exact name of registrant)

**Delaware**  
(State of organization)

**22-3178468**  
(I.R.S. employer  
identification number)

**14200 Shady Grove Road, Rockville, Maryland 20850-7464**  
(address of principal executive offices and zip code)

**(301) 309-8504**

(Registrant's telephone number)

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

Title of Each Class

Name of Each Exchange on Which Registered

Common stock, par value \$0.01 per share

The NASDAQ Stock Market LLC

**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 15(d) of the Exchange 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 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 is not contained herein and will not be contained, to the best of the 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, 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. (Check one):

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☐  
(Do not check if a smaller reporting company)

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

The number of shares of the registrant's common stock outstanding on January 31, 2010 was 185,605,268. As of June 30, 2009, the aggregate market value of the common stock held by non-affiliates of the registrant based on the closing price reported on the National Association of Securities Dealers Automated Quotations System was approximately \$319,024,086.\*

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of Human Genome Sciences, Inc.'s Notice of Annual Stockholder's Meeting and Proxy Statement, to be filed within 120 days after the end of the registrant's fiscal year, are incorporated by reference into Part III of this Annual Report.

\* Excludes 24,897,966 shares of common stock deemed to be held by officers and directors and stockholders whose ownership exceeds five percent of the shares outstanding at June 30, 2009. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

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## PART I

### ITEM 1. BUSINESS

*This annual report on Form 10-K contains forward-looking statements, within the meaning of the Securities Exchange Act of 1934 and the Securities Act of 1933, that involve risks and uncertainties. In some cases, forward-looking statements are identified by words such as “believe,” “anticipate,” “expect,” “intend,” “plan,” “will,” “may” and similar expressions. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this report. All of these forward-looking statements are based on information available to us at this time, and we assume no obligation to update any of these statements. Actual results could differ from those projected in these forward-looking statements as a result of many factors, including those identified in “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere. We urge you to review and consider the various disclosures made by us in this report, and those detailed from time to time in our filings with the Securities and Exchange Commission, that attempt to advise you of the risks and factors that may affect our future results.*

#### Overview

Human Genome Sciences, Inc. (“HGS” or the “Company”) is a commercially focused biopharmaceutical company advancing toward the market with three products in late-stage development: BENLYSTA™ for systemic lupus erythematosus (“SLE”), ZALBIN™ for chronic hepatitis C, and raxibacumab for inhalation anthrax.

BENLYSTA and ZALBIN continue to progress toward commercialization. In July and November 2009, we reported that BENLYSTA successfully met its primary endpoints in two Phase 3 clinical trials in patients with systemic lupus. We and GlaxoSmithKline (“GSK”) plan to submit marketing applications for BENLYSTA in the United States and Europe in the second quarter of 2010. In March 2009, we reported that ZALBIN successfully met its primary endpoint in the second of two Phase 3 clinical trials in chronic hepatitis C. HGS submitted a Biologics License Application (“BLA”) for ZALBIN in the United States in November 2009, and Novartis submitted a Marketing Authorization Application (“MAA”) under the brand name JOULFERON® in Europe in December 2009. We received confirmation from the U.S. Food and Drug Administration (“FDA”) in February 2010 that the BLA submission was accepted for filing with a Prescription Drug User Fee Act (“PDUFA”) date of October 4, 2010.

In the first half of 2009 we achieved our first product sales and recognized \$162.5 million in product sales and manufacturing and development services revenue by delivering 20,001 doses of raxibacumab to the U.S. Strategic National Stockpile (“SNS”). In July 2009, the U.S. Government (“USG”) exercised its option to purchase 45,000 additional doses to be delivered over a three-year period. We expect to receive a total of approximately \$152.0 million from the second order, including \$17.7 million in revenue recognized from our first delivery under the new award in the fourth quarter of 2009. In May 2009, HGS submitted a BLA to the FDA for raxibacumab for the treatment of inhalation anthrax. We received a Complete Response Letter in November 2009, and we continue to work closely with the FDA to determine the additional steps necessary to obtain approval.

In addition to these products in the HGS internal pipeline, we have substantial financial rights to two novel drugs that GSK has advanced to late-stage development. In December 2009, GSK initiated the second Phase 3 clinical trial of darapladib, which was discovered by GSK based on HGS technology, to evaluate whether darapladib can reduce the risk of adverse cardiovascular events such as a heart attack or stroke. With more than 27,000 patients enrolled, the Phase 3 clinical program for darapladib is among the largest ever conducted to evaluate the safety and efficacy of any cardiovascular medication. In the first quarter of 2009, we received a \$9.0 million milestone payment related to GSK’s initiation of a Phase 3 program to evaluate the safety and efficacy of Syncria® (albiglutide) in the long-term treatment of type 2 diabetes mellitus. We created Syncria using our proprietary albumin-fusion technology and licensed it to GSK in 2004. Six Phase 3 trials of Syncria are currently ongoing.

HGS also has several novel drugs in earlier stages of clinical development for the treatment of cancer, led by our TRAIL receptor antibody mapatumumab and a small-molecule antagonist of IAP (inhibitor of apoptosis) proteins.

Strategic partnerships are an important driver of our commercial success. We have co-development and commercialization agreements with prominent pharmaceutical companies for both of our lead products — GSK for BENLYSTA and Novartis for ZALBIN. Raxibacumab is being developed under a contract with the Biomedical Advanced Research and Development Authority (“BARDA”) of the Office of the Assistant Secretary for Preparedness and Response (“ASPR”), U.S. Department of Health and Human Services (“HHS”). Our strategic partnerships with leading pharmaceutical and biotechnology companies allow us to leverage our strengths and gain access to sales and marketing infrastructure, as well as complementary technologies. Some of these partnerships provide us with licensing or other fees, clinical development cost-sharing, milestone payments and rights to royalty payments as products are developed and commercialized. In some cases, we are entitled to certain commercialization, co-promotion, revenue-sharing and other product rights.

In the second half of 2009, we received \$812.9 million in net proceeds from two public offerings of our common stock, bringing our cash and investments at year-end 2009 to \$1.2 billion. With a strong cash position, a management team experienced in bringing products to market, an experienced drug development organization and significant capabilities in biologicals manufacturing, we believe HGS has the resources and capabilities necessary to achieve near-term commercial success while sustaining a viable pipeline that supports the long-term growth of the Company.

We are a Delaware corporation headquartered at 14200 Shady Grove Road, Rockville, Maryland, 20850-7464. Our telephone number is (301) 309-8504. Our website address is [www.hgsi.com](http://www.hgsi.com). Information contained on our website is not a part of, and is not incorporated into, this annual report on Form 10-K. Our filings with the SEC are available without charge on our website as soon as reasonably practicable after filing. HGS, Human Genome Sciences, BENLYSTA, BLYS and ZALBIN are trademarks of Human Genome Sciences, Inc. Other trademarks referenced are the property of their respective owners.

## Strategy

Over the last few years, HGS has made strategic decisions that have transformed the Company on multiple levels and created multiple paths for success. Our two lead products, BENLYSTA and ZALBIN, have significant therapeutic potential and the commercial potential to achieve important positions in the marketplace. Raxibacumab continues to generate revenues under our contract with the USG. Key strategies include:

- *Continue to accelerate the development and commercialization of our late-stage products.* Our priority focus is on completing clinical development, obtaining regulatory approvals, and preparing for the global launch and commercialization of BENLYSTA and ZALBIN.
- *Build strong partnerships with global leaders in the pharmaceutical industry.* The co-development and commercialization agreements we have in place with GSK for BENLYSTA and Novartis for ZALBIN could help HGS assure that these products achieve their full therapeutic and commercial potential. As our earlier-stage products continue to progress, we will consider each individually to assess whether similar collaborations are strategically beneficial.
- *Ensure sustainable growth into the future by continuing to invest in our mid- and early-stage clinical pipeline.* We have taken a number of actions to strengthen our oncology program. Three randomized chemotherapy combination trials of our TRAIL receptor antibody mapatumumab (HGS-ETR1) are currently ongoing to evaluate its potential in the treatment of specific cancers, including non-small cell lung cancer, multiple myeloma and hepatocellular cancer. In November 2009, we initiated a Phase 1 trial of our lead IAP inhibitor HGS1029 as monotherapy in patients with advanced lymphoid tumors. HGS1029 as monotherapy is also being studied in an ongoing Phase 1 study initiated in 2008 in patients with advanced solid tumors. Our novel small-molecule inhibitors of IAP proteins show early promise in the treatment of a number of cancers, and we plan to continue the study of HGS1029 both alone and in combination with other anti-cancer agents, including mapatumumab. We will remain opportunistic in our search for new product candidates, assessing the best of the therapeutic opportunities discovered by HGS alongside therapeutic opportunities discovered by other organizations.
- *Pursue strategic acquisitions and collaborations.* We will pursue strategic acquisitions and collaborations to augment our capabilities, provide access to complementary technologies, and expand our portfolio of new drug candidates. We also rely on collaborations for the development of certain products discovered by HGS



or others based on our technology, including those to which we have substantial financial rights in the GSK clinical pipeline. In addition, we are engaging in collaborations to leverage our extensive capabilities in protein and antibody process development and manufacturing to produce near-term revenue.

- *Capitalize on our intellectual property portfolio.* We pursue patents to protect our intellectual property and have developed a significant intellectual property portfolio, with hundreds of issued U.S. patents covering genes, proteins, antibodies and proprietary technologies. We have also filed U.S. patent applications covering many additional discoveries and inventions. We will seek opportunities to monetize intellectual property assets that we do not plan to develop ourselves internally.
- *Maintain a strong cash position.* HGS has cash resources in place that allow us to maintain a priority focus on advancing our late-stage products to commercialization, while also exploring longer-term opportunities that will drive momentum beyond our lead products. While we expect net cash burn in 2010 to increase as we prepare for commercialization, controlling net cash burn and maintaining a strong cash position will continue to be an important ongoing priority.

## Products

HGS has three products in late-stage clinical development: BENLYSTA for systemic lupus, ZALBIN for chronic hepatitis C, and raxibacumab for inhalation anthrax. We also have substantial financial rights to certain products in the GSK clinical pipeline. GSK has advanced two of these products to Phase 3 clinical trials, darapladib for cardiovascular disease and Syncria for type 2 diabetes mellitus. In addition, we have a portfolio of novel drugs in earlier stages of development, led by our TRAIL receptor antibody mapatumumab in mid-stage development for cancer.

## Clinical Programs

### *Late-Stage Products*

BENLYSTA for systemic lupus and ZALBIN for chronic hepatitis C have met the primary efficacy endpoints of their pivotal Phase 3 trials and have the potential to receive regulatory approval in the United States in 2010. Under our contract with the USG, our third late-stage product, raxibacumab, is generating revenue as we complete deliveries to the SNS for emergency use in the treatment of inhalation anthrax, and we continue to work closely with the FDA to determine the additional steps necessary to achieve licensure.

#### *BENLYSTA (belimumab)*

BENLYSTA is a human monoclonal antibody that specifically recognizes and inhibits the biological activity of B-lymphocyte stimulator, or BLyS<sup>®</sup>. In lupus, rheumatoid arthritis and certain other autoimmune diseases, elevated levels of BLyS are believed to contribute to the production of autoantibodies — antibodies that attack and destroy the body's own healthy tissues. BENLYSTA is being developed by HGS and GSK as a potential treatment for systemic lupus under a co-development and commercialization agreement entered into in 2006 (described below under "Lead Commercial Collaborations").

In July and November 2009, HGS and GSK announced that BENLYSTA met the primary efficacy endpoints in BLISS-52 and BLISS-76, thus becoming the first drug specifically for lupus to achieve positive results in Phase 3 trials. The data showed that BENLYSTA plus standard of care achieved a clinically and statistically significant improvement in patient response rate, compared with placebo plus standard of care. BLISS study results also showed that BENLYSTA was generally well tolerated, with rates of overall adverse events and discontinuations due to adverse events comparable between BENLYSTA and placebo treatment groups.

With nearly 1,700 patients participating, the BLISS studies comprise the largest clinical trial program ever conducted in lupus. In October 2009, HGS provided a full presentation of BLISS-52 results at the Annual Scientific Meeting of the American College of Rheumatology. The BLISS-76 study was analyzed after 52 weeks in support of a potential BLA in the United States and MAAs in Europe and other regions. We expect that additional data from BLISS-76 will be available in the second quarter of 2010 following completion of the full 76-week study period.

HGS and GSK expect to submit marketing applications for BENLYSTA to regulatory authorities in the United States and Europe in the second quarter of 2010, and we believe it has the potential to receive regulatory approval in the U.S. in the fourth quarter of 2010.

#### *ZALBIN (albinterferon alfa-2b)*

ZALBIN (also known as JOULFERON) is a genetic fusion of human albumin and interferon alfa that was created using the Company's proprietary albumin-fusion technology. ZALBIN is being developed by HGS and Novartis for the treatment of chronic hepatitis C under an exclusive worldwide co-development and commercialization agreement entered into in 2006 (described below under "Lead Commercial Collaborations").

HGS submitted a BLA to the FDA for ZALBIN (albinterferon alfa-2b) in the United States in November 2009, and Novartis submitted an MAA under the brand name JOULFERON to the European Medicines Agency ("EMA") in Europe in December 2009. HGS received confirmation from the FDA in February 2010 that the BLA submission was accepted for filing with a PDUFA date of October 4, 2010. ZALBIN will be the brand name for albinterferon alfa-2b in the United States, and JOULFERON will be the brand name in the rest of the world, subject to confirmation by health authorities at the time of product approval.

The regulatory submissions include the results of two pivotal Phase 3 clinical trials, known as ACHIEVE 1 and ACHIEVE 2/3, showing that 900-mcg ZALBIN dosed every two weeks met its primary endpoint of non-inferiority to Pegasys (peginterferon alfa-2a) dosed once each week. Patients also received oral ribavirin. The primary efficacy endpoint of both trials was sustained virologic response, defined as undetectable HCV (hepatitis C) RNA at 24 weeks following the end of treatment. In both studies, ZALBIN, with half the injections, achieved sustained virologic response comparable to that achieved by Pegasys. The rates of serious and/or severe adverse events were also comparable in these studies. ACHIEVE 1 was conducted in patients infected with genotype 1 virus, and ACHIEVE 2/3 was conducted in patients with genotypes 2 or 3 virus. The two studies treated a total of 2,255 patients.

We announced in January 2009 that Novartis initiated a separate Phase 2b trial to explore various doses of ZALBIN administered monthly, in combination with ribavirin, in treatment-naïve patients with genotypes 2 and 3 chronic hepatitis C. In June 2009, Novartis completed the enrollment and randomization of 391 patients randomized into four treatment groups, including three that receive ZALBIN administered once every four weeks (900 mcg, 1200 mcg or 1500 mcg), in addition to the active-control group, which receives peginterferon alfa-2a at the standard 180-mcg dose once every week. All patients in the study receive 800-mg daily oral ribavirin. The total duration of treatment is 24 weeks. The primary efficacy endpoint is sustained virologic response (SVR) at Week 48 (24 weeks following the end of treatment). We expect to have results from the monthly dosing study available in the first half of 2010.

#### *Raxibacumab*

Raxibacumab is a human monoclonal antibody that specifically targets and blocks *Bacillus anthracis* protective antigen, which research has shown to be the key facilitator of the deadly toxicity of anthrax infection. Raxibacumab represents a new way to address the anthrax threat. While antibiotics can kill the anthrax bacteria, they are not effective against the deadly toxins that the bacteria produce. Raxibacumab targets anthrax toxins after they are released by the bacteria into the blood and tissues. In an inhalation anthrax attack, people may not know they are infected with anthrax until the toxins already are circulating in their blood, and it may be too late for antibiotics alone to be effective.

We are developing raxibacumab under a contract entered into in 2006 with BARDA. In the first half of 2009, our Company achieved its first product sales and recognized \$162.5 million in product sales and manufacturing and development services revenue by delivering 20,001 doses of raxibacumab to the SNS. In July 2009, the USG exercised its option to purchase 45,000 additional doses to be delivered over a three-year period. HGS expects to receive approximately \$142.0 million from the second order as deliveries are completed, including \$17.7 million recognized as revenue from delivery of approximately 5,600 doses in fourth quarter 2009. We expect to deliver approximately 15,000 doses to the SNS in 2010.

Also under our contract, HGS submitted a BLA to the FDA for raxibacumab for the treatment of inhalation anthrax in May 2009. The BLA submission included safety and efficacy data published in the July 9, 2009 edition of *The New England Journal of Medicine*. We received a Complete Response Letter in November 2009, and we will continue to work closely with the FDA to obtain approval. HGS will receive \$20.0 million from the USG upon FDA licensure of raxibacumab.

### *Oncology Products*

As our Company's late-stage products are nearing commercialization, we continue to invest strategically to expand and advance our oncology portfolio around our leading expertise in the apoptosis, or programmed cell death, pathway.

#### *Mapatumumab (HGS-ETR1)*

HGS has pioneered the development of highly targeted agonistic antibody therapies for cancer based on the TRAIL receptor apoptotic pathway. Mapatumumab is a human monoclonal antibody that specifically binds to the TRAIL receptor 1 and causes it to induce apoptosis in cancer cells. We believe mapatumumab is the most advanced of any product in development that targets the TRAIL pathway. We have advanced mapatumumab to a proof-of-concept phase that currently includes three randomized trials to evaluate its potential in combination with chemotherapy for the treatment of specific cancers:

*Non-small cell lung cancer:* A randomized Phase 2 trial of mapatumumab in combination with paclitaxel and carboplatin as first-line therapy is ongoing in patients with advanced non-small cell lung cancer ("NSCLC"). We expect to have results from the study in the first quarter of 2010. NSCLC accounts for approximately 75-80% of all lung cancers and is currently the leading cause of cancer death in developed countries in both men and women.

*Multiple myeloma:* A randomized Phase 2 trial of mapatumumab in combination with bortezomib (Velcade) is ongoing in patients with advanced multiple myeloma. The initial data from this study, reported in September 2008, showed that mapatumumab was well tolerated and suggested that disease response rates to that date were comparable for this combination versus bortezomib alone. Patients continue on treatment until the progression of disease, and HGS expects to have final time-to-progression data available from this study in mid-2010. Multiple myeloma is a cancer of the plasma cells in bone marrow and accounts for about 10 percent of all hematologic cancers.

*Hepatocellular cancer:* The safety lead-in to a randomized Phase 2 trial of mapatumumab in combination with Nexavar (sorafenib) is ongoing in patients with advanced hepatocellular cancer, which accounts for 80-90% of all liver cancers. We expect to initiate the randomization stage of this study in 2010.

#### *IAP Inhibitors*

In November 2009, HGS announced the initiation of a Phase 1 trial of our lead IAP inhibitor, HGS1029, as monotherapy in patients with advanced lymphoid tumors. The study's primary objectives include evaluation of safety and tolerability, and dose selection for Phase 2 trials. HGS1029 as monotherapy is also being studied in an ongoing Phase 1 study in patients with advanced solid tumors.

The IAP inhibitors are a novel class of compounds that block the activity of IAP (inhibitor of apoptosis) proteins, allowing apoptosis to proceed and causing the cancer cells to die. When IAP proteins are over-expressed in cancer cells, they can help cancer cells resist apoptosis and resume growth and proliferation. Preclinical studies of HGS1029 in combination with mapatumumab demonstrated dramatic synergistic activity against a number of cancer types, including prostate, breast, esophageal, colorectal and non-small cell lung. HGS1029 has also shown significant anti-tumor activity alone and in combination with other agents in a broad range of cancers. We plan to develop mapatumumab and our IAP inhibitors in combination with one another and in combination with other therapeutic agents.

### *Products in the GSK Pipeline*

HGS has substantial financial rights to certain products in the GSK clinical development pipeline (described below under “Lead Commercial Collaborations”). GSK has advanced two of these products, darapladib and Syncria, to Phase 3 development.

#### *Darapladib*

Darapladib was discovered by GSK based on our technology. It is a small-molecule inhibitor of lipoprotein-associated phospholipase-A2 (Lp-PLA<sub>2</sub>), an enzyme associated with the formation of atherosclerotic plaques and identified in clinical trials as an independent risk factor for coronary heart disease and ischemic stroke. GSK is developing darapladib as a treatment for atherosclerosis, and we believe it has the potential to be an important treatment for the prevention of cardiovascular risk.

In December 2009, GSK announced the initiation of its second pivotal Phase 3 trial to evaluate whether darapladib can reduce the risk of adverse cardiovascular events such as a heart attack or stroke. This second Phase 3 trial will enroll and randomize approximately 11,500 men and women with acute coronary syndrome. GSK initiated its first pivotal Phase 3 trial of darapladib in December 2008. In 2009, the first trial completed enrollment ahead of schedule of approximately 15,000 men and women with chronic artery disease. With more than 27,000 patients enrolled in the two trials, the Phase 3 clinical program for darapladib is among the largest ever conducted to evaluate the safety and efficacy of any cardiovascular medication. HGS will receive 10% royalties on worldwide sales if darapladib is commercialized, and has a 20% co-promotion option in North America and Europe.

#### *Syncria (albiglutide)*

Syncria is a biological product generated from the genetic fusion of human albumin and modified human GLP-1 peptide, and is designed to act throughout the body to help maintain normal blood-sugar levels and to control appetite. GSK is developing Syncria as a treatment for type 2 diabetes mellitus.

HGS received a \$9.0 million milestone payment during the first quarter of 2009, following GSK’s initiation of a Phase 3 program to evaluate the efficacy, safety and tolerability of Syncria in the long-term treatment of type 2 diabetes mellitus. Six Phase 3 trials of Syncria are currently ongoing. Syncria was created by HGS using its proprietary albumin-fusion technology, and the product was licensed to GSK in 2004. HGS is entitled to fees and milestone payments that could amount to as much as \$183.0 million – including \$33.0 million received to date – in addition to single-digit royalties on worldwide sales if Syncria is commercialized.

### **Research and Development**

HGS has developed core competencies in the discovery and understanding of human genes and their biological functions, and in the discovery and development of human protein and antibody drugs.

#### *Human Antibody Technology*

We have acquired rights to a variety of human antibody technologies, have integrated these technologies into our research and development program, and continue to collaborate with certain antibody companies. Many medical conditions are the result of an excess of a specific protein in the body, and some antibody drugs can inactivate such proteins and bring therapeutic benefits to patients. These drugs are known as antagonistic antibodies. For example, BENLYSTA, which is in Phase 3 clinical trials for the treatment of systemic lupus, is an antagonistic human monoclonal antibody.

In certain medical conditions, it may be desirable to stimulate a specific biological activity. Antibodies that stimulate biological activity are known as agonistic antibodies. Mapatumumab is an agonistic antibody that binds to TRAIL receptor 1 and triggers programmed cell death in cancer cells. We believe that it was the first human agonistic monoclonal antibody to enter clinical trials.

## *Albumin-Fusion Technology*

Our albumin-fusion technology allows us to create long-acting forms of protein drugs by fusing the gene that expresses human albumin to the gene that expresses a therapeutically active protein. We and our partners are actively pursuing the development of albumin-fusion drugs based on therapeutic proteins already on the market. For example, ZALBIN is a genetic fusion of human albumin and human interferon alfa, and Syncria was created through the genetic fusion of human albumin and glucagon-like peptide-1 (GLP-1).

Based on preclinical and clinical results to date, we believe that albumin-fusion proteins may provide long-acting treatment options that have efficacy and safety similar to or better than that of existing protein drugs, with the potential additional benefit of considerably more convenient dosage schedules. Albumin-fusion technology also provides for efficient manufacture and purification of the product in our existing facilities.

## *Drug Development*

We have built a drug development organization that has the expertise necessary to design and implement well focused, high-quality clinical trials of multiple compounds. We seek to gather, document and analyze clinical trial data in such a way that they can be submitted to regulatory authorities and used to support BLAs at the appropriate time. We have assembled experienced teams in key strategic areas of development, including:

- *Clinical Research and Biostatistics.* The clinical research and biostatistics groups are responsible for the design, planning and analysis of clinical trials.
- *Clinical Operations.* The clinical operations group executes clinical trials and is responsible for managing clinical trial sites and ensuring that all proper procedures are followed during the collection of clinical data. The group includes our data management team.
- *Project Management.* Our project management team oversees the process of development of a drug from the earliest stages of research through the conduct of clinical development and regulatory filings.
- *Regulatory Affairs.* The regulatory affairs group manages communications with and submissions to regulatory authorities.
- *Drug Safety.* As our products advance in clinical testing, our drug safety group collects and analyzes information on drug experience and safety, and ensures that accurate medical information is distributed.
- *Quality Assurance.* The quality assurance group ensures compliance with all regulatory requirements for the clinical development and manufacture of our products.
- *Bioanalytical Sciences.* The bioanalytical sciences group develops and performs highly specialized assays that are used during monitoring of preclinical tests and clinical trials. Other assays help to ensure the quality and consistency of our products.
- *Biopharmaceutical Development.* The biopharmaceutical development group develops robust manufacturing processes and product formulations to support clinical studies and future commercial supply.

## **Strategic Collaborations**

Strategic collaborations are a key aspect of the HGS business strategy. We have co-development and commercialization agreements with prominent pharmaceutical companies for two of our late-stage products, and our third late-stage product is being developed under a contract with the USG. Strategic collaborations are an important source of revenues and clinical development cost-sharing. They also allow us to leverage our strengths and gain access to sales and marketing infrastructure, international distribution, and complementary technologies.

Other potential collaborations may provide sources of exciting new product opportunities for in-licensing. In addition, we have assets that may be a better fit for another company than for HGS, and therefore could be out-licensed. Each of these collaborative models is of interest to HGS, and we are committed to remaining alert to new opportunities.



## *Lead Commercial Collaborations*

### *Novartis*

**ZALBIN.** In 2006, we entered into an exclusive worldwide agreement for the co-development and commercialization of albinterferon alfa-2b with Novartis, a global leader in the pharmaceutical industry. Under the agreement, HGS and Novartis will co-commercialize albinterferon alfa-2b in the United States under the brand name ZALBIN, and will share clinical development costs, U.S. commercialization costs and U.S. profits equally. Novartis will be responsible for commercialization of albinterferon alfa-2b in the rest of the world under the brand name JOULFERON, and will pay HGS a royalty on those sales. HGS has primary responsibility for the bulk manufacture of albinterferon alfa-2b, and Novartis will have responsibility for commercial manufacturing of the finished drug product.

Clinical development, commercial milestone and other payments to HGS could total as much as \$507.5 million. To date, we have received \$207.5 million under our agreement with Novartis. The remaining payments to HGS under the agreement relate to the achievement of certain regulatory approval and commercial milestones. We are recognizing these payments ratably over the remaining clinical development period. We recognized revenues of \$35.4 million in 2008 and \$54.2 million in 2009. The Novartis agreement also includes cost-sharing provisions under which we and Novartis share clinical costs. We recorded cost reimbursement from Novartis of \$36.1 million in 2008 and \$0.9 million in 2009 under this provision, which was reflected as a reduction in expenses. This agreement will expire on the later of (i) the expiration of Novartis' obligation to pay royalties under the agreement, which could be as early as 2023, and (ii) the date that we and Novartis cease to co-promote ZALBIN in the United States. Novartis has the right to terminate the agreement (i) without cause or (ii) if there are material safety risks associated with ZALBIN or ZALBIN is not approved by the FDA or the EMEA. In addition, either party may terminate if the other party commits a material breach of the agreement or if the other party is bankrupt or insolvent.

### *GlaxoSmithKline*

**BENLYSTA.** In 2006, we entered into an agreement with GSK for the co-development and commercialization of BENLYSTA. GSK is a world leader that brings global pharmaceutical development and marketing capabilities to the BENLYSTA program. Under the BENLYSTA agreement, we and GSK will share Phase 3 and 4 development costs, sales and marketing expenses, and profits equally. We are conducting Phase 3 clinical trials with assistance from GSK, and will have primary responsibility for bulk manufacturing. We have received an execution fee of \$24.0 million under this agreement and we are recognizing this payment ratably over the estimated remaining development period. We recognized revenues of \$6.5 million in 2008 and \$4.7 million in 2009. The GSK BENLYSTA agreement includes cost-sharing provisions under which we and GSK share clinical development costs. We recorded cost reimbursement from GSK under this provision of \$51.8 million in 2008 and \$43.1 million in 2009, which was reflected as a reduction in expenses. This agreement will expire three years after the later of (i) the expiration date of certain patent rights related to BENLYSTA and (ii) a period of ten years after the first commercial sale of BENLYSTA. These certain patent rights are expected to expire by 2023, with the potential for later expiration that may result from any issuance of additional patent and/or patent term extensions. GSK may terminate the agreement if (i) upon the basis of competent scientific evidence or data regarding commercial potential, GSK determines BENLYSTA does not merit incurring additional development or marketing expenses or (ii) BENLYSTA is not approved by the FDA or EMEA. In addition, either party may terminate if the other party commits a material breach of the agreement or if the other party is bankrupt or insolvent.

**Darapladib.** In December 2008, GSK initiated Phase 3 development of darapladib, a small-molecule Lp-PLA<sub>2</sub> inhibitor discovered by GSK based on HGS technology. In December 2009, GSK announced the initiation of its second pivotal Phase 3 trial to evaluate whether darapladib can reduce the risk of adverse cardiovascular events such as a heart attack or stroke. With more than 27,000 patients enrolled in the two trials, the Phase 3 clinical program for darapladib is among the largest ever conducted to evaluate the safety and efficacy of any cardiovascular medication. GSK is developing darapladib as a treatment for atherosclerosis, and it has the potential to become an important treatment for the prevention of cardiovascular risk. We will receive a 10% royalty on worldwide sales of darapladib if it is commercialized, and we have a 20% co-promotion option in North America

and Europe. We are also entitled to receive a milestone payment if darapladib moves through clinical development into registration.

*Syncria.* In February 2009, GSK initiated a Phase 3 clinical trial program to evaluate the efficacy, safety and tolerability of Syncria in the long-term treatment of type 2 diabetes mellitus. HGS received a \$9.0 million milestone payment related to this initiation during the first quarter of 2009. Syncria was created by HGS using its proprietary albumin-fusion technology, and the product was licensed to GSK in 2004. Six Phase 3 trials of Syncria are currently ongoing. HGS is entitled to fees and milestone payments that could amount to as much as \$183.0 million – including \$33.0 million received to date. We are also entitled to single-digit royalties on worldwide sales if Syncria is commercialized.

#### *United States Government*

*Raxibacumab.* In September 2005, we entered into a two-phase contract to supply raxibacumab for inhalation anthrax with BARDA. HHS is the lead agency for public health and medical response to man-made or natural disasters, including acts of bioterrorism. Under the first phase of the contract, we supplied ten grams of raxibacumab to HHS for comparative *in vitro* and *in vivo* testing. In June 2006, under the second phase of the contract, the USG exercised its option to purchase raxibacumab and we agreed to manufacture and deliver 20,001 doses to the SNS. In the first half of 2009, we achieved our company's first product sales by completing these deliveries and recognized \$162.5 million in product sales and manufacturing and development services revenue. In July 2009, the USG exercised its option to purchase 45,000 additional doses to be delivered over a three-year period. HGS expects to receive approximately \$142.0 million from the second award as deliveries are completed. This includes \$17.7 million recognized in the fourth quarter of 2009 as revenue from delivery of approximately 5,600 doses. We expect to deliver approximately 15,000 doses to the SNS in 2010. Also under our contract, HGS submitted a BLA to the FDA for raxibacumab for the treatment of inhalation anthrax in May 2009. We received a Complete Response Letter in November 2009, and we will continue to work closely with the FDA to obtain approval. HGS will receive \$20.0 million from the USG upon FDA licensure of raxibacumab. Our raxibacumab agreement can be terminated by the USG if it determines that a termination is in its interest.

#### *Product Collaborations and Agreements*

*Aegera Therapeutics.* In December 2007, we and Aegera Therapeutics, Inc. ("Aegera") completed a licensing and collaboration agreement providing us with exclusive worldwide rights (excluding Japan) to develop and commercialize HGS1029 (formerly AEG40826) and other small-molecule inhibitors of IAP (inhibitor of apoptosis) proteins in oncology. Under the agreement, we made an upfront payment to Aegera of \$20.0 million as a licensing fee and for an equity investment. Aegera is entitled to receive up to \$295.0 million in additional development and commercial milestone payments, including a \$5.0 million milestone paid in 2008 upon FDA clearance of an Investigational New Drug Application ("IND"). Aegera will receive low double-digit royalties on net sales in the HGS territory. In North America, Aegera will have the option to co-promote, under which it will share certain expenses and profits (30%) in lieu of its royalties. Aegera retains the non-oncology rights to its IAP inhibitors that are not selected for development under this agreement.

*CoGenesys.* In June 2006, we completed a transaction establishing CoGenesys as an independent company to focus on the early development of selected product opportunities and the monetization of certain HGS intellectual property and technology assets that HGS did not plan to develop internally. In February 2008, Teva Pharmaceutical Industries Ltd. ("Teva") acquired all the outstanding shares of CoGenesys. We received a total of approximately \$52.6 million for our 14% equity interest, approximately \$47.3 million of which was received upon closing of the transaction in February 2008, and \$5.3 million of which was received in February 2009. We are also entitled to a portion of the revenue that Teva may receive from outlicensing or sales of certain therapeutic and diagnostic products successfully developed and commercialized.

#### *Research and Technology Collaborations*

HGS has a rich heritage of scientific discovery that has produced a substantial intellectual property estate and a library of thousands of therapeutic and diagnostic targets. After careful review, we have selected targets for further

research and potential development, with the goal of filing new INDs to develop the selected targets through co-development or research collaborations, as well as through our own internal research, including the application of antibody development technology from various collaborators.

#### *Process Development and Manufacturing Alliances*

Protein and antibody process development and manufacturing are core HGS competencies. We currently develop and produce several protein and antibody drugs in three state-of-the-art current good manufacturing practices (“cGMP”)-compliant process development and manufacturing facilities — totaling approximately 520,000 square feet. We are leveraging these capabilities to produce near-term revenue by entering into strategically appropriate process development and manufacturing alliances.

#### **Patents and Proprietary Rights**

We seek U.S. and foreign patent protection for the genes, proteins and antibodies that we discover, as well as patents on therapeutic and diagnostic products and processes, screening and manufacturing technologies, and other inventions based on genes, proteins and antibodies. We also seek patent protection or rely upon trade secret rights to protect certain technologies which may be used to discover and characterize genes, proteins and antibodies and which may be used to develop novel therapeutic and diagnostic products and processes. We believe that, in the aggregate, our patent applications, patents and licenses under patents owned by third parties are of material importance to our operations.

Important legal issues remain to be resolved as to the extent and scope of available patent protection for biotechnology products and processes in the U.S. and other important markets outside the U.S. We expect that litigation or administrative proceedings will likely be necessary to determine the validity and scope of certain of our and others’ proprietary rights. We are currently involved in a number of administrative proceedings and litigations relating to the scope of protection of our patents and those of others, and are likely to be involved in additional proceedings that may affect directly or indirectly patents and patent applications related to our products or the products of our partners. For example, we have been involved in interference and opposition proceedings related to products based on TRAIL receptor 2 (such as HGS-ETR2) and interference, opposition and revocation proceedings related to products based on BLYS (such as BENLYSTA). Any such lawsuit or proceeding may result in a significant commitment of resources in the future. In addition, changes in, or different interpretations of, patent laws in the U.S. and other countries may result in patent laws that allow others to use our discoveries or develop and commercialize our products. We cannot assure you that the patents we obtain or the unpatented technology we hold will afford us significant commercial protection.

We have filed U.S. patent applications with respect to many human genes and their corresponding proteins. We have also filed U.S. patent applications with respect to all or portions of the genomes of several infectious and non-infectious microorganisms. We have hundreds of U.S. patents covering genes, proteins, antibodies and proprietary technologies. Our remaining applications may not result in the issuance of any patents. Our applications may not be sufficient to meet the statutory requirements for patentability in all cases. In certain instances, we will be dependent upon our collaborators to file and prosecute patent applications.

Other companies or institutions have filed, and may in the future file, patent applications that attempt to patent genes similar to those covered in our patent applications, including applications based on our potential products. Any patent application filed by a third party may prevail over our patent applications, in which event the third party may require us to stop pursuing a potential product or to negotiate a royalty arrangement to pursue the potential product.

We also are aware that others, including universities and companies working in the biotechnology and pharmaceutical fields, have filed patent applications and have been granted patents in the U.S. and in other countries that cover subject matter potentially useful or necessary to our business. Some of these patents and patent applications claim only specific products or methods of making products, while others claim more general processes or techniques useful in the discovery and manufacture of a variety of products. The risk of additional patents and patent applications will continue to increase as the biotechnology industry progresses. We cannot predict the ultimate scope and validity of existing patents and patents that have been or may be granted to third

parties, nor can we predict the extent to which we may wish or be required to obtain licenses to such patents, or the availability and cost of acquiring such licenses. To the extent that licenses are required, the owners of the patents could bring legal actions against us to claim damages or to stop our manufacturing and marketing of the affected products.

Issued patents may not provide commercially meaningful protection against competitors and may not provide us with competitive advantages. Other parties may challenge our patents or design around our issued patents or develop products providing effects similar to our products. Furthermore, patents are issued for a limited time period and may expire before the useful life of the covered product. In addition, others may discover uses for genes, proteins or antibodies other than those uses covered in our patents, and these other uses may be separately patentable. The holder of a patent covering the use of a gene, protein or antibody for which we have a patent claim could exclude us from selling a product for a use covered by its patent.

We rely on trade secret protection to protect our confidential and proprietary information. We believe we have developed proprietary procedures for making libraries of DNA sequences and genes. We have not sought patent protection for these procedures. We have developed a substantial database concerning genes we have identified. We have taken security measures to protect our data and continue to explore ways to further enhance the security for our data. However, we may not be able to meaningfully protect our trade secrets. While we have entered into confidentiality agreements with employees and collaborators, we may not be able to prevent their disclosure of these data or materials. Others may independently develop substantially equivalent information and techniques.

## **Competition**

*General.* We face intense competition from a wide range of pharmaceutical, biotechnology and diagnostic companies, as well as academic and research institutions and government agencies. Some of these competitors have substantially greater financial, marketing, research and development and human resources. Most large pharmaceutical companies have considerably more experience in undertaking clinical trials and in obtaining regulatory approval to market pharmaceutical products.

*Basis of Competition.* Principal competitive factors in our industry include:

- the quality and breadth of an organization's technology;
- the skill of an organization's employees and ability to recruit and retain skilled employees;
- an organization's intellectual property estate;
- the range of capabilities, from target identification and validation to drug discovery and development to manufacturing and marketing; and
- the availability of substantial capital resources to fund discovery, development, manufacturing and commercialization activities.

We believe that the quality and breadth of our technology platform, the skill of our employees and our ability to recruit and retain skilled employees, our patent portfolio, our capabilities for research and drug development, and our capital resources are competitive strengths. However, many large pharmaceutical and biotechnology companies have significantly larger intellectual property estates than we do, more substantial capital resources than we have, and greater capabilities and experience than we do in preclinical and clinical development, sales, marketing, manufacturing and regulatory affairs.

*Products.* We are aware of products in research or development by our competitors that address all of the diseases we are targeting. Any of these products may compete with our product candidates. Our competitors may succeed in developing their products before we do, obtaining approvals from the FDA or other regulatory agencies for their products more rapidly than we do, or developing products that are more effective than our products. These products or technologies might render our technology obsolete or noncompetitive. In addition, our albumin fusion protein products are designed to be long-acting versions of existing products. While we believe our albumin fusion protein products will be a more attractive alternative to the existing products, the existing product in many cases has an established market that may make the introduction of our product more difficult. Competition is based primarily

on product efficacy, safety, timing and scope of regulatory approvals, availability of supply, marketing and sales capability, reimbursement coverage, price and patent position.

## **Government Regulation**

Regulations in the U.S. and other countries have a significant impact on our research, product development and manufacturing activities and will be a significant factor in the marketing of our products. All of our products require regulatory approval prior to commercialization. In particular, our products are subject to rigorous preclinical and clinical testing and other premarket approval requirements by the FDA and similar regulatory authorities in other regions. Various statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of our products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect our ability to commercialize our products in a timely manner, or at all.

*Preclinical Testing.* Before a drug may be clinically tested in the U.S., it must be the subject of rigorous preclinical testing. Preclinical tests include laboratory evaluation of product chemistry and animal studies to assess the potential safety and efficacy of the product and its formulations. The results of these studies must be submitted to the FDA as part of an IND, which is reviewed by the FDA before clinical testing in humans can begin.

*Clinical Testing.* Typically, clinical testing involves a three-phase process, which generally lasts four to seven years, and sometimes longer:

- Phase 1 clinical trials are conducted with a small number of subjects to determine the early safety profile and the pattern of drug distribution and metabolism.
- Phase 2 clinical trials are conducted with groups of patients afflicted with a specified disease in order to provide enough data to evaluate preliminary efficacy and optimal dosages statistically and to expand evidence of safety.
- Phase 3 clinical trials are large-scale, multi-center, comparative trials, which are designed to gather additional information for proper dosage and labeling of the drug and to demonstrate its overall safety and efficacy.

The FDA monitors the progress of each phase of testing, and may require the modification, suspension or termination of a trial if it is determined to present excessive risks to patients. The clinical trial process may be accompanied by substantial delay and expense and there can be no assurance that the data generated in these studies will ultimately be sufficient for marketing approval by the FDA.

*Marketing Approvals.* Before a product can be marketed and sold, the results of the preclinical and clinical testing must be submitted to the FDA for approval. This submission will be either a new drug application or a biologics license application, depending on the type of drug. In responding to a new drug application or a biologics license application, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. We cannot assure you that any approval required by the FDA will be obtained on a timely basis, or at all.

In addition, the FDA may condition marketing approval on the conduct of specific post-marketing studies to further evaluate safety and efficacy (such as Phase 4 trials). Rigorous and extensive FDA regulation of pharmaceutical products continues after approval, particularly with respect to compliance with cGMPs, reporting of adverse effects, advertising, promotion and marketing. Discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions, any of which could materially adversely affect our business.

*Other Regulation.* We are also subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances used in connection with our research, including radioactive compounds and



infectious disease agents. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action.

In addition, ethical, social and legal concerns about genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we or our suppliers may use. Federal and state agencies, congressional committees and foreign governments have expressed interest in further regulating biotechnology. More restrictive regulations or claims that our products are unsafe or pose a hazard could prevent us from commercializing our products.

*Foreign Regulation.* We must obtain regulatory approval by governmental agencies in other countries prior to commercialization of our products in those countries. Foreign regulatory systems may be just as rigorous, costly and uncertain as in the U.S.

*Possible Pricing Restrictions.* The levels of revenues and profitability of biopharmaceutical companies like ours may be affected by the continuing efforts of government and third party payers to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In the U.S. there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. While we cannot predict whether any legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability. In addition, in the U.S. and elsewhere, sales of therapeutic and other pharmaceutical products depend in part on the availability of reimbursement to the consumer from third party payers, such as government and private insurance plans. Third party payers are increasingly challenging the prices charged for medical products and services. We cannot assure you that any of our products will be considered cost effective or that reimbursement to the consumer will be available or will be sufficient to allow us to sell our products on a competitive and profitable basis.

## **Sources of Supply**

Most raw materials and other supplies required in our business are generally available from various suppliers in quantities adequate to meet our needs. Certain materials and other supplies required for manufacturing are currently available only from single sources. As we prepare for commercialization of our products, we intend to identify alternative sources of supply wherever possible.

## **Manufacturing**

We are able to manufacture multiple protein and antibody drugs for use in research, clinical and commercial activities. We produce and purify these protein and antibody drugs in three process development and manufacturing facilities that total approximately 520,000 square feet and offer both small-scale and large-scale manufacturing capabilities. We do not currently manufacture any products approved for commercial use. We are, however, manufacturing raxibacumab for supply to the SNS. We believe that we have sufficient manufacturing capacity to launch BENLYSTA, if it is approved by the FDA, and to supply commercial quantities of BENLYSTA to approximately 45,000 to 55,000 patients. If the demand for BENLYSTA exceeds our capacity to supply BENLYSTA to patients, we will need to contract for additional manufacturing capacity with a third-party manufacturer or buy or build additional manufacturing capacity. We cannot assure you that we will be able in the future to consistently manufacture our products economically or in compliance with cGMPs and other regulatory requirements.

Currently each of our products, BENLYSTA, ZALBIN and raxibacumab, is produced at a single manufacturing site. BENLYSTA is produced at our large-scale manufacturing facility in Rockville, Maryland and ZALBIN and raxibacumab are produced in separate parts of our small-scale manufacturing facility also in Rockville, Maryland. Each of these facilities is the sole source for these products. We cannot guarantee that one or more of these manufacturing plants will not encounter problems, including but not limited to loss of power, equipment

failure or viral or microbial contamination, which could impact our ability to deliver adequate supply of one or more of these products to the market.

In the future, we may contract with additional third party manufacturers or develop products with partners and use the partners' manufacturing capabilities. If we use others to manufacture our products, we will depend on those parties to comply with cGMPs and other regulatory requirements, and to deliver materials on a timely basis. These parties may not perform adequately. Any failures by these third parties may delay our development of products or the submission of these products for regulatory approval.

## **Marketing**

We have a strategic marketing group to analyze the commercial value of our product portfolio and the competitive environment. The strategic marketing group also analyzes patient needs and customer preferences with respect to our product development and planning. If we develop products that can be marketed, we intend to market the products either independently or together with collaborators or strategic partners. BENLYSTA and ZALBIN, if approved, will be our first products to be marketed. We have no marketing experience and, therefore, we will be dependent on creating a sales force or retaining outside contractors to meet those needs. We expect to use common pharmaceutical company marketing techniques, including sales representatives calling on individual physicians, medical education programs, professional symposia, promotional materials and public relations. If approved by the FDA, we plan to establish our sales force in the United States for BENLYSTA and ZALBIN and in Europe for BENLYSTA.

GSK has co-marketing rights with respect to BENLYSTA and Novartis has co-marketing rights with respect to ZALBIN. We expect to use the marketing capabilities of our partners with respect to these products. GSK and others also have co-marketing rights with respect to certain of our other products. For any products that we market together with partners, we will rely, in whole or in part, on the marketing capabilities of those parties. We may also contract with third parties to market certain of our products. Ultimately, we and our partners may not be successful in marketing our products. The prices for our products may be impacted by various factors, including economic analyses of the burden of the applicable disease, the perceived value of the product and third party reimbursement policies.

## **Employees**

As of February 1, 2010 we had approximately 850 full-time employees. None of our employees is covered by a collective bargaining agreement and we consider relations with our employees to be good.

## ITEM 1A. RISK FACTORS

*There are a number of risk factors that could cause our actual results to differ materially from those that are indicated by forward-looking statements. Those factors include, without limitation, those listed below and elsewhere herein.*

### RISKS RELATED TO OUR BUSINESS

**If we are unable to commercialize our Phase 3 and earlier development molecules, we may not be able to recover our investment in our product development, manufacturing and marketing efforts.**

We have invested significant time and resources to isolate and study genes and determine their functions. We now devote most of our resources to developing proteins, antibodies and small molecules for the treatment of human disease. We are also devoting substantial resources to our own manufacturing capabilities, to support clinical testing, to supply raxibacumab to the SNS and for potential commercialization of our other products. We expect to devote substantial resources to establish and maintain a marketing capability for any of our products that are approved by the FDA. We have made and are continuing to make substantial expenditures in advance of commercializing any products. Before we can commercialize a product, we must rigorously test the product in the laboratory and complete extensive human studies. We cannot assure you that the tests and studies will yield products approved for marketing by the FDA in the United States or similar regulatory authorities in other countries, or that any such products will be profitable. We will incur substantial additional costs to continue these activities. If we are not successful in commercializing our Phase 3 and earlier development molecules, we may be unable to recover the large investment we have made in research, development, manufacturing and marketing efforts.

**If we are unable to obtain marketing approval for BENLYSTA<sup>TM</sup> or ZALBIN<sup>TM</sup>, our results of operations and business will be materially and adversely affected.**

In July 2009, we reported the results from the first of our two Phase 3 clinical trials for BENLYSTA. In that trial BENLYSTA met its primary efficacy endpoint. In November 2009, we reported the 52-week results from the second of our two Phase 3 clinical trials for BENLYSTA. In that trial, BENLYSTA at a dose of 10 mg/kg also met its primary efficacy endpoint. Although the primary efficacy endpoint of the BLISS-76 trial was assessed after 52 weeks, we will continue to collect additional data from this trial for an additional 24 weeks. There can be no assurance that the additional data collected will be positive. Despite our determination that the results from the two BENLYSTA trials were positive, the FDA may determine that the results from the two trials are insufficient to file a BLA or do not support marketing approval or are insufficient to obtain marketing approval. In March 2009, we reported the results from the second of our two Phase 3 clinical trials for ZALBIN. In that trial, as well as the trial we reported on in December 2008, ZALBIN met its primary efficacy endpoint. In January 2008, we modified the dosing in our two ZALBIN Phase 3 clinical trials. Patients who had been receiving the 1200-mcg dose were moved to the 900-mcg dose based on a recommendation made by our independent data monitoring committee. The recommendation was based on the incidence rate of serious pulmonary adverse events in the 1200-mcg arm of the two ZALBIN trials. In November 2009, we filed a BLA with the FDA on ZALBIN. Despite our determination that the results from the two ZALBIN trials were positive, the FDA may determine that the results do not support marketing approval or are insufficient to obtain marketing approval. In addition, our partners, Novartis for ZALBIN and GSK for BENLYSTA, may determine that the results of these trials do not warrant further development or commercialization and may terminate their respective collaboration agreements. If the results of the BENLYSTA trials are not sufficient to file a BLA, or if we are unable to obtain marketing approval for either or both products or if either of our partners terminates its collaboration agreement, our results of operations and business will be materially adversely affected and we may not have sufficient resources to continue development of these or other products.

**We may be unable to successfully establish commercial manufacturing capability and may be unable to obtain required quantities of our product candidates for commercial use.**

We have not yet manufactured any products approved for commercial use and, except for raxibacumab, have limited experience in manufacturing materials suitable for commercial use. We have only limited experience manufacturing in a large-scale manufacturing facility built to increase our capacity for protein and antibody drug

production. The FDA must inspect and license our facilities to determine compliance with cGMP requirements for commercial production. We may not be able to successfully establish sufficient manufacturing capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements. For example, we believe that we have sufficient manufacturing capacity to launch BENLYSTA, if it is approved by the FDA, and to supply commercial quantities of BENLYSTA to approximately 45,000 to 55,000 patients. If the demand for BENLYSTA exceeds our capacity to supply BENLYSTA to patients, we will need to contract for additional manufacturing capacity with a third-party manufacturer or buy or build additional manufacturing capacity. We believe that engaging a third-party manufacturer or buying or building additional manufacturing capacity will take between two and five years or longer due, in part, to the required regulatory approvals and will require substantial expenditures. We may not be able to contract with a third-party manufacturer on commercially reasonable terms, or at all, or find or build such capacity in the timeframe to meet demand, and our revenues may be limited from BENLYSTA if we are unable to do so successfully.

Currently each of our products, BENLYSTA, ZALBIN and raxibacumab, is produced at a single manufacturing site. BENLYSTA is produced at our large-scale manufacturing facility in Rockville, Maryland and ZALBIN and raxibacumab are produced in separate parts of our small-scale manufacturing facility also in Rockville, Maryland. Each of these facilities is the sole source for these products. We cannot guarantee that one or more of these manufacturing plants will not encounter problems, including but not limited to loss of power, equipment failure or viral or microbial contamination, which could impact our ability to deliver adequate supply of one or more of these products to the market.

While we have expanded our manufacturing capabilities, we have previously contracted and expect to contract with third-party manufacturers or develop products with collaboration partners and use the collaboration partners' manufacturing capabilities. If we use others to manufacture our products, we will depend on those parties to comply with cGMPs, and other regulatory requirements and to deliver materials on a timely basis. These parties may not perform adequately, or comparability between the licensed product and that produced at the third-party may not be established successfully. Any failures by these third parties may delay our development of products or the submission of these products for regulatory approval.

**Because we currently have only a limited marketing capability and in light of various factors, we may be unable to price or sell any of our products effectively.**

We do not have any marketed products, although we have sold raxibacumab to the U.S. Government. If we receive approval for products that can be marketed, we intend to market the products either independently or together with collaborators or strategic partners. GSK, Novartis and others have co-commercialization rights with respect to certain of our products. If we decide to market any products, either independently or together with partners, we will incur significant additional expenditures and commit significant additional management resources to establish a sales force. For any products that we market together with partners, we will rely, in whole or in part, on the marketing capabilities of those parties. We may also contract with third parties to market certain of our products. Ultimately, we and our partners may not be successful in marketing our products. In addition, the prices for our products may be impacted by various factors, including economic analyses of the burden of the applicable disease, the perceived value of the product and third party reimbursement policies. We can provide no assurance as to the price at which we may be able to sell any of our products, or that we will be able to price any of our products at a level that is consistent with other similar products.

**If we are unable to expand label usage of BENLYSTA, we may not recognize the full value of the product candidate and there may be adverse effects on our expected financial and operating results.**

BENLYSTA is a human monoclonal antibody that recognizes and inhibits the biological activity of B-lymphocyte stimulator, or BLyS®, and is being developed as a potential treatment for SLE. If the FDA approves BENLYSTA for the treatment of SLE, we intend to seek expansion of the approved uses, or labeled uses, of BENLYSTA in the U.S. However, we may be unable to obtain approval for such label expansion in full or in part. If we are not able to obtain approval for expansion of the labeled uses for BENLYSTA, or if we are otherwise unable to fulfill our marketing, sales and distribution plans for BENLYSTA, sales of BENLYSTA may be limited. We may conduct additional trials in support of a supplemental BLA for additional approved uses of BENLYSTA. There can

be no guarantee that these trials will be successful or that the FDA will approve a supplemental BLA for expansion of the labeled uses for BENLYSTA.

**Because our product development efforts depend on new technologies, we cannot be certain that our efforts will be successful.**

Our work depends on new technologies and on the marketability and profitability of innovative products. Commercialization involves risks of failure inherent in the development of products based on innovative technologies and the risks associated with drug development generally. These risks include the possibility that:

- these technologies or any or all of the Phase 3 and earlier development molecules based on these technologies will be ineffective or toxic, or otherwise fail to receive necessary regulatory clearances;
- the products, even if safe and effective, will be difficult to manufacture on a large scale or uneconomical to market;
- proprietary rights of third parties will prevent us or our collaborators from exploiting technologies or marketing products; and
- third parties will market superior or equivalent products.

**Because we are a late-stage development company, we cannot be certain that we can develop our business or achieve profitability.**

We expect to continue to incur losses and we cannot assure you that we will ever become profitable on a sustainable basis. A number of our products are in late-stage development; however, it could be one or more years, if ever, before we are likely to receive continuing revenue from product sales or substantial royalty payments. We will continue to incur substantial expenses relating to research, development and manufacturing efforts and human studies. Depending on the stage of development, our products may require significant further research, development, testing and regulatory approvals. We may not be able to develop products that will be commercially successful or that will generate revenue in excess of the cost of development.

**We are continually evaluating our business strategy, and may modify this strategy in light of developments in our business and other factors.**

We continue to evaluate our business strategy and, as a result, may modify this strategy in the future. In this regard, we may, from time to time, focus our product development efforts on different products or may delay or halt the development of various products. In addition, as a result of changes in our strategy, we may also change or refocus our existing drug discovery, development, commercialization and manufacturing activities. This could require changes in our facilities and personnel and the restructuring of various financial arrangements. For example, in March 2009, we reduced the scope of efforts in a number of our programs resulting in cost savings for fiscal year 2009, a portion of which came from a reduction in headcount. However, we cannot assure you that changes will occur or that any changes that we implement will be successful.

Several years ago, we sharpened our focus on our most promising drug candidates. We reduced the number of drugs in early development and focused our resources on the drugs that address the greatest unmet medical needs with substantial growth potential. In 2006, we spun off our CoGenesys division (“CoGenesys”) as an independent company, in a transaction that was treated as a sale for accounting purposes. In 2008, CoGenesys was acquired by Teva Pharmaceuticals Industries, Ltd. (“Teva”) and became a wholly-owned subsidiary of Teva called Teva Biopharmaceuticals USA, Inc. (“Teva Bio”).

Our ability to discover and develop new products will depend on our internal research capabilities and our ability to acquire products. Our internal research capability was reduced when we completed the spin-off of CoGenesys. Although we continue to conduct research and development activities on products, our limited resources for new products may not be sufficient to discover and develop new drug candidates.



## PRODUCT DEVELOPMENT RISKS

**Because we have limited experience in developing and commercializing products, we may be unsuccessful in our efforts to do so.**

Although we are conducting human studies with respect to a number of products, we have limited experience with these activities and may not be successful in developing or commercializing these or other products. Our ability to develop and commercialize products based on proteins, antibodies and small molecules will depend on our ability to:

- successfully complete laboratory testing and human studies;
- obtain and maintain necessary intellectual property rights to our products;
- obtain and maintain necessary regulatory approvals related to the efficacy and safety of our products;
- maintain production facilities meeting all regulatory requirements or enter into arrangements with third parties to manufacture our products on our behalf; and
- deploy sales and marketing resources effectively or enter into arrangements with third parties to provide these functions.

**Because clinical trials for our products are expensive and protracted and their outcome is uncertain, we must invest substantial amounts of time and money that may not yield viable products.**

Conducting clinical trials is a lengthy, time-consuming and expensive process. Before obtaining regulatory approvals for the commercial sale of any product, we must demonstrate through laboratory, animal and human studies that the product is both effective and safe for use in humans. We will incur substantial additional expense for and devote a significant amount of time to conducting ongoing trials and initiating new trials.

Before a drug may be marketed in the United States, a drug must be subject to rigorous preclinical testing. The results of this testing must be submitted to the FDA as part of an IND, which is reviewed by the FDA before clinical testing in humans can begin. The results of preclinical studies do not predict clinical success. A number of potential drugs have shown promising results in early testing but subsequently failed to obtain necessary regulatory approvals. Data obtained from tests are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Regulatory authorities may refuse or delay approval as a result of many other factors, including changes in regulatory policy during the period of product development.

Completion of clinical trials may take many years. The time required varies substantially according to the type, complexity, novelty and intended use of the product candidate. The progress of clinical trials is monitored by both the FDA and independent data monitoring committees, which may require the modification, suspension or termination of a trial if it is determined to present excessive risks to patients. Our rate of commencement and completion of clinical trials may be delayed by many factors, including:

- our inability to manufacture sufficient quantities of materials for use in clinical trials;
- variability in the number and types of patients available for each study;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- unforeseen safety issues or side effects;
- poor or unanticipated effectiveness of products during the clinical trials; or
- government or regulatory delays.

To date, data obtained from our clinical trials may not be sufficient to support an application for regulatory approval without further studies. Studies conducted by us or by third parties on our behalf may not demonstrate sufficient effectiveness and safety to obtain the requisite regulatory approvals for these or any other potential products. For example, we have submitted BLAs to the FDA for raxibacumab and ZALBIN, but the studies we have conducted to date may not be sufficient to obtain FDA approval. In November 2009, we received a Complete Response Letter from the FDA related to our BLA for raxibacumab. In this letter, the FDA determined that it cannot

approve the BLA for raxibacumab in its present form and requested additional studies and data that would be needed prior to the FDA making a decision as to whether or not to approve the raxibacumab BLA. We may not be able to complete the requested studies or to generate the required data in a timely manner, if at all. If the FDA requires that we complete the additional studies and generate the additional data requested in the Complete Response Letter, we may be required to withdraw our existing BLA and resubmit our BLA after completion of such studies. This will start a new review cycle. Even if we could complete such studies and generate such data, the studies and data may not be sufficient for FDA approval. In addition, based on the results of a human study for a particular product candidate, regulatory authorities may not permit us to undertake any additional clinical trials for that product candidate. The clinical trial process may also be accompanied by substantial delay and expense and there can be no assurance that the data generated in these studies will ultimately be sufficient for marketing approval by the FDA. In February 2010, the FDA accepted our ZALBIN BLA filing with a PDUFA action date of October 4, 2010.

The development programs for ZALBIN and BENLYSTA have each involved two large-scale, multi-center Phase 3 clinical trials and have been more expensive than our Phase 1 and Phase 2 clinical trials. In December 2008 and March 2009, we announced that we had completed the Phase 3 clinical studies for ZALBIN; in both studies, ZALBIN met its primary efficacy endpoint of non-inferiority to peginterferon alfa-2a. In November 2009, we filed a BLA for ZALBIN with the FDA. In July 2009, we reported the results from the first of our two Phase 3 clinical trials for BENLYSTA. In that trial, BENLYSTA met its primary efficacy endpoint. In November, 2009, we reported the 52 week data from the second Phase 3 clinical trial for BENLYSTA. In that trial, BENLYSTA at a dose of 10 mg/kg also met its primary efficacy endpoint. Although the primary efficacy endpoint of the BLISS-76 study was assessed after 52 weeks, we will continue to collect additional data from this trial for an additional 24 weeks. We may not be able to complete this second BENLYSTA Phase 3 clinical trial successfully or obtain FDA approval of ZALBIN or BENLYSTA. Even if FDA approval is obtained, it may include limitations on the indicated uses for which ZALBIN and/or BENLYSTA may be marketed.

**We face risks in connection with our raxibacumab product in addition to risks generally associated with drug development.**

The development of raxibacumab presents risks beyond those associated with the development of our other products. Numerous other companies and governmental agencies are known to be developing biodefense pharmaceuticals and related products to combat anthrax disease. These competitors may have financial or other resources greater than ours, and may have easier or preferred access to the likely distribution channels for biodefense products. In addition, since the primary purchaser of biodefense products is the U.S. Government and its agencies, the success of raxibacumab will depend on government spending policies and pricing restrictions. The funding of government biodefense programs is dependent, in part, on budgetary constraints, political considerations and military developments. In the case of the U.S. Government, executive or legislative action could attempt to impose production and pricing requirements on us. We have entered into a two-phase contract, which may be terminated at any time, to supply raxibacumab, a human monoclonal antibody developed for use in the treatment of anthrax disease, to the U.S. Government. Under the first phase of the contract, we supplied ten grams of raxibacumab to the HHS for comparative in vitro and in vivo testing. Under the second phase of the contract, the U.S. Government ordered 20,001 doses of raxibacumab for the U.S. SNS for use in the treatment of anthrax disease. We completed delivery of these doses and the U.S. Government accepted our deliveries. In July 2009, the U.S. Government agreed to purchase 45,000 additional doses. We, therefore, have future deliveries to make and ongoing obligations under the contract, including the obligation to obtain FDA approval. We will continue to face risks related to the requirements of the contract. If we are unable to meet our obligations associated with this contract, the U.S. Government will not be required to make future payments related to that order. Although we have received U.S. Government approval for two orders of raxibacumab, we cannot assure you we will receive additional orders. In November 2009, we received a Complete Response Letter from the FDA related to our BLA for raxibacumab. In this letter, the FDA determined that it cannot approve our BLA for raxibacumab in its present form and requested additional studies and data that would be needed prior to the FDA making a decision as to whether or not to approve the raxibacumab BLA. We may not be able to complete the requested studies or to generate the required data in a timely manner, if at all. If the FDA requires that we complete the additional studies and generate the additional data requested in the Complete Response Letter, we may be required to withdraw our existing BLA

and resubmit our BLA after completion of such studies. This will start a new review cycle. Even if we could complete such studies and generate such data, the studies and data may not be sufficient for FDA approval. Although the government has accepted shipment of raxibacumab subsequent to the receipt of the FDA's Complete Response Letter, we cannot assure you that the government will continue to accept future shipments or place additional orders.

**Because neither we nor any of our collaboration partners have received marketing approval for any product candidate resulting from our research and development efforts, and because we may never be able to obtain any such approval, it is possible that we may not be able to generate any product revenue other than with respect to raxibacumab.**

Although we have submitted BLAs for two of our products (raxibacumab and ZALBIN), we cannot assure you that any of these products will receive marketing approval. It is possible that we will not receive FDA marketing approval for any of our product candidates even if the results of clinical trials are positive. All products being developed by our collaboration partners will also require additional research and development, preclinical studies and extensive clinical trials and regulatory approval prior to any commercial sales. In some cases, the length of time that it takes for our collaboration partners to achieve various regulatory approval milestones may affect the payments that we are eligible to receive under our collaboration agreements. We and our collaboration partners may need to successfully address a number of technical challenges in order to complete development of our products. Moreover, these products may not be effective in treating any disease or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude obtaining regulatory approval or prevent or limit commercial use.

## **RISK FROM COLLABORATION RELATIONSHIPS AND STRATEGIC ACQUISITIONS**

**Our plan to use collaborations to leverage our capabilities and to grow in part through the strategic acquisition of other companies and technologies may not be successful if we are unable to integrate our partners' capabilities or the acquired companies with our operations or if our partners' capabilities do not meet our expectations.**

As part of our strategy, we intend to continue to evaluate strategic partnership opportunities and consider acquiring complementary technologies and businesses. In order for our future collaboration efforts to be successful, we must first identify partners whose capabilities complement and integrate well with ours. Technologies to which we gain access may prove ineffective or unsafe. Our current agreements that grant us access to such technology may expire and may not be renewable or could be terminated if we or our partners do not meet our obligations. These agreements are subject to differing interpretations and we and our partners may not agree on the appropriate interpretation of specific requirements. Our partners may prove difficult to work with or less skilled than we originally expected. In addition, any past collaborative successes are no indication of potential future success.

In order to achieve the anticipated benefits of an acquisition, we must integrate the acquired company's business, technology and employees in an efficient and effective manner. The successful combination of companies in a rapidly changing biotechnology industry may be more difficult to accomplish than in other industries. The combination of two companies requires, among other things, integration of the companies' respective technologies and research and development efforts. We cannot assure you that this integration will be accomplished smoothly or successfully. The difficulties of integration may be increased by any need to coordinate geographically separated organizations and address possible differences in corporate cultures and management philosophies. The integration of certain operations will require the dedication of management resources which may temporarily distract attention from the day-to-day operations of the combined companies. The business of the combined companies may also be disrupted by employee retention uncertainty and lack of focus during integration. The inability of management to integrate successfully the operations of the two companies, in particular, the integration and retention of key personnel, or the inability to integrate successfully two technology platforms, could have a material adverse effect on our business, results of operations and financial condition.

**We reacquired rights to HGS-ETR1 from GSK, as well as all GSK rights to other TRAIL Receptor antibodies. We may be unsuccessful in developing and commercializing products from these antibodies without a collaborative partner.**

As part of our September 1996 agreement with GSK, we granted a 50/50 co-development and co-commercialization option to GSK for certain human therapeutic products that successfully completed Phase 2a clinical trials. In August 2005, we announced that GSK had exercised its option to develop and commercialize HGS-ETR1 (mapatumumab) jointly with us. In April 2008, we announced that we had reacquired all rights to our TRAIL receptor antibodies (including rights to HGS-ETR1 and HGS-ETR2) from GSK, in return for a reduction in royalties due to us if Syncria®, a GSK product for which we would be owed royalties, is commercialized. We also announced that our agreement with the pharmaceutical division of Kirin Brewery Company, Ltd. for joint development of antibodies to TRAIL receptor 2 had been terminated. Takeda Pharmaceutical Company, Ltd. has the right to develop HGS-ETR1 in Japan. As a result of these actions, we have assumed full responsibility for the development and commercialization of products based on these antibodies, except for HGS-ETR1 in Japan.

**Our ability to receive revenues from the assets licensed in connection with our CoGenesys transaction will depend on Teva Bio's ability to develop and commercialize those assets.**

We will depend on Teva Bio to develop and commercialize the assets licensed as part of the spin-off of CoGenesys. If Teva Bio is not successful in its efforts, we will not receive any revenue from the development of these assets. In addition, our relationship with Teva Bio will be subject to the risks and uncertainties inherent in our other collaborations.

**Because we currently depend on our collaboration partners for substantial revenue, we may not become profitable on a sustainable basis if we cannot increase the revenue from our collaboration partners or other sources.**

We have received substantial revenue from payments made under collaboration agreements with GSK and Novartis, and to a lesser extent, other agreements. The research term of our initial GSK collaboration agreement and many of our other collaboration agreements expired in 2001. None of the research terms of these collaboration agreements was renewed and we may not be able to enter into additional collaboration agreements. While our partners under our initial GSK collaboration agreement have informed us that they have been pursuing research programs involving different genes for the creation of small molecule, protein and antibody drugs, we cannot assure you that any of these programs will be continued or will result in any approved drugs.

Under our present collaboration agreements, we are entitled to certain development and commercialization payments based on our development of the applicable product or certain milestone and royalty payments based on our partners' development of the applicable product. We may not receive payments under these agreements if we or our collaborators fail to:

- develop marketable products;
- obtain regulatory approvals for products; or
- successfully market products.

Further, circumstances could arise under which one or more of our collaboration partners may allege that we breached our agreement with them and, accordingly, seek to terminate our relationship with them. Our collaboration partners may also terminate these agreements without cause or if competent scientific evidence or safety risks do not justify moving the applicable product forward. If any one of these agreements terminates, this could adversely affect our ability to commercialize our products and harm our business.

**If one of our collaborators pursues a product that competes with our products, there could be a conflict of interest and we may not receive milestone or royalty payments.**

Each of our collaborators is developing a variety of products, some with other partners. Our collaborators may pursue existing or alternative technologies to develop drugs targeted at the same diseases instead of using our licensed technology to develop products in collaboration with us. Our collaborators may also develop products that are similar to or compete with products they are developing in collaboration with us. If our collaborators pursue



these other products instead of our products, we may not receive milestone or royalty payments. For example, GSK has been developing for the treatment of insomnia an orexin inhibitor based on our technology and to which we are entitled to milestones, royalties and co-promotion rights. In July 2008, GSK announced a collaboration with Actelion Ltd. to co-develop and co-commercialize a different orexin inhibitor. While GSK has stated publicly that it intends to continue work on the inhibitor derived from our technology, there can be no assurance that it will continue to do so or that such work will lead to a commercial product.

## REGULATORY RISKS

**Because we are subject to extensive changing government regulatory requirements, we may be unable to obtain government approval of our products in a timely manner.**

Regulations in the United States and other countries have a significant impact on our research, product development and manufacturing activities and will be a significant factor in the marketing of our products. All of our products require regulatory approval prior to commercialization. In particular, our products are subject to rigorous preclinical and clinical testing and other premarket approval requirements by the FDA and similar regulatory authorities in other regions, such as Europe and Asia. Various statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of our products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect our ability to commercialize our products in a timely manner, or at all.

*Marketing Approvals.* Before a product can be marketed and sold in the United States, the results of the preclinical and clinical testing must be submitted to the FDA for approval. This submission will be either a new drug application or a biologics license application, depending on the type of drug. In responding to a new drug application or a BLA, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. We cannot assure you that any approval required by the FDA will be obtained on a timely basis, or at all. For example, in November 2009, we received a Complete Response Letter from the FDA related to our BLA for raxibacumab. In this letter, the FDA determined that it cannot approve our BLA for raxibacumab in its present form and requested additional studies and data that would be needed prior to the FDA making a decision as to whether or not to approve the raxibacumab BLA. We may not be able to complete the requested studies or to generate the required data in a timely manner if at all. If the FDA requires that we complete the additional studies and generate the additional data requested in the Complete Response Letter, we may be required to withdraw our existing BLA and resubmit our BLA after completion of such studies. This will start a new review cycle. Even if we could complete such studies and generate such data, the studies and data may not be sufficient for FDA approval. In addition, based on the results of a human study for a particular product candidate, regulatory authorities may not permit us to undertake any additional clinical trials for that product candidate.

In November 2009, we filed a BLA with the FDA for ZALBIN. In February 2010, the FDA accepted our ZALBIN BLA filing with a PDUFA action date of October 4, 2010. We plan to file a BLA with the FDA for BENLYSTA in the second quarter of 2010 and to request priority review of that application. The FDA may not grant priority review of our BENLYSTA BLA and may not act on our BLAs in a timely manner. The FDA may determine that our BLAs are insufficient to support marketing approval or may deny our BLAs for either or both products, either of which would materially adversely affect our results of operations and business.

The FDA may condition marketing approval on the conduct of specific post-marketing studies to further evaluate safety and efficacy. Rigorous and extensive FDA regulation of pharmaceutical products continues after approval, particularly with respect to compliance with cGMPs, reporting of adverse effects, advertising, promotion and marketing. Discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions, any of which could materially adversely affect our business.

*Foreign Regulation.* We must obtain regulatory approval by governmental agencies in other countries prior to commercialization of our products in those countries. Foreign regulatory systems may be just as rigorous, costly and uncertain as in the United States.

**Because we are subject to environmental, health and safety laws, we may be unable to conduct our business in the most advantageous manner.**

We are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research, including radioactive compounds and infectious disease agents. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations.

## **INTELLECTUAL PROPERTY RISKS**

**If our patent applications do not result in issued patents or if patent laws or the interpretation of patent laws change, our competitors may be able to obtain rights to and commercialize our discoveries.**

Our pending patent applications, including those covering full-length genes and their corresponding proteins, may not result in the issuance of any patents. Our applications may not be sufficient to meet the statutory requirements for patentability in all cases or may be subject to challenge, if they do issue. Important legal issues remain to be resolved as to the extent and scope of available patent protection for biotechnology products and processes in the United States and other important markets outside the United States, such as Europe and Japan. In the United States, Congress is considering significant changes to U.S. intellectual property laws which could affect the extent and scope of existing protections for biotechnology products and processes. Foreign markets may not provide the same level of patent protection as provided under the U.S. patent system. We expect that litigation or administrative proceedings will likely be necessary to determine the validity and scope of certain of our and others' proprietary rights. We are currently involved in a number of litigation and administrative proceedings relating to the scope of protection of our patents and those of others in both the United States and in the rest of the world.

We are involved in a number of interference proceedings brought by the United States Patent and Trademark Office ("PTO") and may be involved in other interference proceedings in the future. These proceedings determine the priority of inventions and, thus, the right to a patent for technology in the U.S. For example, we were recently involved in interferences in the United States with both Genentech, Inc. and Immunex Corporation, a wholly-owned subsidiary of Amgen, Inc., related to products based on TRAIL Receptor 2 (such as HGS-ETR2). In four of these interferences, we initiated district court litigation to review adverse decisions by the PTO. In two of these cases, we also sought appellate review of a jurisdictional issue decided by the district court. In light of the multiple adverse judgments by the PTO and district court, we requested dismissal of both the district court and appellate actions. Consequently, we will not be able to obtain patent protection for TRAIL Receptor 2 from any of the patents or patent applications that were involved in these litigations. The adverse judgments in these litigations also may prevent us from obtaining other issued patents related to TRAIL Receptor 2.

We are also involved in proceedings in connection with foreign patent filings, including opposition and revocation proceedings and may be involved in other opposition proceedings in the future. For example, we are involved in European opposition proceedings against an issued patent of Biogen Idec. In this opposition, the European Patent Office ("EPO") found the claims of Biogen Idec's patent to be valid. The claims relate to a method of treating autoimmune diseases using an antibody to BLyS (such as BENLYSTA). We and GSK have entered into a definitive license agreement with Biogen Idec that provides for an exclusive license to this European patent. This patent is still under appeal in Europe. We also have been involved in an opposition proceeding brought by Eli Lilly and Company with respect to our European patent related to BLyS compositions, including antibodies. In 2008, the Opposition Division of the EPO held our patent invalid. We appealed this decision, and in October 2009, a Technical Board of Appeal of the EPO reversed the Opposition Division decision and held that our European patent is valid. Although decisions of a Technical Board of Appeal can be appealed only in limited circumstances, Eli Lilly may appeal this decision. In addition, Eli Lilly instituted a revocation proceeding against our United Kingdom patent that corresponds to our BLyS European patent; in this proceeding the United Kingdom trial court found the patent invalid. We appealed this decision and the UK Court of Appeal upheld the lower court ruling that our United Kingdom patent was invalid. We intend to appeal this decision to the UK Supreme Court.

We have also opposed European patents issued to Genentech, Inc. and Immunex Corporation related to products based on TRAIL Receptor 2. Genentech, Inc. and Immunex Corporation also opposed our European patent related to products based on TRAIL Receptor 2. HGS has withdrawn this opposed European patent. Genentech, Inc. also has opposed our Australian patent related to products based on TRAIL Receptor 2. In addition, Genentech, Inc. has opposed our European patent related to products based on TRAIL Receptor 1 (such as HGS-ETR1).

We cannot assure you that we will be successful in any of these proceedings. Moreover, any such litigation or proceeding may result in a significant commitment of resources in the future and could force us to do one or more of the following: cease selling or using any of our products that incorporate the challenged intellectual property, which would adversely affect our revenue; obtain a license from the holder of the intellectual property right alleged to have been infringed, which license may not be available on reasonable terms, if at all; and redesign our products to avoid infringing the intellectual property rights of third parties, which may be time-consuming or impossible to do. In addition, such litigation or proceeding may allow others to use our discoveries or develop or commercialize our products. Changes in, or different interpretations of, patent laws in the United States and other countries may result in patent laws that allow others to use our discoveries or develop and commercialize our products or prevent us from using or commercializing our discoveries and products. We cannot assure you that the patents we obtain or the unpatented technology we hold will afford us significant commercial protection.

**If others file patent applications or obtain patents similar to ours, then the United States Patent and Trademark Office may deny our patent applications, or others may restrict the use of our discoveries.**

We are aware that others, including universities and companies working in the biotechnology and pharmaceutical fields, have filed patent applications and have been granted patents in the United States and in other countries that cover subject matter potentially useful or necessary to our business. Some of these patents and patent applications claim only specific products or methods of making products, while others claim more general processes or techniques useful in the discovery and manufacture of a variety of products. The risk of third parties obtaining additional patents and filing patent applications will continue to increase as the biotechnology industry expands. We cannot predict the ultimate scope and validity of existing patents and patents that may be granted to third parties, nor can we predict the extent to which we may wish or be required to obtain licenses to such patents, or the availability and cost of acquiring such licenses. To the extent that licenses are required, the owners of the patents could bring legal actions against us to claim damages or to stop our manufacturing and marketing of the affected products. We believe that there will continue to be significant litigation in our industry regarding patent and other intellectual property rights. If we become involved in litigation, it could consume a substantial portion of our resources.

**Because issued patents may not fully protect our discoveries, our competitors may be able to commercialize products similar to those covered by our issued patents.**

Issued patents may not provide commercially meaningful protection against competitors and may not provide us with competitive advantages. Other parties may challenge our patents or design around our issued patents or develop products providing effects similar to our products. In addition, others may discover uses for genes, proteins or antibodies other than those uses covered in our patents, and these other uses may be separately patentable. The holder of a patent covering the use of a gene, protein or antibody for which we have a patent claim could exclude us from selling a product for a use covered by its patent.

**We rely on our collaboration partners to seek patent protection for the products they develop based on our research.**

A significant portion of our future revenue may be derived from royalty payments from our collaboration partners. These partners face the same patent protection issues that we and other biotechnology or pharmaceutical companies face. As a result, we cannot assure you that any product developed by our collaboration partners will be patentable, and therefore, revenue from any such product may be limited, which would reduce the amount of any royalty payments. We also rely on our collaboration partners to effectively prosecute their patent applications. Their failure to obtain or protect necessary patents could also result in a loss of royalty revenue to us.

**If we are unable to protect our trade secrets, others may be able to use our secrets to compete more effectively.**

We may not be able to meaningfully protect our trade secrets. We rely on trade secret protection to protect our confidential and proprietary information. We believe we have acquired or developed proprietary procedures and materials for the production of proteins and antibodies. We have not sought patent protection for these procedures. While we have entered into confidentiality agreements with employees and collaborators, we may not be able to prevent their disclosure of these data or materials. Others may independently develop substantially equivalent information and processes.

## **FINANCIAL AND MARKET RISKS**

**Because of our substantial indebtedness and lease obligations, we may be unable to adjust our strategy to meet changing conditions in the future.**

As of December 31, 2009, we had convertible subordinated debt of \$349.8 million (\$403.9 million on a face value basis) and a long-term lease financing for our large-scale manufacturing facility of \$248.6 million on our balance sheet. During 2009 we made cash interest payments on our convertible subordinated debt of \$9.9 million. In addition we repurchased \$106.2 million of our convertible subordinated debt during 2009 for approximately \$50.0 million plus accrued interest. During 2009 we made cash payments on our long-term lease financing of \$24.0 million. In addition, we have operating leases, primarily our long-term operating lease for our headquarters, for which we made cash payments of \$22.3 million during 2009. Our substantial debt and long-term lease obligations will have several important consequences for our future operations. For instance:

- payments of interest on, and principal of, our indebtedness and our long-term lease obligations will be substantial and may exceed then current income and available cash;
- we may be unable to obtain additional future financing for continued clinical trials, capital expenditures, acquisitions or general corporate purposes;
- we may be unable to withstand changing competitive pressures, economic conditions and governmental regulations; and
- we may be unable to make acquisitions or otherwise take advantage of significant business opportunities that may arise.

**We may not have adequate resources available to repay our Convertible Subordinated Notes due 2011 (“2011 Notes”) and our Convertible Subordinated Notes due 2012 (“2012 Notes”) at maturity.**

As of December 31, 2009, we had \$403.9 million in face value of convertible subordinated debt outstanding, with \$197.1 million and \$206.8 million due in 2011 and 2012, respectively. Those notes are convertible into our common stock at conversion prices of approximately \$15.55 and \$17.78 per share, respectively. If our stock price does not exceed the applicable conversion price of those notes, upon maturity, we may need to pay the note holders in cash or restructure some or all of the debt. Our recent stock price has been above the conversion price and we currently have sufficient unrestricted cash should note holders seek cash payment upon maturity. However, since it may be one or more years, if ever, before we are likely to generate significant positive cash flow from operations, we may not have enough cash, cash equivalents, short-term investments and marketable securities available to repay our debt upon maturity.

**To become a successful biopharmaceutical company, we may need additional funding in the future. If we do not obtain this funding on acceptable terms, we may not be able to generate sufficient revenue to repay our convertible debt, to launch and market successfully our products and to continue our biopharmaceutical discovery and development efforts.**

We continue to expend substantial funds on our research and development programs and human studies on current and future drug candidates. We expect to expend significant funds to support pre-launch and commercial marketing activities and acquire additional manufacturing capacity. We may need additional financing to fund our operating expenses, including pre-commercial launch activities, manufacturing activities, marketing activities,



research and development and capital requirements. In addition, even if our products are successful, if our stock price does not exceed the applicable conversion price when our remaining convertible debt matures, we may need to pay the note holders in cash or restructure some or all of the debt. If we are unable to restructure the debt, we may not have enough cash, cash equivalents, short-term investments and marketable securities available to repay the remaining debt. We may not be able to obtain additional financing on acceptable terms either to fund operating expenses or to repay the convertible debt. If we raise additional funds by issuing equity securities, equity-linked securities or debt securities, the new equity securities may dilute the interests of our existing stockholders and the new debt securities may contain restrictive financial covenants. For example, in August 2009 and December 2009, we completed public offerings of 26,697,250 and 17,825,000 newly issued shares of common stock, respectively.

Our need for additional funding will depend on many factors, including, without limitation:

- the amount of revenue or cost sharing, if any, that we are able to obtain from our collaborations, any approved products, and the time and costs required to achieve those revenues;
- the timing, scope and results of preclinical studies and clinical trials;
- the size and complexity of our development programs;
- the time and costs involved in obtaining regulatory approvals;
- the timing and costs of increasing our manufacturing capacity;
- the costs of launching our products;
- the costs of commercializing our products, including marketing, promotional and sales costs;
- the commercial success of our products;
- our stock price;
- our ability to establish and maintain collaboration partnerships;
- competing technological and market developments;
- the costs involved in filing, prosecuting and enforcing patent claims; and
- scientific progress in our research and development programs.

If we are unable to raise additional funds, we may, among other things:

- delay, scale back or eliminate some or all of our research and development programs;
- delay, scale back or eliminate some or all of our commercialization activities;
- lose rights under existing licenses;
- relinquish more of, or all of, our rights to product candidates on less favorable terms than we would otherwise seek; and
- be unable to operate as a going concern.

**Our short-term investments, marketable securities and restricted investments are subject to certain risks which could materially adversely affect our overall financial position.**

We invest our cash in accordance with an established internal policy and customarily in instruments which historically have been highly liquid and carried relatively low risk. However, the capital and credit markets have been experiencing extreme volatility and disruption. Over the past two years, the volatility and disruption have reached unprecedented levels. We maintain a significant portfolio of investments in short-term investments, marketable debt securities and restricted investments, which are recorded at fair value. Certain of these transactions expose us to credit risk in the event of default by the issuer. To minimize our exposure to credit risk, we invest in securities with strong credit ratings and have established guidelines relative to diversification and maturity with the objective of maintaining safety of principal and liquidity. We do not invest in derivative financial instruments or auction rate securities, and we generally hold our investments in debt securities until maturity. In September 2008,

Lehman Brothers Holdings, Inc. (“LBHI”) filed for bankruptcy and the debt securities issued by LBHI experienced a significant decline in market value, which caused an other-than-temporary impairment of our investment in LBHI. As a result, we recorded an impairment charge of \$6.3 million during 2008. In recent years, certain financial instruments, including some of the securities in which we invest, have sustained downgrades in credit ratings and some high quality short-term investment securities have suffered illiquidity or events of default. Deterioration in the credit market may have an adverse effect on the fair value of our investment portfolio. Should any of our short-term investments, marketable securities or restricted investments lose significant value or have their liquidity impaired, it could materially and adversely affect our overall financial position by imperiling our ability to fund our operations and forcing us to seek additional financing sooner than we would otherwise. Such financing may not be available on commercially attractive terms or at all.

**Our insurance policies are expensive and protect us only from some business risks, which could leave us exposed to significant, uninsured liabilities.**

We do not carry insurance for all categories of risk that our business may encounter. We currently maintain general liability, property, auto, workers’ compensation, product liability, fiduciary and directors’ and officers’ insurance policies. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. For example, the premiums for our directors’ and officers’ insurance policy have increased in the past and may increase in the future, and this type of insurance may not be available on acceptable terms or at all in the future. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

**We may be subject to product liability or other litigation, which could result in an inefficient allocation of our critical resources, delay the implementation of our business strategy and, if successful, materially and adversely harm our business and financial condition as a result of the costs of liabilities that may be imposed thereby.**

Our business exposes us to the risk of product liability claims. If any of our product candidates harm people, or are alleged to be harmful, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, corporate partners or others. We have product liability insurance covering our ongoing clinical trials and raxibacumab, but do not have insurance for any of our other commercial activities. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we may be exposed to significant litigation costs and liabilities, which may materially and adversely affect our business and financial position. If we are sued for injuries allegedly caused by any of our product candidates, our litigation costs and liability could exceed our total assets and our ability to pay. In addition, we may from time to time become involved in various lawsuits and legal proceedings which arise in the ordinary course of our business. Any litigation to which we are subject could require significant involvement of our senior management and may divert management’s attention from our business and operations. Litigation costs or an adverse result in any litigation that may arise from time to time may adversely impact our operating results or financial condition.

## **OTHER RISKS RELATED TO OUR BUSINESS**

**Many of our competitors have substantially greater capabilities and resources and may be able to develop and commercialize products before we do or develop generic drugs that are similar to our products.**

We face intense competition from a wide range of pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies.

Principal competitive factors in our industry include:

- the quality and breadth of an organization’s technology;
- the skill of an organization’s employees and ability to recruit and retain skilled employees;
- an organization’s intellectual property portfolio;

- the range of capabilities, from target identification and validation to drug discovery and development to manufacturing and marketing; and
- the availability of substantial capital resources to fund discovery, development and commercialization activities.

Many large pharmaceutical and biotechnology companies have significantly larger intellectual property estates than we do, more substantial capital resources than we have, and greater capabilities and experience than we do in preclinical and clinical development, sales, marketing, manufacturing and regulatory affairs.

We are aware of existing products and products in research or development by our competitors that address the diseases we are targeting. Any of these products may compete with our product candidates. Our competitors may succeed in developing their products before we do, obtaining approvals from the FDA or other regulatory agencies for their products more rapidly than we do, or developing products that are more effective than our products. These products or technologies might render our technology or drugs under development obsolete or noncompetitive. In addition, our albumin fusion protein product, ZALBIN, is designed to be a longer-acting version of existing products. The existing products in many cases have an established market that may make the introduction of ZALBIN more difficult.

If our products are approved and marketed, we may also face risks from generic drug manufacturers. Legislation currently pending in the United States Congress and regulatory and legislative activity in other countries may make it easier for generic drug manufacturers to manufacture and sell in the United States biological drugs similar or identical to ZALBIN, BENLYSTA and raxibacumab which might affect the profitability or commercial viability of our products.

**If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance (including as a result of failing to differentiate our products from competitor products or as a result of failing to obtain reimbursement rates for our products that are competitive from the healthcare provider's perspective), the revenues we generate from their sales will be limited and our business may not be profitable.**

Our success will depend in substantial part on the extent to which our products for which we obtain marketing approval from the FDA and comparable foreign regulatory authorities are accepted by the medical community and reimbursed by third-party payors, including government payors. The degree of market acceptance will depend upon a number of factors, including, among other things:

- our product's perceived advantages over existing treatment methods (including relative convenience and ease of administration and prevalence and severity of any adverse events, including any unexpected adverse events of which we become aware after marketing approval);
- claims or other information (including limitations or warnings) in our product's approved labeling;
- reimbursement and coverage policies of government and other third-party payors;
- pricing and cost-effectiveness;
- in the United States, the ability of group purchasing organizations, or GPOs (including distributors and other network providers), to sell our products to their constituencies;
- the establishment and demonstration in the medical community of the safety and efficacy of our products and our ability to provide acceptable evidence of safety and efficacy;
- availability of alternative treatments; and
- the prevalence of off-label substitution of biologically equivalent products.

We cannot predict whether physicians, patients, healthcare insurers or maintenance organizations, or the medical community in general, will accept or utilize any of our products. If our products are approved but do not achieve an adequate level of acceptance by these parties, we may not generate sufficient revenues from these

products to become or remain profitable. In addition, our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

**If the health care system or reimbursement policies change, the prices of our potential products may be lower than expected and our potential sales may decline.**

The levels of revenues and profitability of biopharmaceutical companies like ours may be affected by the continuing efforts of government and third-party payors to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. In addition, in the United States, a number of proposals have been made to reduce the regulatory burden of follow-on biologics, which could affect the prices and sales of our products in the future. Additional and broad health care proposals currently are being considered by the United States Congress. While we cannot predict whether any legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability. In addition, in the United States and elsewhere, sales of therapeutic and other pharmaceutical products depend in part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. We cannot assure you that any of our products will be considered cost effective or that reimbursement to the consumer will be available or will be sufficient to allow us to sell our products on a competitive and profitable basis.

**If we lose or are unable to attract key management or other personnel, we may experience delays in product development.**

We depend on our senior executive officers as well as other key personnel. If any key employee decides to terminate his or her employment with us, this termination could delay the commercialization of our products or prevent us from becoming profitable. Competition for qualified employees is intense among pharmaceutical and biotechnology companies, and the loss of qualified employees, or an inability to attract, retain and motivate additional highly skilled employees required for the expansion of our activities, could hinder our ability to complete human studies successfully and develop marketable products. The reduction in scope of some programs in March 2009 included decreasing headcount. This reduction in headcount may adversely affect our ability to attract, retain and motivate current and new employees.

**We may be unable to fulfill the terms of our agreement with Hospira, Inc. and other agreements, if any, with potential customers for manufacturing process development and supply of selected biopharmaceutical products.**

We have entered into agreements for manufacturing process development, clinical and commercial supply of certain biopharmaceutical products, including an agreement with Hospira, Inc., and may enter into similar agreements with other potential customers. We may not be able to successfully manufacture products under the agreement with Hospira or under other agreements, if any. We have not yet manufactured any products approved for commercial use and, except for raxibacumab, have limited experience in manufacturing materials suitable for commercial use. We have limited experience manufacturing in a large-scale manufacturing facility built to increase our capacity for protein and antibody drug production. The FDA must inspect and license our facilities to determine compliance with cGMP requirements for commercial production. We may not be able to enter into additional agreements with other customers. Hospira or any future customer may decide to discontinue the products contemplated under the agreements, and therefore we may not receive revenue from these agreements.

**Because we depend on third parties to conduct many of our human studies, we may encounter delays in or lose some control over our efforts to develop products.**

We are dependent on third-party research organizations to conduct most of our human studies. We have engaged contract research organizations to manage our global Phase 3 clinical studies. If we are unable to obtain any necessary services on acceptable terms, we may not complete our product development efforts in a timely manner. If we rely on third parties for the management of these human studies, we may lose some control over these activities and become too dependent upon these parties. These third parties may not complete the activities on schedule.



## **RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK**

**Because our stock price has been and will likely continue to be highly volatile, the market price of our common stock may be lower or more volatile than you expected.**

Our stock price, like the stock prices of many other biotechnology companies, has been highly volatile. During the preceding twelve months, the closing price of our common stock has been as low as \$0.48 per share and as high as \$31.15 per share. The market price of our common stock could fluctuate widely because of:

- future announcements about our company or our competitors, including the results of testing, clinical trials, technological innovations or new commercial products;
- negative regulatory actions with respect to our potential products or regulatory approvals with respect to our competitors' products;
- changes in government regulations;
- developments in our relationships with our collaboration partners;
- developments affecting our collaboration partners;
- announcements relating to health care reform and reimbursement levels for new drugs;
- our failure to acquire or maintain proprietary rights to the gene sequences we discover or the products we develop;
- litigation; and
- public concern as to the safety of our products.

The stock market has experienced price and volume fluctuations that have particularly affected the market price for many emerging and biotechnology companies. These fluctuations have often been unrelated to the operating performance of these companies. These broad market fluctuations may cause the market price of our common stock to be lower or more volatile than you expected.

**The issuance and sale of shares underlying our outstanding convertible debt securities and options, as well as the sale of additional equity or equity-linked securities may materially and adversely affect the price of our common stock.**

Sales of substantial amounts of shares of our common stock or securities convertible into or exchangeable for our common stock in the public market, or the perception that those sales may occur, could cause the market price of our common stock to decline. We have used and may continue to use our common stock or securities convertible into or exchangeable for our common stock to acquire technology, product rights or businesses, or for other purposes. Our authorized capital stock consists of 400,000,000 shares of common stock, par value \$0.01 per share. As of December 31, 2009, we had 185,254,660 shares of common stock outstanding, including an aggregate of 44,522,250 shares issued in public offerings in August and December 2009. In addition, an aggregate of approximately 24,306,115 shares of our common stock are issuable upon conversion of our outstanding 2011 Notes and outstanding 2012 Notes at an applicable conversion price of \$15.55 and \$17.78 per share, respectively; 24,601,174 shares of our common stock are issuable upon the exercise of options outstanding as of December 31, 2009, having a weighted-average exercise price of \$13.62 per share, including 4,352,003 stock options granted during the year ended December 31, 2009 with a weighted-average grant date fair value of \$0.91 per share; and 205,737 shares of our common stock are issuable upon the vesting of restricted stock unit awards outstanding as of December 31, 2009. If we issue additional equity securities, including in exchange for our outstanding convertible debt, the price of our common stock may be materially and adversely affected and the holdings of our existing stockholders would be diluted. The issuance and sale of shares issuable upon conversion of our outstanding convertible debt securities and options or the sale of additional equity or equity-linked securities could materially and adversely affect the price of our common stock.

**Our certificate of incorporation and bylaws could discourage acquisition proposals, delay a change in control or prevent transactions that are in your best interests.**

Provisions of our certificate of incorporation and bylaws, as well as Section 203 of the Delaware General Corporation Law, may discourage, delay or prevent a change in control of our company that you as a stockholder may consider favorable and may be in your best interest. Our certificate of incorporation and bylaws contain provisions that:

- authorize the issuance of up to 20,000,000 shares of “blank check” preferred stock that could be issued by our board of directors to increase the number of outstanding shares and discourage a takeover attempt;
- limit who may call special meetings of stockholders; and
- establish advance notice requirements for nomination of candidates for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholders’ meetings.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

We currently lease and occupy approximately 1,020,000 square feet of laboratory, manufacturing and office space in Rockville, Maryland. Our space includes approximately 200,000 square feet of laboratory space, approximately 520,000 square feet of manufacturing and manufacturing support space and approximately 300,000 square feet of office space. This excludes a portion of our headquarters facility under lease which is not being utilized.

We anticipate that existing commercial real estate or the available land located at our laboratory and office campus will enable us to continue to expand our operations in close proximity to one another. We believe that our properties are generally in good condition, well maintained, suitable and adequate to carry on our business.

**ITEM 3. LEGAL PROCEEDINGS**

We are party to various claims and legal proceedings from time to time. We are not aware of any legal proceedings that we believe could have, individually or in the aggregate, a material adverse effect on our results of operations, financial condition or liquidity.

**ITEM 4. (REMOVED AND RESERVED)**

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

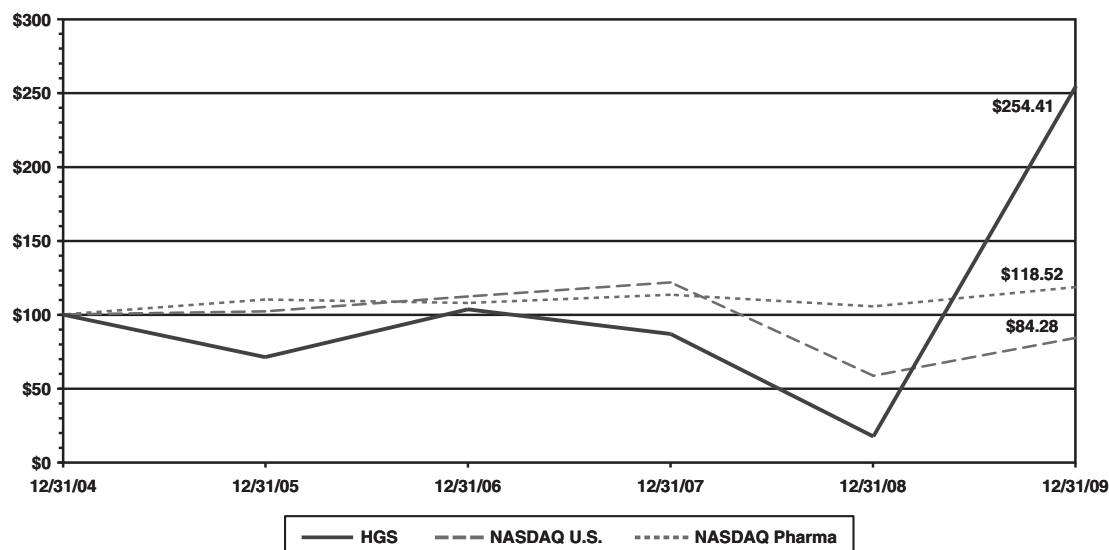
Our common stock is traded on the NASDAQ Global Market under the symbol HGSI. The following table presents the quarterly high and low closing prices as quoted by NASDAQ.

	<u>High</u>	<u>Low</u>
<b>2008</b>		
First Quarter . . . . .	\$11.79	\$ 4.86
Second Quarter . . . . .	\$ 6.79	\$ 5.21
Third Quarter . . . . .	\$ 7.94	\$ 5.17
Fourth Quarter . . . . .	\$ 6.06	\$ 1.24
<b>2009</b>		
First Quarter . . . . .	\$ 2.78	\$ 0.48
Second Quarter . . . . .	\$ 3.19	\$ 0.82
Third Quarter . . . . .	\$20.50	\$ 2.39
Fourth Quarter . . . . .	\$31.15	\$17.96

As of January 31, 2010, there were approximately 624 holders of record of our common stock. We have never declared or paid any cash dividends. We do not anticipate declaring or paying cash dividends for the foreseeable future, in part because existing contractual agreements prohibit such dividends. Instead, we will retain our earnings, if any, for the future operation and expansion of our business.

The following graph compares the performance of our Common Stock for the periods indicated with the performance of the NASDAQ U.S. Stock Market Total Return Index (the "TRI") and the NASDAQ Pharmaceutical Index (the "NPI"). The comparison assumes \$100 was invested on December 31, 2004 in our Common Stock and in each of the foregoing indices and assumes the reinvestment of dividends, if any.

**Comparison of 5 Year Cumulative Total Return**



The performance graph and related information shall not be deemed "soliciting material" or be "filed" with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference into such filing.



## ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

We present below our selected consolidated financial data for the years ended December 31, 2009, 2008 and 2007, and as of December 31, 2009 and 2008, which have been derived from the audited consolidated financial statements included elsewhere herein and should be read in conjunction with such consolidated financial statements and the accompanying notes. We present below our selected financial data for the years ended December 31, 2006 and 2005, and as of December 31, 2007, 2006 and 2005, which have been derived from audited financial statements not included herein. The results of operations of prior periods are not necessarily indicative of results that may be expected for any other period. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.”

	Year Ended December 31,				
	2009	2008	2007	2006	2005
	(in thousands, except per share and ratio data)				
<b>Statement of Operations Data:</b>					
Revenue:					
Product sales . . . . .	\$154,074	\$ —	\$ —	\$ —	\$ —
Manufacturing and development services . . . . .	50,653	—	—	—	—
Research and development collaborative agreements . . . . .	71,022	48,422	41,851	25,755	19,113
Total revenue . . . . .	275,749	48,422	41,851	25,755	19,113
Costs and expenses:					
Cost of product sales . . . . .	15,805	—	—	—	—
Cost of manufacturing and development services . . . . .	18,215	—	—	—	—
Research and development expenses . . . . .	173,709	243,257	246,293	209,515	228,717
General and administrative expenses . . . . .	61,073	60,865	55,874	53,101	42,066
Facility-related exit charges (credits) . . . . .	759	—	(3,673)	29,510	—
Total costs and expenses . . . . .	269,561	304,122	298,494	292,126	270,783
Income (loss) from operations . . . . .	6,188	(255,700)	(256,643)	(266,371)	(251,670)
Investment income . . . . .	12,727	23,487	32,988	27,131	24,218
Interest expense . . . . .	(58,424)	(62,912)	(60,716)	(39,606)	(17,199)
Gain (loss) on extinguishment of debt . . . . .	38,873	—	—	—	(1,204)
Gain on sale of long-term equity investment . . . . .	5,259	32,518	—	14,759	1,302
Other expense . . . . .	(238)	(6,284)	—	—	—
Income (loss) before taxes . . . . .	4,385	(268,891)	(284,371)	(264,087)	(244,553)
Income tax benefit . . . . .	1,274	—	—	—	—
Net income (loss) . . . . .	\$ 5,659	\$(268,891)	\$(284,371)	\$(264,087)	\$(244,553)
Net income (loss) per share, basic and diluted . . . . .	\$ 0.04	\$ (1.99)	\$ (2.12)	\$ (2.00)	\$ (1.87)
<b>Other Data:</b>					
Ratio of earnings to fixed charges . . . . .	1.06	—	—	—	—
Coverage deficiency . . . . .	\$ —	\$(268,891)	\$(284,371)	\$(264,087)	\$(244,553)

# **ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA, CONTINUED**

	As of December 31,				
	2009	2008	2007	2006	2005
			(in thousands)		
<b>Balance Sheet Data:</b>					
Cash, cash equivalents, short-term investments, marketable securities and restricted investments <sup>(1)</sup> . . . . .	\$ 1,191,660	\$ 372,939	\$ 603,840	\$ 763,084	\$ 646,220
Total assets <sup>(1)</sup> . . . . .	1,530,630	686,832	961,566	1,161,922	1,001,963
Total debt and lease financing, less current portion <sup>(2)</sup> . . . . .	598,435	664,074	637,513	612,811	351,034
Accumulated deficit . . . . .	(2,186,666)	(2,192,325)	(1,923,434)	(1,639,063)	(1,374,322)
Total stockholders' equity (deficit). . . . .	755,415	(136,304)	117,145	364,892	580,849

(1) "Cash, cash equivalents, short-term investments, marketable securities and restricted investments" and "Total assets" for 2009, 2008, 2007, 2006 and 2005 include \$88,437, \$69,360, \$70,931, \$61,165 and \$220,171 respectively, of restricted investments relating to certain leases.

(2) "Total debt and lease financing, less current portion" for 2009, 2008, 2007, 2006 and 2005 does not include any operating lease obligations under various facility and equipment lease arrangements. See "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources" for additional discussion.

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Overview

Human Genome Sciences, Inc. ("HGS") is a commercially focused biopharmaceutical company advancing toward the market with three products in late-stage development: BENLYSTA™ for systemic lupus erythematosus ("SLE"), ZALBIN™ for chronic hepatitis C, and raxibacumab for inhalation anthrax.

BENLYSTA and ZALBIN continue to progress toward commercialization. In July and November 2009, we reported that BENLYSTA successfully met its primary endpoints in two Phase 3 clinical trials in patients with systemic lupus. We and GlaxoSmithKline ("GSK") plan to submit marketing applications for BENLYSTA in the United States and Europe in the second quarter of 2010. In March 2009, we reported that ZALBIN successfully met its primary endpoint in the second of two Phase 3 clinical trials in chronic hepatitis C. HGS submitted a Biologics License Application ("BLA") for ZALBIN in the United States in November 2009, and Novartis submitted a Marketing Authorization Application ("MAA") under the brand name JOULFERON® in Europe in December 2009. We received confirmation from the U.S. Food and Drug Administration ("FDA") in February 2010 that the BLA submission was accepted for filing with a Prescription Drug User Fee Act ("PDUFA") date of October 4, 2010.

In the first half of 2009 we achieved our first product sales and recognized \$162.5 million in product sales and manufacturing and development services revenue by delivering 20,001 doses of raxibacumab to the U.S. Strategic National Stockpile ("SNS"). In July 2009, the U.S. Government ("USG") exercised its option to purchase 45,000 additional doses to be delivered over a three-year period. We expect to receive a total of approximately \$152.0 million from the second order, including \$17.7 million in revenue recognized from our first delivery under the new award in the fourth quarter of 2009. In May 2009, we submitted a BLA to the FDA for raxibacumab for the treatment of inhalation anthrax. We received a Complete Response Letter in November 2009, and we continue to work closely with the FDA to determine the additional steps necessary to obtain approval.

In addition to these products in our internal pipeline, we have substantial financial rights to two novel drugs that GSK has advanced to late-stage development. In December 2009, GSK initiated the second Phase 3 clinical trial of darapladib, which was discovered by GSK based on our technology, to evaluate whether darapladib can reduce the risk of adverse cardiovascular events such as a heart attack or stroke. With more than 27,000 patients enrolled, the Phase 3 clinical program for darapladib is among the largest ever conducted to evaluate the safety and efficacy of any cardiovascular medication. In the first quarter of 2009, we received a \$9.0 million milestone payment related to GSK's initiation of a Phase 3 program to evaluate the safety and efficacy of Syncria® (albiglutide) in the long-term treatment of type 2 diabetes mellitus. We created Syncria using our proprietary albumin-fusion technology and licensed it to GSK in 2004. Six Phase 3 trials of Syncria are currently ongoing.

We also have several novel drugs in earlier stages of clinical development for the treatment of cancer, led by our TRAIL receptor antibody mapatumumab and a small-molecule antagonist of IAP (inhibitor of apoptosis) proteins.

Strategic partnerships are an important driver of our commercial success. We have co-development and commercialization agreements with prominent pharmaceutical companies for both of our lead products — GSK for BENLYSTA and Novartis for ZALBIN. Raxibacumab is being developed under a contract with the Biomedical Advanced Research and Development Authority ("BARDA") of the Office of the Assistant Secretary for Preparedness and Response ("ASPR"), U.S. Department of Health and Human Services ("HHS"). Our strategic partnerships with leading pharmaceutical and biotechnology companies allow us to leverage our strengths and gain access to sales and marketing infrastructure, as well as complementary technologies. Some of these partnerships provide us with licensing or other fees, clinical development cost-sharing, milestone payments and rights to royalty payments as products are developed and commercialized. In some cases, we are entitled to certain commercialization, co-promotion, revenue-sharing and other product rights.

In the second half of 2009, we received \$812.9 million in net proceeds from two public offerings of our common stock, bringing our cash and investments at December 31, 2009 to approximately \$1.2 billion.

## Overview (continued)

During 2006, we entered into a collaboration agreement with Novartis. Under this agreement, Novartis will co-develop and co-commercialize ZALBIN and share development costs, sales and marketing expenses and profits of any product that is commercialized in the U.S. Novartis will be responsible for commercialization outside the U.S. and will pay us a royalty on these sales. We received a \$45.0 million up-front fee from Novartis upon the execution of the agreement. Including this up-front fee, we are entitled to payments aggregating up to \$507.5 million upon the successful attainment of certain milestones. As of December 31, 2009, we have contractually earned and received payments aggregating \$207.5 million, including \$75.0 million received in 2009. We are recognizing these payments as revenue ratably over the estimated remaining development period, estimated to end in the fall of 2010.

In 2005, GSK exercised its option to co-develop and co-commercialize BENLYSTA. In accordance with a co-development and co-commercialization agreement signed during 2006, we and GSK will share Phase 3 and 4 development costs, and will share equally in sales and marketing expenses and profits of any product that is commercialized. We received a \$24.0 million payment during 2006 as partial consideration for entering into this agreement with respect to BENLYSTA and are recognizing this payment as revenue ratably over the development period, estimated to end in the fall of 2010.

We expect that any significant revenue or income through at least 2010 may be limited to raxibacumab revenue, payments under collaboration agreements (to the extent milestones are met), cost reimbursements from GSK and Novartis, payments from the license of product rights, payments under manufacturing agreements, such as our agreement with Hospira, Inc., investment income and other payments from other collaborators and licensees under existing or future arrangements, to the extent that we enter into any future arrangements, and possibly initial sales of BENLYSTA and/or ZALBIN. We expect to continue to incur substantial expenses relating to our research and development efforts and increased expenses relating to our commercialization efforts. As a result, we expect to incur losses over at least the next two years unless we are able to realize additional revenues under existing or any future agreements. The timing and amounts of such revenues, if any, cannot be predicted with certainty and will likely fluctuate sharply. Results of operations for any period may be unrelated to the results of operations for any other period. In addition, historical results should not be viewed as indicative of future operating results.

## Critical Accounting Policies and the Use of Estimates

A “critical accounting policy” is one that is both important to the portrayal of our financial condition and results of operations and that requires management’s most difficult, subjective or complex judgments. Such judgments are often the result of a need to make estimates about the effect of matters that are inherently uncertain. The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from those estimates. See Note B, Summary of Significant Accounting Policies, of the Notes to the Consolidated Financial Statements for further discussion.

We currently believe the following accounting policies to be critical:

*Investments.* We account for investments in accordance with the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“FASB ASC”) Topic 320, *Investments - Debt and Equity Securities*. We carry our investments at their respective fair values. We periodically evaluate the fair values of our investments to determine whether any declines in the fair value of investments represent an other-than-temporary impairment. This evaluation consists of a review of several factors, including but not limited to the length of time and extent that a security has been in an unrealized loss position, the existence of an event that would impair the issuer’s future repayment potential, the near term prospects for recovery of the market value of a security and our intent to hold the security until the market value recovers, which may be maturity. We also evaluate whether it is more likely than not that we will be required to sell the security before its anticipated recovery. If management determines that such an impairment exists we would recognize an impairment charge. Because we may determine that market or business conditions may lead us to sell a short-term investment or marketable security prior to maturity, we classify our short-term investments and marketable securities as “available-for-sale.” Investments in securities that are classified as



## Critical Accounting Policies and the Use of Estimates (continued)

available-for-sale and have readily determinable fair values are measured at fair market value in the balance sheets, and unrealized holding gains and losses for these investments are reported as a separate component of stockholders' equity until realized, or an other-than-temporary impairment is recorded. We classify those marketable securities that may be used in operations within one year as short-term investments. Those marketable securities in which we have both the ability to hold until maturity and have a maturity date beyond one year from our most recent consolidated balance sheet date are classified as non-current marketable securities.

For investments carried at fair value, we disclose the level within the fair value hierarchy as prescribed by FASB ASC Topic 820, *Fair Value Measurements and Disclosures*. We evaluate the types of securities in our investment portfolio to determine the proper classification in the fair value hierarchy based on trading activity and the observability of market inputs. We generally obtain a single quote or price per instrument from independent third parties to help us determine the fair value of securities in Level 1 and Level 2 of the fair value hierarchy.

*Inventory.* Inventory costs incurred prior to receiving regulatory approval for a product are expensed. Inventory costs associated with raxibacumab produced subsequent to receiving the follow-on order from the USG are capitalized using the first-in, first-out method.

*Leases.* We lease various real properties under operating leases that generally require us to pay taxes, insurance and maintenance. During 2006, we entered into a 20-year lease agreement with BioMed Realty Trust, Inc. ("BioMed") for our Traville facility. We account for the Traville lease with BioMed as an operating lease.

During 2006 and as described further in Note F, Long-Term Debt, of the Notes to the Consolidated Financial Statements, we sold our large-scale manufacturing ("LSM") facility and headquarters land to BioMed, and simultaneously agreed to lease such assets back over 20 years. We recorded the sale and leaseback of these assets as a financing transaction and accordingly recorded the allocated sale proceeds as outstanding debt on our balance sheet. We account for lease payments under the related lease agreements as principal and interest payments on this debt.

*Impairments of long-lived assets.* Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. Determination of recoverability is based on an estimate of undiscounted cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount the assets, the assets are written down to their estimated fair values. Long-lived assets to be sold are carried at fair value less costs to sell.

*Product sales.* Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and we have no further performance obligations.

*Manufacturing and development services.* We have entered into agreements for manufacturing process development, clinical and commercial supply of certain biopharmaceutical products. Revenue under these agreements is recognized as services are performed or products delivered, depending on the nature of the work contracted, using a proportional performance method of accounting. Performance is assessed using output measures such as units-of-work performed to date as compared to total units-of-work contracted. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

*Research and development collaborative agreements.* Our revenue recognition policies for all non-refundable up-front license fees and milestone arrangements are in accordance with the guidance provided in FASB ASC Topic 605, *Revenue Recognition*. FASB ASC Topic 605 provides guidance on when an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes, and if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. If the deliverables in a revenue arrangement constitute separate

## Critical Accounting Policies and the Use of Estimates (continued)

units of accounting according to FASB ASC Topic 605's separation criteria, the revenue recognition policy must be determined for each identified unit. If the arrangement is a single unit of accounting, the revenue recognition policy must be determined for the entire arrangement. Under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting, non-refundable up-front license fees are deferred and recognized as revenue on a straight-line basis over the expected term of our continued involvement in the research and development process. Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved, and the milestone payments are due and collectible. If not deemed substantive, we would recognize such milestones as revenue on a straight-line basis over the remaining expected term of continued involvement in the research and development process. Milestones are considered substantive if all of the following conditions are met: (1) the milestone is non-refundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and, (4) the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone and any ongoing research and development or other services are priced at fair value. Payments received in advance of work performed are recorded as deferred revenue.

The up-front license fee received in 2006 from Novartis in connection with ZALBIN is being recognized ratably over an estimated four-year clinical development period ending in 2010. To the extent we achieve the clinical development milestones set forth in the Novartis agreement, the amounts received for these milestones will be recognized ratably over the remaining estimated clinical development period from the date of attainment. Our initial payment from GSK in connection with BENLYSTA is being recognized ratably over the estimated four-year clinical development period ending in 2010. Our up-front license fee with GSK in connection with Syncria is being recognized ratably over the estimated eight-year clinical development period ending in 2012. Our other revenues from research and development collaborative agreements in 2009, 2008 and 2007 have been recognized in full upon receipt, as we have met the criteria for recognition.

*Research and Development.* Research and development expenses primarily include related salaries, outside services, materials and supplies and allocated facility costs. Such costs are charged to research and development expense as incurred. Our drug development expenses include accruals for clinical site and clinical research organization ("CRO") costs. Estimates of the incurred to date but not yet received invoices must be made for clinical site and CRO costs in determining the accrued balance in any accounting period. Reimbursement of research and development expenses received in connection with collaborative cost-sharing agreements is recorded as a reduction of such expenses.

*Stock Compensation.* We have a stock incentive plan (the "Incentive Plan") under which options to purchase shares of our common stock may be granted to employees, consultants and directors at a price no less than the quoted market value on the date of grant. The Incentive Plan also provides for awards in the form of stock appreciation rights, restricted (non-vested) or unrestricted stock awards, stock-equivalent units or performance-based stock awards.

We account for share-based awards to employees and non-employee directors pursuant to FASB guidance that compensation cost resulting from share-based payment transactions be recognized in the financial statements at fair value. The amount of compensation expense recognized using the fair value method requires us to exercise judgment and make assumptions relating to the factors that determine the fair value of our stock option grants. We use the Black-Scholes-Merton model to estimate the fair value of our option grants. The fair value calculated by this model is a function of several factors, including grant price, the risk-free interest rate, the estimated term of the option and the estimated future volatility of the option. The estimated term and estimated future volatility of the options require our judgment.

*Exit Accruals.* In 2006, we exited certain facilities, including certain headquarters space ("Wing C"), which required us to make significant estimates in several areas including the realizable values of assets deemed redundant or excess and the ability to generate sublease income. We recorded an initial liability of approximately \$9.0 million

## **Critical Accounting Policies and the Use of Estimates (continued)**

in lease-related costs with respect to our 2006 exit activities. During the second quarter of 2009, our Wing C subtenant terminated its sublease, which resulted in a charge of approximately \$11.4 million. During the fourth quarter of 2009, we decided to resume production activities in Wing C and reversed approximately \$10.6 million, representing the portion of the Wing C exit reserve related to the production space. As of December 31, 2009, the exit reserve, which is primarily for the non-production space in Wing C, is approximately \$4.2 million.

*Income taxes.* Deferred tax assets and liabilities are determined based on temporary differences between the financial reporting basis and the tax basis of assets and liabilities. These deferred tax assets and liabilities are measured using the enacted tax rates and laws that will be in effect when such amounts are expected to reverse or be utilized. The realization of total deferred tax assets is contingent upon the generation of future taxable income. A valuation allowance is provided to reduce such deferred tax assets to amounts more likely than not to be ultimately realized.

In determining the effective income tax rate, we analyze various factors, including projections of our annual earnings and taxing jurisdictions in which the earnings will be generated, the impact of state and local and foreign income taxes and our ability to use tax incentives. We file income tax returns in U.S. federal, state and foreign jurisdictions. Our income taxes have not been subject to examination by any tax jurisdictions since its inception. Accordingly, all our filed income tax returns are subject to examination by the taxing jurisdictions.

## **Results of Operations**

### *Years Ended December 31, 2009 and 2008*

*Revenues.* We had revenues of \$275.7 million and \$48.4 million for the years ended December 31, 2009 and 2008, respectively. Revenues for the year ended December 31, 2009 consisted primarily of \$154.1 million in raxibacumab product sales, \$26.1 million related to raxibacumab development services, \$24.4 million from contract manufacturing services and \$54.2 million recognized from Novartis related to straight-line recognition of up-front license fees and milestones reached for ZALBIN. Revenue for the year ended December 31, 2008 consisted primarily of \$35.4 million recognized from Novartis related to straight-line recognition of up-front license fees and milestones reached for ZALBIN and \$6.5 million recognized from GSK related to straight-line recognition of an up-front fee for BENLYSTA. Revenue recognized from Novartis increased in 2009 due to receipt of a \$75.0 million milestone which is being recognized over the remaining development period, estimated to end in the fall of 2010.

*Cost of sales.* Cost of sales includes both cost of product sales of \$15.8 million and cost of manufacturing and development services of \$18.2 million for the year ended December 31, 2009. No cost of sales were incurred in 2008 as we had no revenue from product sales or manufacturing and development services. With respect to the initial 2006 order for raxibacumab, we incurred substantially all of the product and service costs prior to 2009, and expensed these costs as incurred. We incurred royalty costs associated with the initial order during 2009, which are included in cost of product sales. In addition, we have recorded as cost of product sales the expenses associated with manufacturing additional raxibacumab incurred prior to receiving the follow-on order in July 2009. Our manufacturing and development service costs include raxibacumab development service costs incurred in 2009 and costs associated with contract manufacturing services. After approval of a product, inventoriable costs are capitalized into inventory and will be expensed as the inventory is sold.

*Expenses.* Research and development expenses were \$173.7 million for the year ended December 31, 2009 as compared to \$243.3 million for the year ended December 31, 2008. Our research and development expenses for the year ended December 31, 2009 are net of \$0.9 million and \$43.1 million of costs reimbursed by Novartis and GSK, respectively. Our research and development expenses for the year ended December 31, 2008 are net of \$36.1 million and \$51.8 million of costs reimbursed by Novartis and GSK, respectively.

We track our research and development expenditures by type of cost incurred — research, pharmaceutical sciences, manufacturing and clinical development costs.

## Results of Operations (continued)

### *Years Ended December 31, 2009 and 2008 (continued)*

Our research costs amounted to \$19.0 million for the year ended December 31, 2009 as compared to \$25.6 million for the year ended December 31, 2008. This decrease is primarily due to the conclusion of animal studies being conducted for raxibacumab in 2008, and a \$5.0 million milestone payment made to Aegera Therapeutics, Inc. (“Aegera”) in 2008. Our research costs for the years ended December 31, 2009 and 2008 are net of \$3.2 million and \$2.4 million, respectively, of cost reimbursement from Novartis and GSK under cost sharing provisions in our collaboration agreements.

Our pharmaceutical sciences costs, where we focus on improving formulation, process development and production methods, decreased to \$31.4 million for the year ended December 31, 2009 from \$35.9 million for the year ended December 31, 2008. This decrease is primarily due to decreased activity related to raxibacumab and ZALBIN, partially offset by increased activity related to contract manufacturing services. Pharmaceutical sciences costs for the years ended December 31, 2009 and 2008 are net of \$0.5 million and \$1.2 million, respectively, of cost reimbursement from Novartis and GSK under cost sharing provisions in our collaboration agreements.

Our manufacturing costs decreased to \$49.0 million for the year ended December 31, 2009 from \$77.1 million for the year ended December 31, 2008. This decrease is primarily due to capitalizing raxibacumab production costs beginning in 2009 and decreased production of raxibacumab, ZALBIN and BENLYSTA, partially offset by increased manufacturing services activities. Our manufacturing costs for the years ended December 31, 2009 and 2008 are net of \$9.7 million and \$19.9 million, respectively, of anticipated cost reimbursement from Novartis and GSK under the commercial cost sharing provisions in our collaboration agreements. Our manufacturing costs in 2010 are expected to increase as we produce commercial product in anticipation of launch. These costs are expensed as incurred until regulatory approval of the product is obtained.

Our clinical development costs decreased to \$74.3 million for the year ended December 31, 2009 from \$104.7 million for the year ended December 31, 2008. This decrease is primarily due to the substantial completion of our ZALBIN Phase 3 clinical trials in late 2008, completion of the first Phase 3 BENLYSTA clinical trial and wind down of the second Phase 3 BENLYSTA clinical trial during 2009 and decreased HGS-ETR1 clinical trial costs. Our clinical development costs for the years ended December 31, 2009 and 2008 are net of \$30.5 million and \$64.4 million, respectively, of cost reimbursement from Novartis and GSK under cost sharing provisions in our collaboration agreements.

The research and development expenditures noted above are categorized by functional area. We evaluate and prioritize our activities according to functional area, rather than on a per-project basis. For this reason, we do not maintain a formal accounting system that captures or allocates all costs, both direct and indirect, on a per-project basis. Therefore, we do not believe that our available project-by-project information would form a reasonable basis for disclosure to investors.

General and administrative expenses increased to \$61.1 million for the year ended December 31, 2009 from \$60.9 million for the year ended December 31, 2008. This increase is primarily due to increased pre-commercial launch activities, partially offset by decreased legal expenses associated with our patents. General and administrative expenses in future periods may increase as the level of pre-commercial launch activities rises.

Facility-related exit charges of \$0.8 million for the year ended December 31, 2009 relate to an adjustment to our exit reserve for Wing C. Our Wing C subtenant terminated its lease during 2009, which resulted in an exit charge of \$11.4 million during the second quarter of 2009. During the fourth quarter of 2009, we decided to resume production activities in most of Wing C and accordingly, reversed \$10.6 million of the \$11.4 million charge, resulting in a net exit charge of \$0.8 million for the full year. During 2008, we did not incur any facility-related exit charges. See Note K, Facility-Related Exit Charges (Credits), of the Notes to the Consolidated Financial Statements for additional discussion.

Investment income decreased to \$12.7 million for the year ended December 31, 2009 from \$23.5 million for the year ended December 31, 2008. The decrease is primarily due to lower yields in 2009 as compared to 2008, partially offset by higher average investment balances. Investment income also includes realized net losses on our



## Results of Operations (continued)

### *Years Ended December 31, 2009 and 2008 (continued)*

short-term investments, marketable securities and restricted investments of \$0.8 million for the year ended December 31, 2009 as compared to net gains of \$0.9 million for the year ended December 31, 2008. The yield on our investments was approximately 2.5% for the year ended December 31, 2009, as compared to approximately 4.6% for the year ended December 31, 2008. Our average investment balance for 2010 will be higher than 2009 due to the proceeds from our two 2009 public offerings of common stock, however our overall yield on investments may be lower as those proceeds are invested in securities with lower interest rates than our maturing investments. A general decline in interest rates may adversely affect the interest earned from our portfolio as securities mature and may be replaced with securities having a lower interest rate.

Interest expense decreased to \$58.4 million for the year ended December 31, 2009 compared to \$62.9 million for the year ended December 31, 2008. Interest expense includes non-cash interest expense related to amortization of debt discount of \$21.9 million and \$24.2 million for the year ended December 31, 2009 and 2008, respectively, as a result of the adoption of FASB ASC Topic 470 which requires that the liability and equity components of convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) be separately accounted for in a manner that reflects an issuer's non-convertible debt borrowing rate. The decrease in interest expense is primarily due to the February 2009 repurchase of convertible subordinated debt due in 2011 and 2012.

The gain on extinguishment of debt of \$38.9 million for the year ended December 31, 2009 relates to the repurchase of convertible subordinated debt due in 2011 and 2012 with a face value of approximately \$106.2 million for an aggregate cost of approximately \$50.0 million plus accrued interest. The gain on extinguishment of debt is net of write-offs of related debt discount of \$16.4 million and deferred financing charges of \$0.9 million.

The gain on sale of long-term equity investment for the year ended December 31, 2009 and 2008 of \$5.3 million and \$32.5 million respectively, relates to the 2008 sale of our investment in CoGenesys, Inc. ("CoGenesys"). We received initial proceeds in 2008 of \$47.3 million. Our cost basis in this investment was \$14.8 million, resulting in a gain of \$32.5 million. The agreement between CoGenesys and Teva Pharmaceutical Industries Ltd. ("Teva") provided for an escrow of a portion of the purchase price. We received the final payment for our equity investment during 2009 and recorded an additional gain of \$5.3 million.

Other expense of \$0.2 million for the year ended December 31, 2009 primarily represents unrealized, non-cash foreign currency translation losses related to our investment in Aegera, which is denominated in Canadian dollars. Other expense of \$6.3 million for the year ended December 31, 2008 was due to an other-than-temporary impairment of our investment in debt securities issued by Lehman Brothers Holdings, Inc. ("LBHI"). During 2008, LBHI experienced a significant deterioration in its credit worthiness and filed a petition under Chapter 11 of the U.S. Bankruptcy Code.

*Income Tax Benefit.* Income tax benefit of \$1.3 million represents a credit received in 2009 of \$0.5 million for 2008 and an accrued income tax benefit of \$0.8 million for 2009. We elected to accelerate recognition of research and development tax credits by electing out of bonus depreciation pursuant to regulations passed in 2008.

*Net Income (Loss).* We recorded net income of \$5.7 million, or \$0.04 per basic and diluted share, for the year ended December 31, 2009, compared to a net loss of \$268.9 million, or \$1.99 per share, for the year ended December 31, 2008. The improvement to net income from a net loss is primarily due to 2009 activity including revenue from raxibacumab, gain on extinguishment of debt and reduced research and development expenses.

### *Years Ended December 31, 2008 and 2007*

*Revenues.* We had revenues of \$48.4 million and \$41.9 million for the years ended December 31, 2008 and 2007, respectively. Revenues for the year ended December 31, 2008 consisted primarily of revenue recognized from Novartis of \$35.4 million for the straight-line recognition of up-front license fees and milestones reached for ZALBIN and \$6.5 million from GSK related to straight-line recognition of up-front license fees for BENLYSTA.

## Results of Operations (continued)

### *Years Ended December 31, 2008 and 2007 (continued)*

The 2007 revenues consisted primarily of \$28.0 million in revenue recognized from Novartis for the straight-line recognition of up-front license fees and milestones reached for ZALBIN and \$6.5 million from GSK related to straight-line recognition of up-front license fees for BENYLSTA.

*Expenses.* Research and development expenses were \$243.3 million for the year ended December 31, 2008 as compared to \$246.3 million for the year ended December 31, 2007. Research and development expenses for 2007 include \$16.9 million paid to Aegera in connection with a collaboration and license agreement. Our research and development expenses for the year ended December 31, 2008 are net of \$36.1 million and \$51.8 million of costs reimbursed by Novartis and GSK, respectively. Our research and development expenses for the year ended December 31, 2007 are net of \$46.5 million and \$39.3 million of costs reimbursed by Novartis and GSK respectively.

We track our research and development expenditures by type of cost incurred — research, pharmaceutical sciences, manufacturing and clinical development costs.

Our research costs amounted to \$25.6 million for the year ended December 31, 2008 as compared to \$34.0 million for the year ended December 31, 2007. This decrease is due to the \$16.9 million paid to Aegera in 2007 in connection with our licensing and collaboration agreement and purchase price premium as compared to a \$5.0 million milestone paid to Aegera in 2008, partially offset by an increase in activities supporting new target development. Our research costs for the years ended December 31, 2008 and 2007 are net of \$2.4 million and \$3.0 million, respectively, of cost reimbursement from Novartis and GSK under cost sharing provisions in our collaboration agreements.

Our pharmaceutical sciences costs, where we focus on improving formulation, process development and production methods, increased to \$35.9 million for the year ended December 31, 2008 from \$30.5 million for the year ended December 31, 2007. This increase is primarily due to less cost reimbursement under the ZALBIN program and greater activity in other projects for which we have no cost sharing provisions. Pharmaceutical sciences costs for the years ended December 31, 2008 and 2007 are net of \$1.2 million and \$4.8 million, respectively, of cost reimbursement from Novartis and GSK under cost sharing provisions in our collaboration agreements.

Our manufacturing costs increased to \$77.1 million for the year ended December 31, 2008 from \$73.3 million for the year ended December 31, 2007. This increase is primarily due to increased production activities for raxibacumab and BENLYSTA, partially offset by decreased activities for HGS-ETR2 and ZALBIN. Our manufacturing costs for the years ended December 31, 2008 and 2007 are net of \$19.9 million and \$15.1 million, respectively, of cost reimbursement from Novartis and GSK under cost sharing provisions in our collaboration agreements.

Our clinical development costs decreased to \$104.7 million for the year ended December 31, 2008 from \$108.5 million for the year ended December 31, 2007. This decrease is primarily due to reduced Phase 3 ZALBIN clinical trial costs as the trials near completion, partially offset by increased Phase 3 trial costs related to BENLYSTA. Our clinical development costs for the years ended December 31, 2008 and 2007 are net of \$64.4 million and \$62.9 million, respectively, of cost reimbursement from Novartis and GSK under cost sharing provisions in our collaboration agreements.

The research and development expenditures noted above are categorized by functional area. We evaluate and prioritize our activities according to functional area, rather than on a per-project basis. For this reason, we do not maintain a formal accounting system that captures or allocates all costs, both direct and indirect, on a per-project basis. Therefore, we do not believe that our available project-by-project information would form a reasonable basis for disclosure to investors.

General and administrative expenses increased to \$60.9 million for the year ended December 31, 2008 from \$55.9 million for the year ended December 31, 2007. This increase is primarily due to increased preparatory

## Results of Operations (continued)

### *Years Ended December 31, 2008 and 2007 (continued)*

activities for commercialization. General and administrative expenses include approximately \$2.2 million related to the settlement of certain patent proceedings, which were offset by a decrease in other legal expenses.

During 2008, we did not incur any facility-related exit charges. Facility-related exit credits in 2007 related to the reversal of a liability and the recording of a gain aggregating \$3.7 million in connection with the purchase and sale of a small laboratory and office building. See Note K, Facility-Related Exit Charges (Credits), of the Notes to the Consolidated Financial Statements for additional discussion.

Investment income decreased to \$23.5 million for the year ended December 31, 2008 from \$33.0 million for the year ended December 31, 2007. The decrease is primarily due to lower average investment balances in 2008 as compared to 2007. Investment income also includes realized net gains on our short-term investments, marketable securities and restricted investments of \$0.9 million for the year ended December 31, 2008 as compared to net gains of \$0.1 million for the year ended December 31, 2007. The yield on our investments was approximately 4.6% for the year ended December 31, 2008, as compared to approximately 4.8% for the year ended December 31, 2007.

Interest expense increased to \$62.9 million for the year ended December 31, 2008 compared to \$60.7 million for the year ended December 31, 2007.

Our gain on sale of long-term equity investments for the year ended December 31, 2008 of \$32.5 million relates to the sale of our investment in CoGenesys. In 2006, we completed the sale of assets of our CoGenesys division and held a 14% equity interest in CoGenesys, a newly-formed company. In 2008, CoGenesys was acquired by Teva. We received initial proceeds of \$47.3 million. Our cost basis in this investment was \$14.8 million. We received additional proceeds of approximately \$5.3 million in February 2009 related to this transaction. See Note D, Collaborations and U.S. Government Agreement, of the Notes to the Consolidated Financial Statements for additional discussion.

Other expense of \$6.3 million for the year ended December 31, 2008 was due to an other-than-temporary impairment of our investment in debt securities issued by LBHI. During 2008, LBHI experienced a significant deterioration in its credit worthiness and filed a petition under Chapter 11 of the U.S. Bankruptcy Code. As a result, we determined that our investment in LBHI debt securities had incurred an other-than-temporary impairment. See Note C, Investments, of the Notes to the Consolidated Financial Statements for additional discussion.

*Net Income (Loss).* We recorded a net loss of \$268.9 million, or \$1.99 per share, for the year ended December 31, 2008, compared to a net loss of \$284.4 million, or \$2.12 per share, for the year ended December 31, 2007. The decreased loss for 2008 compared to 2007 is primarily due to the gain on sale of our CoGenesys investment of \$32.5 million, or \$0.24 per share, and increased revenues, partially offset by a decrease in investment income and a charge for impaired investments of \$6.3 million, or \$0.04 per share.

## Liquidity and Capital Resources

We had working capital of \$616.6 million at December 31, 2009 compared to a working capital shortfall of \$52.5 million at December 31, 2008. The improvement in our working capital is primarily due to the cash provided by our two 2009 public offerings of common stock totaling approximately \$812.9 million and our raxibacumab revenue of \$180.2 million, net of \$50.0 million used in February 2009 to extinguish approximately \$106.2 million of our convertible subordinated debt, partially offset by our costs and expenses in 2009.

We expect to continue to incur substantial expenses relating to our research and development efforts, as we focus on clinical trials and manufacturing required for the development of our active product candidates. We will also incur costs related to our pre-commercial launch activities. In the event our working capital needs exceed our available working capital, we can utilize our non-current marketable securities, which are classified as “available-for-sale”. In 2009, the USG agreed to purchase 45,000 additional doses of raxibacumab for the SNS, to be delivered over a three-year period, which began in 2009. We expect to receive a total of approximately \$152.0 million from this order as deliveries are completed, \$17.7 million of which was recognized in 2009.

## Liquidity and Capital Resources (continued)

We may also receive payments under collaboration agreements, to the extent milestones are met, which would further improve our working capital position. We continue to evaluate our working capital position on an ongoing basis.

To minimize our exposure to credit risk, we invest in securities with strong credit ratings and have established guidelines relative to diversification and maturity with the objectives of maintaining safety of principal and liquidity. We do not invest in derivative financial instruments or auction rate securities, and we generally hold our investments in debt securities until maturity. The deterioration of the credit markets during 2008 had a detrimental effect on our investment portfolio, but as of December 31, 2009 the gross unrealized losses on our available-for-sale securities have decreased to \$1.4 million from \$9.9 million as of December 31, 2008.

The amounts of expenditures that will be needed to carry out our business plan are subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. We are completing our fourth Phase 3 trial and have several ongoing Phase 1 and Phase 2 trials and expect to initiate additional trials in the future. Completion of these trials may extend several years or more, but the length of time generally varies considerably according to the type, complexity, novelty and intended use of the drug candidate. We estimate that the completion periods for our Phase 1, Phase 2, and Phase 3 trials could span one year, one to two years and two to four years, respectively. Some trials may take considerably longer to complete. The duration and cost of our clinical trials are a function of numerous factors such as the number of patients to be enrolled in the trial, the amount of time it takes to enroll them, the length of time they must be treated and observed, and the number of clinical sites and countries for the trial.

Our clinical development expenses are impacted by the clinical phase of our drug candidates. Our expenses increase as our drug candidates move to later phases of clinical development. The status of our clinical projects is as follows:

<b>Product Candidate <sup>(1)</sup></b>	<b>Indication</b>	<b>Clinical Trial Status as of December 31, <sup>(2)</sup></b>		
		<b>2009</b>	<b>2008</b>	<b>2007</b>
ZALBIN . . . . .	Hepatitis C	Phase 3 <sup>(3)</sup>	Phase 3	Phase 3
BENLYSTA . . . . .	Systemic Lupus Erythematosus	Phase 3 <sup>(4)</sup>	Phase 3	Phase 3
BENLYSTA . . . . .	Rheumatoid Arthritis	Phase 2 <sup>(5)</sup>	Phase 2 <sup>(5)</sup>	Phase 2 <sup>(5)</sup>
Raxibacumab . . . . .	Anthrax	(6)	(6)	(6)
HGS1029 . . . . .	Cancer	Phase 1	Phase 1	(7)
HGS-ETR1 . . . . .	Cancer	Phase 2	Phase 2	Phase 2
HGS-ETR2 . . . . .	Cancer	(8)	Phase 1	Phase 1

(1) Includes only those candidates for which an Investigational New Drug Application (“IND”) has been filed with the FDA.

(2) Clinical Trial Status defined as when patients are being dosed.

(3) Phase 3 results reported; BLA filed in 2009. Phase 2 monthly dosing study underway.

(4) Results from two Phase 3 clinical trials reported; second of these two concluding in 2010; pre-BLA activities underway.

(5) Initial Phase 2 trial completed; treatment IND ongoing and further development under review.

(6) BLA filed in 2009; Complete Response Letter received from FDA; additional work ongoing.

(7) IND filed in December 2007 with respect to HGS1029 (formerly AEG40826).

(8) Ongoing Phase 1 trial by National Institutes of Health; further development not anticipated.

We identify our drug candidates by conducting numerous preclinical studies. We may conduct multiple clinical trials to cover a variety of indications for each drug candidate. Based upon the results from our trials, we

## **Liquidity and Capital Resources (continued)**

may elect to discontinue clinical trials for certain indications or certain drugs in order to concentrate our resources on more promising drug candidates.

We are advancing a number of drug candidates, including antibodies, an albumin fusion protein and a small molecule, in part to diversify the risks associated with our research and development spending. In addition, our manufacturing plants have been designed to enable multi-product manufacturing capability. Accordingly, we believe our future financial commitments, including those for preclinical, clinical or manufacturing activities, are not substantially dependent on any single drug candidate. Should we be unable to sustain a multi-product drug pipeline, our dependence on the success of a single drug candidate would increase.

We must receive regulatory clearance to advance each of our products into and through each phase of clinical testing. Moreover, we must receive regulatory approval to launch any of our products commercially. In order to receive such approval, the appropriate regulatory agency must conclude that our clinical data establish safety and efficacy and that our products and the manufacturing facilities meet all applicable regulatory requirements. We cannot be certain that we will establish sufficient safety and efficacy data to receive regulatory approval for any of our drugs or that our drugs and the manufacturing facilities will meet all applicable regulatory requirements.

Part of our business plan includes collaborating with others. For example, we entered into a collaboration agreement in 2006 with Novartis to co-develop and co-commercialize ZALBIN. Under this agreement, we will co-commercialize ZALBIN in the United States, and will share U.S. commercialization costs and U.S. profits equally. Novartis will be responsible for commercialization outside the U.S. and will pay us a royalty on those sales. We and Novartis share clinical development costs. Including a non-refundable up-front license fee, we are entitled to payments aggregating approximately \$507.5 million upon successful attainment of certain milestones. As of December 31, 2009, we have contractually earned and received milestones aggregating \$207.5 million, including \$75.0 million received in 2009. In 2006, we entered into a collaboration agreement with GSK with respect to BENLYSTA and received a payment of \$24.0 million. We and GSK share Phase 3 and 4 development costs, and will share sales and marketing expenses and profits of any product that is commercialized in accordance with the collaboration agreement. During 2009, we recorded approximately \$44.0 million of reimbursement from Novartis and GSK with respect to our cost sharing agreements as a reduction of research and development expenses. We are recognizing the up-front fees and milestones received from Novartis and GSK as revenue ratably over the estimated remaining development periods.

We have collaborators who have sole responsibility for product development. For example, GSK is developing other products under separate agreements as part of our overall relationship with them. We have no control over the progress of GSK's development plans. We cannot forecast with any degree of certainty whether any of our current or future collaborations will affect our drug development.

Because of the uncertainties discussed above, the costs to advance our research and development projects are difficult to estimate and may vary significantly. We expect that our existing funds, payments received under the raxibacumab contract and other agreements and investment income will be sufficient to fund our operations for at least the next twelve months.

Our future capital requirements and the adequacy of our available funds will depend on many factors, primarily including the scope and costs of our clinical development programs, the scope and costs of our manufacturing and process development activities, the magnitude of our discovery and preclinical development programs and the level of our pre-commercial launch activities. There can be no assurance that any additional financing required in the future will be available on acceptable terms, if at all.

Depending upon market and interest rate conditions, we are exploring, and, from time to time, may take actions to strengthen further our financial position. We may undertake financings and may repurchase or restructure some or all of our outstanding convertible debt instruments in the future depending upon market and other conditions. During 2009 we repurchased approximately \$106.2 million of our convertible subordinated debt due in 2011 and 2012 at a cost of approximately \$50.0 million plus accrued interest. In August and December 2009 we completed public offerings of our common stock, resulting in net cash proceeds of approximately \$812.9 million.



## Liquidity and Capital Resources (continued)

We have certain contractual obligations which may have a future effect on our financial condition, changes in financial condition, results of operations, liquidity, capital expenditures or capital resources that are material to investors. Our operating leases, along with our unconditional purchase obligations, are not recorded on our balance sheets. Debt associated with the sale and accompanying leaseback of our LSM facility to BioMed in 2006 is recorded on our balance sheet as of December 31, 2009 and 2008. We have an option to purchase the Traville facility in 2016 for \$303.0 million. This is not reflected in the contractual obligations table below because we are not obligated to exercise this option.

Our contractual obligations as of December 31, 2009 are summarized as follows:

	Payments Due by Period				
	Total	One Year or Less	Two to Three Years	Four to Five Years	After Five Years
(dollars in millions)					
<b>Contractual Obligations</b>					
Long-term debt — convertible notes <sup>(1)</sup> . . . . .	\$ 426.7	\$ 9.1	\$417.6	\$ —	\$ —
Long-term lease commitment — BioMed <sup>(2)</sup> . . . . .	471.0	24.5	50.5	52.6	343.4
Operating leases <sup>(3)</sup> . . . . .	367.1	20.5	42.1	43.6	260.9
Unconditional purchase obligations <sup>(4)</sup> . . . . .	1.0	1.0	—	—	—
Raxibacumab milestones and royalties <sup>(5)</sup> . . . . .	11.2	3.2	8.0	—	—
Other long-term liabilities reflected on our balance sheets <sup>(6)</sup> . . . . .	—	—	—	—	—
Total contractual cash obligations <sup>(7)</sup> . . . . .	<u>\$1,277.0</u>	<u>\$58.3</u>	<u>\$518.2</u>	<u>\$96.2</u>	<u>\$604.3</u>

- (1) Contractual interest obligations related to our convertible subordinated notes included above total \$22.8 million as of December 31, 2009. Contractual interest obligations of \$9.1 million, \$13.7 million are due in one year or less and two to three years, respectively.
- (2) Contractual interest obligations related to BioMed are included above and aggregate \$418.1 million as of December 31, 2009. Contractual interest obligations of \$24.5 million, \$50.5 million, \$52.6 million and \$290.5 million are due in one year or less, two to three years, four to five years and after five years, respectively.
- (3) Includes Traville headquarters operating lease with BioMed with aggregate payments of \$343.4 million. Lease payments of \$17.9 million, \$36.8 million, \$38.3 million and \$250.4 million are due in one year or less, two to three years, four to five years and after five years, respectively.
- (4) Our unconditional purchase obligations relate to commitments for capital expenditures.
- (5) Includes milestone payments and royalties associated with the delivery of raxibacumab to the U.S. Strategic National Stockpile.
- (6) In the event we reach certain development milestones for ZALBIN, BENLYSTA or raxibacumab such as successful completion of Phase 3 trials or regulatory approval, we would be obligated to make payments of up to \$9.0 million over the next five years. In the event we reach certain development milestones related to HGS1029, we would be obligated to pay up to \$204.0 million. Our other products are in either Phase 1 or Phase 2 and would also obligate us to make certain milestone payments should they reach Phase 3 or regulatory approval. These other payments could result in aggregate milestone payments of \$14.5 million. Because we cannot forecast with any degree of certainty whether any of these products will reach these milestones, we have excluded these amounts and any royalty payments, except for those related to raxibacumab sales under the current order from the USG, from the above table.
- (7) For additional discussion of our debt obligations and lease commitments, see Note F, Long-Term Debt and Note G, Commitments and Other Matters, of the Notes to the Consolidated Financial Statements.

**Liquidity and Capital Resources (continued)**

As of December 31, 2009, we had net operating loss carryforwards (“NOLs”) for federal income tax purposes of approximately \$1.6 billion, excluding approximately \$0.3 billion of stock-based compensation NOLs, which expire, if unused, through December 31, 2029. We also have available research and development tax credit and other tax credit carryforwards of approximately \$35.0 million, the majority of which will expire, if unused, through December 31, 2029.

Our unrestricted and restricted funds may be invested in U.S. Treasury securities, government agency obligations, high grade corporate debt securities and various money market instruments rated “A–” or better. Such investments reflect our policy regarding the investment of liquid assets, which is to seek a reasonable rate of return consistent with an emphasis on safety, liquidity and preservation of capital.

**Off-Balance Sheet Arrangements**

During 1997 and 1999, we entered into two long-term leases with the Maryland Economic Development Corporation (“MEDCO”) expiring January 1, 2019 for a small-scale manufacturing facility aggregating 127,000 square feet and built to our specifications. We have accounted for these leases as operating leases. The facility was financed primarily through a combination of bonds issued by MEDCO (“MEDCO Bonds”) and loans issued to MEDCO by certain State of Maryland agencies. We have no equity interest in MEDCO.

Rent is based upon MEDCO’s debt service obligations and annual base rent under the leases is currently approximately \$2.6 million. The MEDCO Bonds are secured by letters of credit issued for the account of MEDCO which were renewed in December 2009. We are required to have restricted investments of approximately \$34.3 million which serve as security for the MEDCO letters of credit reimbursement obligation. Upon default or early lease termination, the MEDCO Bond indenture trustee can draw upon the letters of credit to pay the MEDCO Bonds as they are tendered. In such an event, we could lose part or all of our restricted investments and could record a charge to earnings for a corresponding amount. Alternatively, we have an option through the end of the lease term to purchase this facility for an aggregate amount that declines from approximately \$37.0 million in 2010 to approximately \$21.0 million in 2019.

## **Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995**

Certain statements contained in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements are based on our current intent, belief and expectations. These statements are not guarantees of future performance and are subject to certain risks and uncertainties that are difficult to predict. Actual results may differ materially from these forward-looking statements because of our unproven business model, our dependence on new technologies, the uncertainty and timing of clinical trials, our ability to develop and commercialize products, our dependence on collaborators for services and revenue, our substantial indebtedness and lease obligations, our changing requirements and costs associated with facilities, intense competition, the uncertainty of patent and intellectual property protection, our dependence on key management and key suppliers, the uncertainty of regulation of products, the impact of future alliances or transactions and other risks described in this filing and our other filings with the Securities and Exchange Commission. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today’s date. We undertake no obligation to update or revise the information contained in this Annual Report on Form 10-K whether as a result of new information, future events or circumstances or otherwise.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We do not have operations of a material nature that are subject to risks of foreign currency fluctuations. We do, however, have certain aspects of our global clinical studies that are subject to risks of foreign currency fluctuations. We do not use derivative financial instruments in our operations or investment portfolio. Our investment portfolio may be comprised of low-risk U.S. Treasuries, government-sponsored enterprise securities, high-grade debt having at least an “A-” rating at time of purchase and various money market instruments. The short-term nature of these securities, which currently have an average term of approximately nine months, decreases the risk of a material loss caused by a market change related to interest rates.

We believe that a hypothetical 100 basis point adverse move (increase) in interest rates along the entire interest rate yield curve would adversely affect the fair value of our cash, cash equivalents, short-term investments, marketable securities and restricted investments by approximately \$8.8 million, or approximately 0.7% of the aggregate fair value of \$1.2 billion, at December 31, 2009. For these reasons, and because these securities are generally held to maturity, we believe we do not have significant exposure to market risks associated with changes in interest rates related to our debt securities held as of December 31, 2009. We believe that any interest rate change related to our investment securities held as of December 31, 2009 is not material to our consolidated financial statements. As of December 31, 2009, the yield on comparable one-year investments was approximately 0.4%, as compared to our current portfolio yield of approximately 1.1%. However, given the short-term nature of these securities, a general decline in interest rates may adversely affect the interest earned from our portfolio as securities mature and may be replaced with securities having a lower interest rate.

To minimize our exposure to credit risk, we invest in securities with strong credit ratings and have established guidelines relative to diversification and maturity with the objectives of maintaining safety of principal and liquidity. We do not invest in derivative financial instruments, auction rate securities, loans held for sale or mortgage-backed securities backed by sub-prime or Alt-A collateral, and we generally hold our investments in debt securities until maturity. However, adverse changes in the credit markets relating to credit risks would adversely affect the fair value of our cash, cash equivalents, short-term investments, marketable securities and restricted investments. During the year ended December 31, 2009, the gross unrealized losses in our portfolio decreased from \$9.9 million to \$1.4 million. The majority of these unrealized losses related to our holdings of corporate debt securities. At December 31, 2009, the fair value of our corporate debt securities was approximately \$379.7 million, or 61% of our total investment portfolio of \$624.0 million. The remaining securities in our portfolio are either U.S. Treasury and agency securities or government-sponsored enterprise securities, which we believe are subject to less credit risk. Although there has been improvement in our gross unrealized losses, in the event there is further deterioration in the credit market, the fair value of our corporate debt securities could decline.

The facility leases we entered into during 2006 require us to maintain minimum levels of restricted investments of approximately \$46.0 million, or \$39.5 million if in the form of cash, as collateral for these facilities. Together with the requirement to maintain approximately \$34.3 million in restricted investments with respect to our small-scale manufacturing facility leases, our overall level of restricted investments is currently required to be approximately \$80.3 million. Although the market value for these investments may rise or fall as a result of changes in interest rates, we will be required to maintain this level of restricted investments in either a rising or declining interest rate environment.

Our convertible subordinated notes bear interest at fixed rates. As a result, our interest expense on these notes is not affected by changes in interest rates.

During 2002, we established a wholly-owned subsidiary, Human Genome Sciences Europe GmbH (“HGS Europe”) that is assisting in our clinical trials and clinical research collaborations in European countries. Although HGS Europe’s activities are denominated primarily in euros, we believe the foreign currency fluctuation risks to be immaterial to our operations as a whole. During 2005, we established a wholly-owned subsidiary, Human Genome Sciences Pacific Pty Ltd. (“HGS Pacific”) that is sponsoring some of our clinical trials in the Asia/Pacific region. We currently do not anticipate HGS Pacific to have any operational activity and therefore we do not believe we will have any foreign currency fluctuation risks with respect to HGS Pacific.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The information required by this item is set forth on pages F-1 — F-39.

## **ITEM 9. CHANGES AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### **Disclosure Controls and Procedures**

Our management, including our principal executive and principal financial officers, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2009. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed in this annual report on Form 10-K has been appropriately recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, to allow timely decisions regarding required disclosure. Based on that evaluation, our principal executive and principal financial officers have concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

### **Changes in Internal Control**

Our management, including our principal executive and principal financial officers, has evaluated any changes in our internal control over financial reporting that occurred during the year ended December 31, 2009, and has concluded that there was no change that occurred during the year ended December 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### **Management Report on Internal Control over Financial Reporting**

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel, 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 and includes those policies and procedures that:

- pertain to the management of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- 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
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls



**ITEM 9A. CONTROLS AND PROCEDURES (continued)**

may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2009. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.

Based on our assessment, management believes that, as of December 31, 2009, the Company's internal control over financial reporting is effective based on those criteria.

The Company's independent auditors have issued an audit report on internal control over financial reporting which follows herein.

**ITEM 9B. OTHER INFORMATION**

None.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM  
ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

Board of Directors and Stockholders of  
Human Genome Sciences, Inc.  
Rockville, Maryland

We have audited Human Genome Sciences Inc.'s internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Human Genome Sciences, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying "Management Report on Internal Control over Financial Reporting." Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Human Genome Sciences, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Human Genome Sciences, Inc. as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2009 and our report dated March 2, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Baltimore, Maryland  
March 2, 2010

### **PART III**

#### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

We incorporate herein by reference the information concerning directors, executive officers and corporate governance in our Notice of Annual Stockholders' Meeting and Proxy Statement to be filed within 120 days after the end of our fiscal year (the "2010 Proxy Statement").

#### **ITEM 11. EXECUTIVE COMPENSATION**

We incorporate herein by reference the information concerning executive compensation to be contained in the 2010 Proxy Statement.

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

We incorporate herein by reference the information concerning security ownership of certain beneficial owners and management to be contained in the 2010 Proxy Statement.

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

We incorporate herein by reference the information concerning the CoGenesys transaction set forth in Note M to our consolidated financial statements. We incorporate herein by reference the information concerning certain other relationships and related transactions to be contained in the 2010 Proxy Statement.

#### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

We incorporate herein by reference the information concerning principal accounting fees and services to be contained in the 2010 Proxy Statement.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report:

(1) Index to Consolidated Financial Statements

	<u>Page Number</u>
Report of Ernst & Young LLP, Independent Registered Public Accounting Firm . . . . .	F-2
Consolidated Balance Sheets at December 31, 2009 and 2008 . . . . .	F-3
Consolidated Statements of Operations for the years ended December 31, 2009, 2008 and 2007 . .	F-4
Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2009, 2008 and 2007 . . . . .	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2009, 2008 and 2007 . . . . .	F-6
Notes to Consolidated Financial Statements . . . . .	F-8

(2) Financial Statement Schedules

Financial statement schedules are omitted because they are not required.

(3) Exhibits

<u>Exhibit No.</u>	
3.1*	Certificate of Incorporation of the Registrant (Filed as Exhibit 3.1 to the Registrant's Form 10-K for the fiscal year ended December 31, 1993, Exhibit 3.3 to the Form 10-K for the fiscal year ended December 31, 1997, Exhibit 3.1 to the Form 8-K filed December 16, 1999, Exhibit 3.1 to the Form 10-Q filed July 31, 2001, and Exhibit 3.1 to the Form 8-K filed on May 8, 2008).
3.2*	By-laws of the Registrant (Filed as Exhibit 3.2 to the Registrant's Form 8-K filed May 8, 2008).
4.1*	Form of Common Stock Certificate (Filed as Exhibit 4.1 to the Registrant's Form S-3 Registration Statement, as amended (Commission File No. 333-45272), filed September 6, 2000).
4.2*	Indenture dated as of October 4, 2004 between the Registrant and The Bank of New York, as trustee, including the form of 2¼% Convertible Subordinated Notes due 2011 (Filed as Exhibit 4.1 to the Registrant's Form 8-K filed October 4, 2004).
4.3*	Indenture dated as of August 9, 2005 between the Registrant and The Bank of New York, as trustee, including the form of 2¼% Convertible Subordinated Notes due 2012 (Filed as Exhibit 4.1 to the Registrant's 8-K filed August 9, 2005).
10.1*	Employment Agreement, dated November 21, 2004, with H. Thomas Watkins (Filed as Exhibit 10.1 to the Registrant's Form 8-K filed November 23, 2004).
10.2*	First Amendment to the Employment Agreement by and between Human Genome Sciences, Inc. and H. Thomas Watkins (Filed as Exhibit 10.1 to the Registrant's Form 8-K filed December 20, 2007).
10.3*	Form of Executive Agreement (Filed as Exhibit 10.3 to the Registrant's Form 8-K filed December 20, 2007).
10.4*	Human Genome Sciences, Inc. Discretionary Bonus Policy (Filed as Exhibit 10.4 to the Registrant's Form 8-K filed December 20, 2007).
10.5*	Form of Stock Unit Grant Agreement under the Non-Employee Director Equity Compensation Plan (Filed as Exhibit 10.5 to the Registrant's Form 8-K filed December 20, 2007).
10.6*	Second Amended and Restated Key Executive Severance Plan (Filed as Exhibit 10.2 to the Registrant's Form 8-K filed December 20, 2007).
10.7*	Human Genome Sciences, Inc. Amended and Restated Stock Incentive Plan (Filed as Annex A to the Registrant's Definitive Proxy Statement on Schedule 14A filed March 24, 2009).
10.8*	Employee Stock Purchase Plan dated January 1, 2009 (Filed as Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 filed December 19, 2008).

<u>Exhibit No.</u>	
10.9*	Lease Agreement between Maryland Economic Development Corporation and Human Genome Sciences, Inc., dated December 1, 1997 (Filed as Exhibit 10.67 to the Registrant's Form 10-K for the fiscal year ended December 31, 1997 and amended by Exhibit 10.10 hereto).
10.10	Amendment No. 1 dated December 1, 2009 to Lease Agreement between Maryland Economic Development Corporation and Human Genome Sciences, Inc. dated December 1, 1997.
10.11	Reimbursement Agreement dated December 1, 2009 by and between Human Genome Sciences, Inc. and Manufacturers and Traders Trust Company relating to 1997 Series Revenue Bonds.
10.12	Amended and Restated Lease Agreement between Maryland Economic Development Corporation and Human Genome Sciences, Inc. dated December 1, 2009.
10.13	Reimbursement Agreement dated December 1, 2009 by and between Human Genome Sciences, Inc. and Manufacturers and Traders Trust Company relating to Series 1999 A and B Revenue Bonds.
10.14	Collateral Pledge Agreement dated December 1, 2009 among Human Genome Sciences, Inc., as Pledgor, Manufacturers and Traders Trust Company, as Pledgee, and Manufacturers and Traders Trust Company, as the Collateral Agent.
10.15*	Form of Restricted Stock Agreement (Filed as Exhibit 10.20 to the Registrant's Form 10-Q filed August 1, 2005).
10.16*	Form of Stock Option Agreement (Filed as Exhibit 10.2 to the Registrant's Form 8-K filed September 20, 2004).
10.17*†	Asset Purchase Agreement dated December 12, 2005 by and between TriGenesys, Inc and the Registrant (Filed as Exhibit 10.22 to the Registrant's Form 10-K for the fiscal year ended December 31, 2005).
10.18*†	Co-development and Commercialization Agreement between Novartis International Pharmaceutical Ltd. and Human Genome Sciences, Inc., dated June 5, 2006 (Filed as Exhibit 10.1 to the Registrant's Form 10-Q filed August 9, 2006).
10.19*	Purchase and Sale Agreement between BioMed Realty, L.P. and Human Genome Sciences, Inc., dated May 2, 2006 (Filed as Exhibit 10.2 to the Registrant's Form 10-Q filed August 9, 2006).
10.20*	Lease Agreement between BMR-Belward Campus Drive LSM LLC and Human Genome Sciences, Inc., dated May 24, 2006 (Filed as Exhibit 10.3 to the Registrant's Form 10-Q filed August 9, 2006).
10.21*	Lease Agreement between BMR-Shady Grove Road HQ LLC and Human Genome Sciences, Inc., dated May 24, 2006 (Filed as Exhibit 10.4 to the Registrant's Form 10-Q filed August 9, 2006).
10.22*†	Solicitation (as amended) and Modification of Contract awarded by the Department of Health and Human Services to Human Genome Sciences, Inc. dated June 24, 2006 (Filed as Exhibit 10.5 to the Registrant's Amended Form 10-Q filed September 27, 2007).
10.23*†	Amendment of Solicitation/Modification of Contract awarded by the Department of Health and Human Services to Human Genome Sciences, Inc. dated July 17, 2009. (Filed as Exhibit 10.1 to the Registrant's Form 10-Q filed October 29, 2009).
10.24*†	Co-development and Commercialization Agreement between Glaxo Group Limited and Human Genome Sciences, Inc., dated August 1, 2006 (Filed as Exhibit 10.25 to the Registrant's Form 10-K filed February 26, 2009).
10.25*	Second Amendment to the Employment Agreement by and between Human Genome Sciences, Inc., and H. Thomas Watkins (Filed as Exhibit 10.26 to the Registrant's Form 10-K filed February 26, 2009).
10.26*	Form of First Amendment to Executive Agreement (Filed as Exhibit 10.27 to the Registrant's Form 10-K filed February 26, 2009).
10.27*	Form of First Amendment to the Registrant's Second Amended and Restated Key Executive Severance Plan (Filed as Exhibit 10.28 to the Registrant's Form 10-K filed February 26, 2009).
12.1	Ratio of Earnings to Fixed Charges.



**Exhibit  
No.**

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- |      |  |
|------|--|
| 21.1 | Subsidiaries.  |
| 23.1 | Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm. |
| 31.1 | Rule 13a-14(a) Certification of Principal Executive Officer.                 |
| 31.2 | Rule 13a-14(a) Certification of Principal Financial Officer.                 |
| 32.1 | Section 1350 Certification of Chief Executive Officer.                       |
| 32.2 | Section 1350 Certification of Chief Financial Officer.                       |
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\* Incorporated by reference.

† Confidential treatment requested for certain portions of this Exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended, which portions are omitted and filed separately with the Securities and Exchange Commission.

## 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.

HUMAN GENOME SCIENCES, INC.

BY: /s/ H. Thomas Watkins

H. Thomas Watkins  
President and Chief Executive Officer

Dated: March 2, 2010

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 the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ H. Thomas Watkins</u> H. Thomas Watkins	President, Chief Executive Officer and Director (Principal Executive Officer)	March 2, 2010
<u>/s/ Timothy C. Barabe</u> Timothy C. Barabe	Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 2, 2010
<u>/s/ Argeris N. Karabelas, Ph.D.</u> Argeris N. Karabelas, Ph.D.	Chairman of the Board	March 2, 2010
<u>/s/ Richard J. Danzig</u> Richard J. Danzig	Director	March 2, 2010
<u>/s/ Jürgen Drews, M.D.</u> Jürgen Drews, M.D.	Director	March 2, 2010
<u>/s/ Maxine Gowen, Ph.D.</u> Maxine Gowen, Ph.D.	Director	March 2, 2010
<u>/s/ Tuan Ha-Ngoc</u> Tuan Ha-Ngoc	Director	March 2, 2010
<u>/s/ John LaMattina, Ph.D.</u> John LaMattina, Ph.D.	Director	March 2, 2010
<u>/s/ Augustine Lawlor</u> Augustine Lawlor	Director	March 2, 2010
<u>/s/ David Southwell</u> David Southwell	Director	March 2, 2010
<u>/s/ Robert C. Young, M.D.</u> Robert C. Young, M.D.	Director	March 2, 2010

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Stockholders of  
Human Genome Sciences, Inc.  
Rockville, Maryland

We have audited the accompanying consolidated balance sheets of Human Genome Sciences, Inc. as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Human Genome Sciences, Inc. at December 31, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Human Genome Sciences, Inc.'s internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 2, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Baltimore, Maryland  
March 2, 2010

**HUMAN GENOME SCIENCES, INC.**  
**CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2009	2008
	(in thousands, except share and per share amounts)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$ 567,667	\$ 15,248
Short-term investments . . . . .	151,528	22,691
Collaboration receivables . . . . .	10,356	22,076
Accounts receivable . . . . .	23,892	2,871
Inventory . . . . .	20,149	—
Prepaid expenses and other current assets . . . . .	7,176	5,280
Total current assets . . . . .	780,768	68,166
Marketable securities . . . . .	384,028	265,640
Property, plant and equipment (net of accumulated depreciation) . . . . .	263,123	274,315
Restricted investments . . . . .	88,437	69,360
Long-term equity investments . . . . .	3,016	2,606
Other assets . . . . .	11,258	6,745
TOTAL ASSETS . . . . .	<u>\$ 1,530,630</u>	<u>\$ 686,832</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable and accrued expenses . . . . .	\$ 42,369	\$ 55,434
Accrued payroll and related taxes . . . . .	30,997	18,574
Accrued exit expenses . . . . .	2,227	2,952
Deferred revenues . . . . .	88,565	43,746
Total current liabilities . . . . .	164,158	120,706
Convertible subordinated debt . . . . .	349,807	417,597
Lease financing . . . . .	248,628	246,477
Deferred revenues, net of current portion . . . . .	1,978	29,563
Accrued exit expenses, net of current portion . . . . .	1,979	2,075
Deferred rent . . . . .	8,665	6,718
Total liabilities . . . . .	<u>775,215</u>	<u>823,136</u>
Stockholders' equity (deficit):		
Preferred stock — \$0.01 par value; shares authorized — 20,000,000; no shares issued or outstanding . . . . .	—	—
Common stock — \$0.01 par value; shares authorized — 400,000,000; shares issued and outstanding of 185,254,660 and 135,739,978 at December 31, 2009 and 2008, respectively . . . . .	1,853	1,357
Additional paid-in capital . . . . .	2,932,863	2,059,154
Accumulated other comprehensive income (loss) . . . . .	7,365	(4,490)
Accumulated deficit . . . . .	<u>(2,186,666)</u>	<u>(2,192,325)</u>
Total stockholders' equity (deficit) . . . . .	<u>755,415</u>	<u>(136,304)</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) . . . . .	<u>\$ 1,530,630</u>	<u>\$ 686,832</u>

The accompanying Notes to Consolidated Financial Statements are an integral part hereof.



**HUMAN GENOME SCIENCES, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended December 31,		
	2009	2008	2007
	(in thousands, except share and per share amounts)		
Revenue:			
Product sales . . . . .	\$ 154,074	\$ —	\$ —
Manufacturing and development services . . . . .	50,653	—	—
Research and development collaborative agreements . . . . .	71,022	48,422	41,851
Total revenue . . . . .	<u>275,749</u>	<u>48,422</u>	<u>41,851</u>
Costs and expenses:			
Cost of product sales . . . . .	15,805	—	—
Cost of manufacturing and development services . . . . .	18,215	—	—
Research and development expenses . . . . .	173,709	243,257	246,293
General and administrative expenses . . . . .	61,073	60,865	55,874
Facility-related exit charges (credits) . . . . .	759	—	(3,673)
Total costs and expenses . . . . .	<u>269,561</u>	<u>304,122</u>	<u>298,494</u>
Income (loss) from operations . . . . .	6,188	(255,700)	(256,643)
Investment income . . . . .	12,727	23,487	32,988
Interest expense . . . . .	(58,424)	(62,912)	(60,716)
Gain on extinguishment of debt . . . . .	38,873	—	—
Gain on sale of long-term equity investment . . . . .	5,259	32,518	—
Other expense . . . . .	(238)	(6,284)	—
Income (loss) before taxes . . . . .	4,385	(268,891)	(284,371)
Income tax benefit . . . . .	1,274	—	—
Net income (loss) . . . . .	<u>\$ 5,659</u>	<u>\$ (268,891)</u>	<u>\$ (284,371)</u>
Basic net income (loss) per share . . . . .	<u>\$ 0.04</u>	<u>\$ (1.99)</u>	<u>\$ (2.12)</u>
Diluted net income (loss) per share . . . . .	<u>\$ 0.04</u>	<u>\$ (1.99)</u>	<u>\$ (2.12)</u>
Weighted average shares outstanding, basic . . . . .	<u>149,334,426</u>	<u>135,406,642</u>	<u>134,333,418</u>
Weighted average shares outstanding, diluted . . . . .	<u>155,053,473</u>	<u>135,406,642</u>	<u>134,333,418</u>

The accompanying Notes to Consolidated Financial Statements are an integral part hereof.

# HUMAN GENOME SCIENCES, INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Additional	Accumulated		
	Shares	Amount	Paid-In	Other	Accumulated	Total
			Capital	Comprehensive	Deficit	
			(in thousands, except share amounts)			
Balance — December 31, 2006. . . . .	133,820,053	\$1,338	\$2,006,212	\$ (3,594)	\$(1,639,063)	\$ 364,893
Comprehensive income (loss):						
Net loss . . . . .	—	—	—	—	(284,371)	(284,371)
Unrealized gain on investments . . . . .	—	—	—	6,724	—	6,724
Cumulative translation adjustment . . . . .	—	—	—	22	—	22
Comprehensive loss . . . . .						(277,625)
Shares of common stock issued pursuant to stock-based compensation plans . . . . .	1,116,459	11	8,175	—	—	8,186
Stock-based compensation expense . . . . .	—	—	21,691	—	—	21,691
Balance — December 31, 2007. . . . .	134,936,512	1,349	2,036,078	3,152	(1,923,434)	117,145
Comprehensive income (loss):						
Net loss . . . . .	—	—	—	—	(268,891)	(268,891)
Unrealized loss on investments . . . . .	—	—	—	(7,052)	—	(7,052)
Cumulative translation adjustment . . . . .	—	—	—	(590)	—	(590)
Comprehensive loss . . . . .						(276,533)
Shares of common stock issued pursuant to stock-based compensation plans . . . . .	803,466	8	4,589	—	—	4,597
Stock-based compensation expense . . . . .	—	—	18,487	—	—	18,487
Balance — December 31, 2008. . . . .	135,739,978	1,357	2,059,154	(4,490)	(2,192,325)	(136,304)
Comprehensive income (loss):						
Net income. . . . .	—	—	—	—	5,659	5,659
Unrealized gain on investments . . . . .	—	—	—	11,264	—	11,264
Cumulative translation adjustment . . . . .	—	—	—	591	—	591
Comprehensive income . . . . .						17,514
Issuance of common stock pursuant to public offerings . . . . .	44,522,250	446	812,423	—	—	812,869
Shares of common stock issued pursuant to stock-based compensation plans . . . . .	4,992,432	50	48,762	—	—	48,812
Stock-based compensation expense . . . . .	—	—	12,524	—	—	12,524
Balance — December 31, 2009. . . . .	<u>185,254,660</u>	<u>\$1,853</u>	<u>\$2,932,863</u>	<u>\$ 7,365</u>	<u>\$(2,186,666)</u>	<u>\$ 755,415</u>

The accompanying Notes to Consolidated Financial Statements are an integral part hereof.

**HUMAN GENOME SCIENCES, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Year Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
	<b>(in thousands)</b>		
<b>Cash flows from operating activities:</b>			
Net income (loss) . . . . .	\$ 5,659	\$(268,891)	\$(284,371)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Stock-based compensation expense . . . . .	12,524	18,593	21,691
Depreciation and amortization . . . . .	21,255	21,143	21,907
Amortization of debt discount . . . . .	21,936	24,183	22,130
Gain on extinguishment of debt . . . . .	(38,873)	—	—
Gain on sale of building . . . . .	—	—	(1,704)
Facility-related exit charges (credits) . . . . .	759	—	(1,969)
Gain on sale of long-term equity investment . . . . .	(5,259)	(32,518)	—
Accrued interest on short-term investments, marketable securities and restricted investments . . . . .	(493)	581	(4,631)
Non-cash expenses and other . . . . .	3,759	8,265	2,995
Changes in operating assets and liabilities:			
Collaboration receivables . . . . .	4,800	13,792	25,807
Accounts receivable . . . . .	(21,021)	—	—
Inventory . . . . .	(20,149)	—	—
Prepaid expenses and other assets . . . . .	(1,640)	2,760	(366)
Accounts payable and accrued expenses . . . . .	(13,152)	(7,247)	25,770
Accrued payroll and related taxes . . . . .	12,423	4,126	(930)
Deferred revenues . . . . .	17,234	(44,959)	(633)
Accrued exit expenses . . . . .	(1,953)	(2,083)	(2,376)
Deferred rent . . . . .	1,859	1,992	2,021
Net cash used in operating activities . . . . .	<u>(332)</u>	<u>(260,263)</u>	<u>(174,659)</u>
<b>Cash flows from investing activities:</b>			
Purchase of short-term investments and marketable securities . . . . .	(625,041)	(15,065)	(160,379)
Proceeds from sale and maturities of short-term investments and marketable securities . . . . .	388,277	211,722	278,031
Proceeds from sale of long-term equity investment . . . . .	5,259	47,336	—
Capital expenditures — property, plant, and equipment . . . . .	(10,019)	(9,724)	(3,042)
Release of restricted investments . . . . .	3,291	4,877	—
Proceeds from sale of building, net of transaction costs . . . . .	—	—	14,824
Purchase of building, net of transaction costs . . . . .	—	—	(13,120)
Purchase of long-term equity investment . . . . .	—	—	(3,148)
Net cash provided by (used in) investing activities . . . . .	<u>(238,233)</u>	<u>239,146</u>	<u>113,166</u>
<b>Cash flows from financing activities:</b>			
Purchase of restricted investments . . . . .	(47,002)	(28,897)	(26,642)
Proceeds from sale and maturities of restricted investments . . . . .	26,426	26,120	17,857
Proceeds from issuance of common stock, net of issuance costs . . . . .	861,573	4,432	8,151
Extinguishment of long-term debt . . . . .	(49,998)	—	—
Purchase of treasury stock . . . . .	(15)	(105)	—
Net cash provided by (used in) financing activities . . . . .	<u>790,984</u>	<u>1,550</u>	<u>(634)</u>
<b>Net increase (decrease) in cash and cash equivalents . . . . .</b>	<b>552,419</b>	<b>(19,567)</b>	<b>(62,127)</b>
Cash and cash equivalents — beginning of period . . . . .	<u>15,248</u>	<u>34,815</u>	<u>96,942</u>
<b>Cash and cash equivalents — end of period . . . . .</b>	<b><u>\$ 567,667</u></b>	<b><u>\$ 15,248</u></b>	<b><u>\$ 34,815</u></b>

**SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION, NON-CASH OPERATING,  
INVESTING AND FINANCING ACTIVITIES**

	Year Ended December 31,		
	2009	2008	2007
	(in thousands)		
Cash paid during the period for:			
Interest . . . . .	\$33,609	\$34,729	\$34,319
Income taxes . . . . .	\$ 809	\$ —	\$ —

During the years ended December 31, 2009, 2008 and 2007, the Company recorded non-cash accretion of \$1,384, \$466 and \$653, respectively, related to its exit accrual for certain exited space.

During the years ended December 31, 2009, 2008 and 2007, lease financing increased as a result of non-cash accretion with respect to the Company's 2006 leases with BioMed Realty Trust, Inc. ("BioMed") by \$2,151, \$2,378 and \$2,573 respectively. Because the lease payments are less than the amount of calculated interest expense for the first nine years of the leases, the lease balance will increase during this period.

The accompanying Notes to Consolidated Financial Statements are an integral part hereof.

**HUMAN GENOME SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(dollars in thousands, except per share data)**

**(NOTE A) — The Company**

Human Genome Sciences, Inc. (the “Company”) is a commercially focused biopharmaceutical company advancing toward the market with three products in late-stage development. The Company also has several novel drugs in earlier stages of clinical development in oncology, immunology and infectious disease. Additional products are in clinical development by companies with which the Company is collaborating.

The Company has entered into relationships with a number of leading pharmaceutical and biotechnology companies to leverage its strengths and to gain access to sales and marketing infrastructure as well as complementary technologies. Some of these partnerships provide the Company with licensing or other fees, clinical development cost-sharing, milestone payments and rights to royalty payments as products are developed and commercialized. In some cases, the Company is entitled to certain commercialization, co-promotion, revenue-sharing and other product rights. The Company’s revenues were derived from license fees and milestone payments under collaboration agreements through 2008. In 2009, the Company generated its first product sales when it delivered raxibacumab to the U.S. Strategic National Stockpile (“SNS”). The Company, which operates primarily in the United States, operates in a single business segment.

**(NOTE B) — Summary of Significant Accounting Policies**

**Use of Estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Such estimates are based on historical experience and on various assumptions that the Company believes to be reasonable under the circumstances. Actual results could differ from these estimates under different assumptions or conditions.

**Principles of Consolidation**

The consolidated financial statements include the accounts of Human Genome Sciences, Inc. and its subsidiaries, all of which are wholly-owned. All significant intercompany accounts and transactions have been eliminated.

**Cash Equivalents, Short-term Investments, Marketable Securities, Long-term Equity Investments and Restricted Investments**

The Company considers all highly liquid investment instruments purchased with a maturity of three months or less to be cash equivalents.

The Company classifies its short-term investments, marketable securities and long-term equity investments with readily determinable fair values as “available-for-sale.” Investments in securities that are classified as available-for-sale are measured at fair market value in the balance sheets, and unrealized holding gains and losses on investments are reported as a separate component of stockholders’ equity until realized. Investments of less than 20% of privately-held companies are accounted for as cost-method investments. The Company reviews the carrying value of such investments on a periodic basis for indicators of impairment. Additionally, certain of the Company’s investments are held as restricted investments. Restricted investments with maturities less than three months are not classified as cash in the Company’s consolidated balance sheets. See Note C, Investments, for additional information.



## HUMAN GENOME SCIENCES, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

#### (NOTE B) — Summary of Significant Accounting Policies (continued)

##### Investment Risk

The Company has invested its cash in obligations of the U.S. Government, government agencies and in high-grade debt securities and various money market instruments. The Company's investment policy limits investments to certain types of instruments issued by institutions with credit ratings of "A—" or better, and places restrictions on maturities and concentrations in certain industries and by issuer. The Company does not hold auction rate securities, loans held for sale or mortgage-backed securities backed by sub-prime or Alt-A collateral.

##### Other-Than-Temporary Impairment of Investments

Periodically, the Company evaluates whether any investments have incurred an other-than-temporary impairment, based on the criteria under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("FASB ASC") Topic 320, *Investments — Debt and Equity Securities*. This evaluation consists of a review of several factors, including but not limited to the length of time and extent that a security has been in an unrealized loss position, the existence of an event that would impair the issuer's future repayment potential, the near term prospects for recovery of the market value of a security and the intent of the Company to hold the security until the market value recovers and whether it is not more likely than not that the Company will be required to sell the security. If the Company determines that such impairment exists, the Company will recognize a charge in the consolidated statement of operations equal to the amount of such impairment. See Note C, Investments, for additional discussion.

##### Inventory

The Company has capitalized inventory costs related to raxibacumab incurred subsequent to receiving a follow-on order from the U.S. Government ("USG") in July 2009. Inventory includes material, labor and other direct and indirect costs and is valued using the first-in, first-out method. See Note E, Other Financial Information and Cost of product sales discussion within this Note B, for additional information.

##### Depreciation

Depreciation is computed using the straight-line method over the estimated useful lives of the assets as follows:

Buildings . . . . .	30 years
Land improvements . . . . .	lesser of the lease term or the useful life
Production equipment . . . . .	5 - 10 years
Laboratory equipment . . . . .	3 - 10 years
Computer equipment and software . . . . .	3 - 5 years
Furniture and office equipment . . . . .	3 - 5 years
Leasehold improvements . . . . .	lesser of the lease term or the useful life

##### Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable based on the criteria for accounting for the impairment or disposal of long-lived assets under FASB ASC Topic 360, *Property, Plant and Equipment*.

## HUMAN GENOME SCIENCES, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

#### **(NOTE B) — Summary of Significant Accounting Policies (continued)**

##### Product sales

Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and the Company has no further performance obligations.

##### Manufacturing and development services

As part of its raxibacumab contract with the USG and the Biomedical Advanced Research and Development Authority (“BARDA”), the Company performed a variety of drug development services primarily relating to the conduct of animal and human studies. Upon BARDA’s acceptance of the initial raxibacumab delivery, the Company billed the USG for the drug development work previously performed, and recorded this as manufacturing and development services revenue during the year ended December 31, 2009. The Company will record additional development revenue as services are performed. The Company has entered into agreements with certain commercial parties for manufacturing process development, clinical and commercial supply of certain biopharmaceutical products. Revenue under these agreements is recognized as services are performed or products delivered, depending on the nature of the work contracted, using the proportional performance method of accounting. Performance is assessed using output measures such as units-of-work performed to date as compared to total units-of-work contracted. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

##### Research and development collaborative agreements

Collaborative research and development agreements can provide for one or more of up-front license fees, research payments and milestone payments. Agreements with multiple components (“deliverables” or “items”) are evaluated to determine if the deliverables can be divided into more than one unit of accounting. An item can generally be considered a separate unit of accounting if all of the following criteria are met: (1) the delivered item(s) has value to the customer on a stand-alone basis; (2) there is objective and reliable evidence of the fair value of the undelivered item(s); and (3) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in control of the Company. Items that cannot be divided into separate units are combined with other units of accounting, as appropriate. Consideration received is allocated among the separate units based on their respective fair values or based on the residual value method and is recognized in full when the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the sales price is fixed or determinable; and (4) collectibility is probable. The Company deems service to have been rendered if no continuing obligation exists on the part of the Company.

Revenue associated with non-refundable up-front license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting are deferred and recognized as revenue on a straight-line basis over the expected term of the Company’s continued involvement in the research and development process. Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved, and the milestone payments are due and collectible. If not deemed substantive, the Company would recognize such milestone as revenue on a straight-line basis over the remaining expected term of continued involvement in the research and development process. Milestones are considered substantive if all of the following conditions are met: (1) the milestone is non-refundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and, (4) the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone and any ongoing research and development or other services are priced at fair value. Payments received in advance of work performed are recorded as deferred revenue.

## HUMAN GENOME SCIENCES, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

#### (NOTE B) — Summary of Significant Accounting Policies (continued)

##### Cost of product sales

Except for raxibacumab inventory as described below, the Company does not capitalize inventory costs associated with commercial supplies of drug product until it has received marketing approval from the U.S. Food and Drug Administration (“FDA”). Prior to these approvals, the cost of manufacturing drug product is recognized as research and development expense in the period that the cost is incurred. Therefore, manufacturing costs incurred prior to product approval are not included in cost of product sales when revenue is recognized from the sale of that drug product.

Prior to receiving a follow-on order for raxibacumab from the USG in July 2009, the Company did not capitalize inventory costs related to this product. Although authorization to ship to the SNS was received in January 2009, there continued to be uncertainty around future product orders. Beginning in July 2009, the cost of manufacturing raxibacumab is recognized as a cost of product sales (capitalized and then expensed when revenue is recognized), rather than research and development expenses in the period that the cost is incurred.

Cost of product sales also includes royalties paid or payable to third parties based on the sales levels of certain products.

##### Cost of manufacturing and development services

Cost of manufacturing and development services represents costs associated with the Company’s contract manufacturing arrangements and other development services. The costs associated with work previously performed to conduct animal and human studies for raxibacumab were recognized as research and development expenses in the period that the costs were incurred. Therefore, these pre-acceptance development costs are not included in cost of manufacturing and development services for the year ended December 31, 2009. The Company is recording additional raxibacumab development services costs as incurred.

##### Research and Development

Research and development costs are charged to expense as incurred, unless otherwise capitalized pursuant to FASB ASC Topic 730, *Research and Development*. Research and development costs include salaries and related benefits, outside services, licensing fees or milestones, materials and supplies, building costs and allocations of certain support costs. Research and development direct expenditures were \$173,709, \$243,257 and \$246,293 for 2009, 2008 and 2007, respectively. Reimbursement of research and development expenses received in connection with collaborative cost-sharing agreements is recorded as a reduction of such expenses.

##### Leases

The Company accounts for its leases under FASB ASC Topic 840, *Leases*, and other related guidance. The Company has a number of operating leases and has entered into sale-leaseback transactions for land and facilities. See Note G, Commitments and Other Matters, for additional discussion.

##### Stock-Based Compensation

The Company has a stock incentive plan (the “Incentive Plan”) under which options to purchase shares of the Company’s common stock may be granted to employees, consultants and directors with an exercise price no less than the quoted market value on the date of grant. The Incentive Plan also provides for the issuance of non-vested common stock (restricted stock) and other share-based compensation. The Company recognizes stock-based compensation expense related to employee stock options under FASB ASC Topic 718, *Compensation — Stock Compensation*. For income tax purposes, the Company follows the “with and without” method of accounting for the tax effect of excess tax benefits generated from stock-based compensation. See Note H, Stockholders’ Equity, for additional discussion.

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE B) — Summary of Significant Accounting Policies (continued)

#### Financing Costs Related to Long-term Debt

Costs associated with obtaining long-term debt are deferred and amortized over the term of the related debt on a straight-line basis which approximates the effective interest method.

#### Patent Application Costs

Patent application costs are charged to expense as incurred.

#### Net Income (Loss) Per Share

The Company follows the provisions under FASB ASC Topic 260, *Earnings Per Share*, which requires the Company to present basic and diluted earnings per share. The Company's basic and diluted income (loss) per share is calculated by dividing the net income (loss) by the weighted average number of shares of common stock outstanding during all periods presented. Shares issuable upon the conversion of the Company's convertible subordinated debt are excluded from diluted earnings per share calculations for the years ended December 31, 2009, 2008 and 2007 because the effects are anti-dilutive.

#### Foreign Currency

Assets and liabilities of the Company's international operations are translated into U.S. dollars at exchange rates that are in effect as of the balance sheet date, and equity accounts are translated at historical rates. Revenue and expenses are translated at average exchange rates that are in effect during the year. Translation adjustments are accumulated in other comprehensive income (loss) as a separate component of stockholders' equity in the consolidated balance sheet. Transaction gains and losses are included in other expense in the consolidated statement of operations.

#### Comprehensive Income (Loss)

FASB ASC Topic 220, *Comprehensive Income*, requires unrealized gains and losses on the Company's available-for-sale short-term investments, marketable securities and long-term equity investments and the activity for the cumulative translation adjustment to be included in other comprehensive income.

The components of accumulated other comprehensive income (loss) are as follows:

	<u>December 31,</u>	
	<u>2009</u>	<u>2008</u>
Net unrealized gains (losses) on:		
Short-term investments and marketable securities . . . . .	\$5,496	\$(4,077)
Long-term equity investment in VIA Pharmaceuticals . . . . .	21	38
Restricted investments . . . . .	1,816	108
Foreign currency translation . . . . .	<u>32</u>	<u>(559)</u>
Accumulated other comprehensive income (loss) . . . . .	<u>\$7,365</u>	<u>\$(4,490)</u>

Accumulated other comprehensive income (loss) excludes net realized gains included in net income (loss) of \$4,504, \$33,619 and \$55 for the years ended December 31, 2009, 2008 and 2007, respectively. The effect of income taxes on items in other comprehensive income is \$0 for all periods presented.

During 2008, the Company recorded an impairment charge relating to its investment in debt securities issued by Lehman Brothers Holdings, Inc. ("LBHI") of \$6,284 due to the significant reduction in the market value of LBHI's debt securities that the Company believes may not be temporary as a result of LBHI's bankruptcy. See Note C, Investments, for additional discussion.

## HUMAN GENOME SCIENCES, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

#### **(NOTE B) — Summary of Significant Accounting Policies (continued)**

##### Sources of Supply

The Company is currently able to obtain most of its raw materials, supplies and equipment from various sources, and generally has no dependence upon a single supplier. However, certain materials required for manufacturing are currently available only from single sources. As the Company prepares for commercialization of its products, it intends to identify alternative sources of supply wherever possible.

##### Recent Accounting Pronouncements

In December 2007, the FASB ratified guidance regarding financial statement presentation and disclosure of collaborative arrangements, as defined, which includes arrangements the Company has entered into regarding development and commercialization of products. The Company adopted this guidance as of January 1, 2009. The adoption of this guidance did not have a material effect on the Company's consolidated results of operations, financial position or liquidity.

In February 2008, the FASB issued guidance which delayed the effective date of FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, for most non-financial assets and non-financial liabilities until fiscal years beginning after November 15, 2008. The implementation of FASB ASC Topic 820 for non-financial assets and non-financial liabilities had no material effect on the Company's consolidated results of operations, financial position or liquidity.

In May 2008, the FASB issued guidance contained in FASB ASC Topic 470, *Debt*, which requires that the liability and equity components of convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) be separately accounted for in a manner that reflects an issuer's non-convertible debt borrowing rate. The resulting debt discount is amortized over the period the convertible debt is expected to be outstanding as non-cash interest expense. FASB ASC Topic 470 was effective for the Company as of January 1, 2009 and retroactive application to all periods presented was required. See Note F, Long-term Debt, for additional information.

In June 2008, the FASB issued authoritative guidance which mandates a two-step process for evaluating whether an equity-linked financial instrument or embedded feature is indexed to the entity's own stock. The adoption of this guidance as of January 1, 2009 had no material effect on the Company's consolidated results of operations, financial position or liquidity.

In April 2009, the FASB issued authoritative accounting guidance on how to determine the fair value of assets and liabilities in the current economic environment, which reemphasizes that the objective of a fair value measurement remains an exit price. If the Company were to conclude that there has been a significant decrease in the volume and level of activity of the asset or liability in relation to normal market activities, quoted market values may not be representative of fair value and the Company may conclude that a change in valuation technique or the use of multiple valuation techniques may be appropriate. Additional guidance also issued in April 2009 modifies the requirements for recognizing other-than-temporarily impaired debt securities and revises the existing impairment model for such securities by modifying the current intent and ability indicator in determining whether a debt security is other-than-temporarily impaired. The FASB also issued guidance to enhance the disclosure of financial instruments for both interim and annual periods. The adoption of this guidance during the year ended December 31, 2009 had no material effect on the Company's consolidated results of operations, financial position or liquidity.

In June 2009, the FASB issued *The FASB Accounting Standards Codification*<sup>™</sup> and the *Hierarchy of Generally Accepted Accounting Principles*, a replacement of FASB Statement No. 162 ("FASB ASC" or "Codification"). The Codification, which was released on July 1, 2009, became the single source of authoritative non-governmental U.S. generally accepted accounting principles ("U.S. GAAP"), superseding various existing authoritative accounting pronouncements. The Codification eliminates the U.S. GAAP hierarchy contained in FASB Statement No. 162



**HUMAN GENOME SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(dollars in thousands, except per share data)**

**(NOTE B) — Summary of Significant Accounting Policies (continued)**

**Recent Accounting Pronouncements (continued)**

and establishes one level of authoritative U.S. GAAP. All other literature is considered non-authoritative. This Codification is effective for financial statements issued for interim and annual periods ending after September 15, 2009. There has been no change to the Company's consolidated financial statements due to the implementation of the Codification other than changes in reference to various authoritative accounting pronouncements in the consolidated financial statements.

In October 2009, the FASB issued new revenue recognition standards for arrangements with multiple deliverables. The new standards permit entities to initially use management's best estimate of selling price to value individual deliverables when those deliverables do not have objective and reliable evidence of fair value. Additionally, these new standards modify the manner in which the transaction consideration is allocated across the separately identified deliverables. These new standards are effective for the Company as of January 1, 2011, however early adoption is permitted. Management is currently evaluating the impact of adopting these new standards on the Company's consolidated results of operations, financial position and liquidity.

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE C) — Investments

Available for sale investments, including accrued interest, at December 31, 2009 and 2008 were as follows:

	December 31, 2009			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury and agencies . . . . .	\$ 7,997	\$ 32	\$ —	\$ 8,029
Government-sponsored enterprise securities . . . . .	34,667	672	(29)	35,310
Corporate debt securities . . . . .	107,283	1,099	(193)	108,189
Subtotal — Short-term investments . . . . .	149,947	1,803	(222)	151,528
Government-sponsored enterprise securities . . . . .	172,191	2,009	(673)	173,527
Corporate debt securities . . . . .	208,824	2,106	(429)	210,501
Subtotal — Marketable securities . . . . .	381,015	4,115	(1,102)	384,028
Cash and cash equivalents . . . . .	6,693	—	—	6,693
Government-sponsored enterprise securities . . . . .	20,316	394	(17)	20,693
Corporate debt securities . . . . .	59,612	1,470	(31)	61,051
Subtotal — Restricted investments . . . . .	86,621	1,864	(48)	88,437
Total . . . . .	<u>\$617,583</u>	<u>\$7,782</u>	<u>\$(1,372)</u>	<u>\$623,993</u>

	December 31, 2008			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury and agencies . . . . .	\$ 755	\$ 27	\$ —	\$ 782
Government-sponsored enterprise securities . . . . .	10,507	271	(22)	10,756
Corporate debt securities . . . . .	11,421	29	(297)	11,153
Subtotal — Short-term investments . . . . .	22,683	327	(319)	22,691
U.S. Treasury and agencies . . . . .	16,150	368	(455)	16,063
Government-sponsored enterprise securities . . . . .	108,877	3,229	(262)	111,844
Corporate debt securities . . . . .	145,621	263	(8,151)	137,733
Subtotal — Marketable securities . . . . .	270,648	3,860	(8,868)	265,640
Cash and cash equivalents . . . . .	5,773	—	—	5,773
U.S. Treasury and agencies . . . . .	6,044	95	—	6,139
Government-sponsored enterprise securities . . . . .	18,145	403	(11)	18,537
Corporate debt securities . . . . .	39,289	299	(677)	38,911
Subtotal — Restricted investments . . . . .	69,251	797	(688)	69,360
Total . . . . .	<u>\$362,582</u>	<u>\$4,984</u>	<u>\$(9,875)</u>	<u>\$357,691</u>

The Company's restricted investments with respect to its headquarters ("Traville") and large-scale manufacturing facility ("LSM") leases will serve as collateral for a security deposit for the duration of the leases, although the Company has the ability to reduce the restricted investments that are in the form of securities for the Traville and LSM facility leases by substituting cash security deposits. For the Traville and LSM leases, the Company is required

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE C) — Investments (continued)

to maintain restricted investments of at least \$46,000, or \$39,500 if in the form of cash, in order to satisfy the security deposit requirements of these leases.

In addition, the Company is also required to maintain \$34,300 in restricted investments with respect to two leases with the Maryland Economic Development Corporation (“MEDCO”) for its small-scale manufacturing facility. The facility was financed primarily through a combination of bonds issued by MEDCO (“MEDCO Bonds”) and loans issued to MEDCO by certain State of Maryland agencies. The MEDCO Bonds are secured by letters of credit issued for the account of MEDCO which expire in December 2011. The Company is required to maintain restricted investments which serve as security for the MEDCO letters of credit reimbursement obligation.

The Company’s restricted investments were \$88,437 and \$69,360 as of December 31, 2009 and 2008, respectively.

### Short-term investments, Marketable securities and Restricted investments — unrealized losses

The Company’s gross unrealized losses and fair value of investments with unrealized losses were as follows:

	December 31, 2009					
	Loss Position for Less Than Twelve Months		Loss Position for Greater Than Twelve Months		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Government-sponsored enterprise securities . . . . .	\$ 23,026	\$ (29)	\$ —	\$ —	\$ 23,026	\$ (29)
Corporate debt securities . . . . .	24,751	(181)	4,474	(12)	29,225	(193)
Subtotal — Short-term investments . . .	47,777	(210)	4,474	(12)	52,251	(222)
Government-sponsored enterprise securities . . . . .	154,032	(673)	—	—	154,032	(673)
Corporate debt securities . . . . .	76,595	(405)	1,231	(24)	77,826	(429)
Subtotal — Marketable securities . . . . .	230,627	(1,078)	1,231	(24)	231,858	(1,102)
Government-sponsored enterprise securities . . . . .	7,317	(17)	14	—	7,331	(17)
Corporate debt securities . . . . .	6,212	(31)	—	—	6,212	(31)
Subtotal — Restricted investments . . . . .	13,529	(48)	14	—	13,543	(48)
Total . . . . .	\$291,933	\$(1,336)	\$5,719	\$(36)	\$297,652	\$(1,372)

**HUMAN GENOME SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(dollars in thousands, except per share data)

**(NOTE C) — Investments (continued)**

*Short-term investments, Marketable securities and Restricted investments — unrealized losses (continued)*

	December 31, 2008					
	Loss Position for Less Than Twelve Months		Loss Position for Greater Than Twelve Months		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Government-sponsored enterprise securities . . . . .	\$ —	\$ —	\$ 962	\$ (22)	\$ 962	\$ (22)
Corporate debt securities . . . . .	6,543	(284)	145	(13)	6,688	(297)
Subtotal — Short-term investments . .	6,543	(284)	1,107	(35)	7,650	(319)
U.S. Treasury and agencies . . . . .	7,540	(455)	—	—	7,540	(455)
Government-sponsored enterprise securities . . . . .	1,714	(4)	11,259	(258)	12,973	(262)
Corporate debt securities . . . . .	77,637	(4,597)	39,334	(3,554)	116,971	(8,151)
Subtotal — Marketable securities . . . .	86,891	(5,056)	50,593	(3,812)	137,484	(8,868)
Government-sponsored enterprise securities . . . . .	2,975	(5)	337	(6)	3,312	(11)
Corporate debt securities . . . . .	19,002	(637)	4,016	(40)	23,018	(677)
Subtotal — Restricted investments . . .	21,977	(642)	4,353	(46)	26,330	(688)
Total . . . . .	<u>\$115,411</u>	<u>\$(5,982)</u>	<u>\$56,053</u>	<u>\$(3,893)</u>	<u>\$171,464</u>	<u>\$(9,875)</u>

The deterioration of the credit markets during 2008 had a detrimental effect on the Company's investment portfolio. During 2008, LBHI experienced a significant deterioration in its credit worthiness and filed a petition under Chapter 11 of the U.S. Bankruptcy Code. As a result, the Company determined that its investment in LBHI debt securities had incurred an other-than-temporary impairment, and accordingly, recorded an impairment charge of \$6,284 which is reflected as other expense in the 2008 consolidated statement of operations. At December 31, 2009, the Company has evaluated its investments and has determined that no other investments have an other-than-temporary impairment, as it has no intent to sell other securities with unrealized losses and it is not more likely than not that the Company will be required to sell any additional securities with unrealized losses, given the Company's current and anticipated financial position.

The Company owned 162 available-for-sale U.S Treasury obligations, government-sponsored enterprise securities and corporate debt securities at December 31, 2009. Of these 162 securities, 58 had unrealized losses at December 31, 2009.

The Company's equity investments of less than 20% in privately-held companies are carried at cost. There were no events or circumstances during the year ended December 31, 2009 that would have a significant adverse effect on the carrying value of these investments.

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE C) — Investments (continued)

#### *Other Information*

The following table summarizes maturities of the Company's short-term investments, marketable securities and restricted investment securities at December 31, 2009:

	Short-term Investments		Marketable Securities		Restricted Investments	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Less than one year . . . . .	\$149,947	\$151,528	\$ —	\$ —	\$19,551	\$19,781
Due in year two through year three . . . . .	—	—	205,558	208,402	52,640	53,819
Due in year four through year five . . . . .	—	—	75,312	75,450	7,482	7,761
Due after five years . . . . .	—	—	100,145	100,176	6,948	7,076
Total . . . . .	<u>\$149,947</u>	<u>\$151,528</u>	<u>\$381,015</u>	<u>\$384,028</u>	<u>\$86,621</u>	<u>\$88,437</u>

The Company's short-term investments include mortgage-backed securities with an aggregate cost of \$22,471 and \$6,434 at December 31, 2009 and 2008 respectively, and an aggregate fair value of \$23,026 and \$6,576 at December 31, 2009 and 2008, respectively. The Company's marketable securities include mortgage-backed securities with an aggregate cost of \$58,534 and \$75,321 at December 31, 2009 and 2008, respectively, and an aggregate fair value of \$59,981 and \$76,983 at December 31, 2009 and 2008, respectively. The Company's restricted investments include mortgage-backed securities with an aggregate cost of \$7,483 and \$4,953 at December 31, 2009 and 2008, respectively, and an aggregate fair value of \$7,593 and \$5,043 at December 31, 2009 and 2008, respectively. These securities have no single maturity date and, accordingly, have been allocated on a pro rata basis to each maturity range based on each maturity range's percentage of the total value.

The Company's net proceeds, realized gains and realized losses from its investments are as follows:

	Year Ended December 31,		
	2009	2008	2007
Proceeds on sale of investments prior to maturity . . . . .	\$368,560	\$237,861	\$123,522
Realized gains . . . . .	7,026	34,113	494
Realized losses . . . . .	(2,522)	(494)	(439)

Realized gains and losses related to the Company's short-term investments, marketable securities and restricted investments are included in investment income in the consolidated statements of operations. The cost of the securities sold is based on the specific identification method. Realized gains shown above also include gains related to the sale of long-term equity investments, which are shown separately on the consolidated statements of operations.

During 2009, 2008 and 2007, the Company recognized interest income of \$13,506, \$22,406 and \$32,983 respectively, in investment income.

### (NOTE D) — Collaborations and U.S. Government Agreement

#### Principal Agreements

##### *Agreement with Novartis*

During 2006, the Company entered into an agreement with Novartis International Pharmaceutical Ltd. ("Novartis") for the co-development and commercialization of ZALBIN. Under the agreement, the Company and Novartis will



## HUMAN GENOME SCIENCES, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

#### **(NOTE D) — Collaborations and U.S. Government Agreement (continued)**

##### Principal Agreements (continued)

##### *Agreement with Novartis (continued)*

co-commercialize ZALBIN in the United States, and will share U.S. commercialization costs and U.S. profits equally. Novartis will be responsible for commercialization outside the U.S. and will pay the Company a royalty on those sales. The Company will have primary responsibility for the bulk manufacture of ZALBIN, and Novartis will have primary responsibility for commercial manufacturing of the finished drug product. The Company is entitled to payments aggregating up to approximately \$507,500, including a non-refundable up-front license fee, upon the successful attainment of certain milestones. The Company and Novartis will share clinical development costs. The Company received an up-front license fee of \$45,000 in 2006. As of December 31, 2009, the Company has contractually earned and received payments aggregating \$207,500, including \$75,000 received during the three months ended December 31, 2009. The Company is recognizing these payments as revenue ratably over the estimated remaining development period, estimated to end in the fall of 2010. The Company recognized revenue of \$54,158, \$35,408 and \$28,039 in 2009, 2008 and 2007, respectively, under this agreement.

##### *Agreements with GlaxoSmithKline*

During 2006, the Company entered into a license agreement with GlaxoSmithKline (“GSK”) for the co-development and commercialization of BENLYSTA™ arising from an option GSK exercised in 2005, relating to an earlier collaboration agreement. The agreement grants GSK a co-development and co-commercialization license, under which both companies will jointly conduct activities related to the development and sale of products in the United States and abroad. The Company and GSK share Phase 3 and 4 development costs, and will share sales and marketing expenses and profits of any product commercialized under the agreement. The Company will have primary responsibility for bulk manufacturing and for commercial manufacturing of the finished drug product. During 2009, the Company completed one Phase 3 clinical trial and the primary phase of a second Phase 3 clinical trial. In partial consideration of the rights granted to GSK in this agreement, the Company received a non-refundable payment of \$24,000 during 2006 and is recognizing this payment as revenue over the remaining clinical development period, estimated to end in the fall of 2010. The Company recognized revenue of \$4,737, \$6,545 and \$6,545 in 2009, 2008 and 2007, respectively, relating to this payment.

The BENLYSTA agreement arises from a 1993 agreement, as amended, in which the Company entered into a collaboration agreement providing GSK a first right to develop and market products in human and animal health care (“GSK Products”), based upon human genes identified by the Company. In June 1996, this agreement was substantially amended (the “1996 GSK Agreement”).

With respect to the Company’s rights under the 1996 GSK Agreement, the Company is entitled to (1) royalties on the net sales of certain GSK Products developed pursuant to the agreement, (2) product development milestones and (3) the option to co-promote up to 20% of any product developed by GSK under the collaboration agreement. If the Company were to exercise its option to co-promote any GSK Products, it would be entitled to receive additional amounts from GSK in proportion to its level of co-promotion. The Company has been informed that GSK is pursuing research programs involving specific genes for the creation of small molecule, protein and antibody drugs. The Company cannot provide any assurance that any of these programs will be continued or result in any approved drugs.

During 2005, GSK exercised its option under an earlier collaboration agreement to develop and commercialize HGS-ETR1 jointly with the Company. During 2008, the Company reacquired GSK’s rights to TRAIL Receptor antibodies (including rights to HGS-ETR1 and HGS-ETR2) from GSK, in exchange for a reduction in potential future royalties due to the Company for a product currently being developed by GSK. The Company determined the fair value of the rights reacquired by estimating a probability-weighted net present value of the future cash stream of

**HUMAN GENOME SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(dollars in thousands, except per share data)**

**(NOTE D) — Collaborations and U.S. Government Agreement (continued)**

Principal Agreements (continued)

*Agreements with GlaxoSmithKline (continued)*

such rights. The transaction was accounted for in accordance with FASB ASC Topic 845, *Nonmonetary Transactions*. Both the rights reacquired and the royalty concessions related to in-process research and development projects. Therefore, no assets or liabilities were recorded as part of this transaction and no gain or loss was recorded.

In 2004, the Company entered into an agreement with GSK under which GSK acquired exclusive worldwide rights to develop and commercialize Syncria<sup>®</sup>, a drug that had been in late-stage preclinical development by the Company for potential use in the treatment of diabetes. In 2004, the Company received an up-front fee of \$6,000 and is recognizing this revenue ratably over the clinical development period, which is now estimated to be eight years. With respect to this fee, the Company recognized \$741 as revenue each year in the three year period ended December 31, 2009. As of December 31, 2009, the Company has also received and recognized development milestones aggregating \$27,000 under the agreement, including \$9,000 received and recognized in 2009.

*License Agreement and Manufacturing Services Agreement with Teva Biopharmaceuticals USA, Inc. (formerly CoGenesys)*

In 2008, Teva Pharmaceuticals Industries, Ltd. (“Teva”) acquired all of the outstanding stock of CoGenesys and CoGenesys became a wholly-owned subsidiary of Teva called Teva Biopharmaceuticals USA, Inc. (“Teva Bio”). The Company had sold its CoGenesys division in 2006 and entered into a license agreement, as amended that is now with Teva Bio, and acquired an equity investment in CoGenesys valued at \$14,818. Under the license agreement, as amended, the Company is entitled to various milestone and royalty rights on certain products, if they are developed and commercialized. Teva Bio can obtain additional product rights by extending the initial seven-year research term upon the payment of additional consideration. In addition, the Company entered into a three-year manufacturing services agreement, as amended, which ended during 2009. The Company allocated, based on estimated fair values, \$7,575 of its consideration received to the product license and manufacturing services agreement, which was recognized ratably over the term of the manufacturing services agreement, as amended. The Company recognized license revenue of \$1,052, \$2,525 and \$2,525 during the years ended December 31, 2009, 2008 and 2007, respectively, and manufacturing services revenue of \$1,035, \$367 and \$278 during the years ended December 31, 2009, 2008 and 2007, respectively, relating to these agreements, which represents related party revenue in 2007. See Note M, Teva Biopharmaceuticals USA, Inc. (formerly CoGenesys), for additional discussion.

*Collaboration reimbursements with respect to Novartis and GSK*

The Company’s research and development expenses in 2009 of \$173,709 are net of \$851 and \$43,069 of costs reimbursed by Novartis and GSK, respectively. Research and development expenses of \$243,257 in 2008 were net of \$36,104 and \$51,783 of costs reimbursed by Novartis and GSK, respectively. Research and development expenses of \$246,293 in 2007 were net of \$46,508 and \$39,301 reimbursed by Novartis and GSK, respectively. The Company shares certain research and development costs including personnel costs, outside services, manufacturing, and overhead with Novartis and GSK under cost sharing provisions in the collaboration agreements.

*U.S. Government Agreement*

During 2006, the USG exercised its option under the second phase of a 2005 contract to purchase 20,001 doses of raxibacumab for its SNS. Under this two-phase contract, the Company has supplied raxibacumab, a human monoclonal antibody developed for use in the treatment of anthrax disease, to the USG. Along with the cost to manufacture the 20,001 doses, the Company has incurred the cost to conduct several animal and human studies as part of this contract. During 2009, the Company received authorization from BARDA to ship raxibacumab to the

## HUMAN GENOME SCIENCES, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

#### **(NOTE D) — Collaborations and U.S. Government Agreement (continued)**

##### Principal Agreements (continued)

##### *U.S. Government Agreement (continued)*

SNS and delivered all of the 20,001 doses. During the year ended December 31, 2009, the Company recognized \$136,381 in product revenue related to this order and \$26,146 in manufacturing and development services revenue related to the work to conduct the animal and human studies and other raxibacumab activities. The Company expects to receive approximately \$10,000 from this first order if the Company obtains licensure by the FDA.

In July 2009, the USG agreed to purchase 45,000 additional doses of raxibacumab for the SNS, to be delivered over a three-year period, beginning in 2009. The Company expects to receive approximately \$142,000 from this order as deliveries are completed, including \$17,693 earned and recognized in 2009 and an additional \$10,000 from this order if the Company obtains licensure by the FDA.

##### Other Collaborative and License Agreements

During 2007, the Company entered into a collaboration and license agreement with Aegea Therapeutics, Inc. (“Aegea”) of Montreal, Canada under which the Company acquired exclusive worldwide rights (excluding Japan) to develop and commercialize certain oncology molecules and related backup compounds to be chosen during a three-year research period. Under the agreement, the Company paid Aegea an aggregate of \$20,000 for the license and for an equity investment in Aegea. The Company allocated \$16,852 to the license fee and \$3,148 to the investment. The value per share assigned to this investment was equal to the value per share obtained by Aegea through external financing earlier in 2007. Aegea will be entitled to receive up to \$295,000 in future development and commercial milestone payments, including a \$5,000 milestone payment made by the Company during 2008. Aegea will receive royalties on net sales in the Company’s territory. In North America, Aegea will have the option to co-promote with the Company, under which Aegea will share certain expenses and profits in lieu of its royalties. The Company incurred and expensed research costs of \$2,321 and \$2,249 related to the Aegea agreement during 2009 and 2008, respectively.

At December 31, 2009, the Company values its cost basis investment in Aegea at \$2,994, based on year-end exchange rates, which is included in long-term equity investments on the consolidated balance sheets.

In 1999, the Company entered into a collaborative agreement with Cambridge Antibody Technology (“CAT”) of Melbourn, United Kingdom (now “MedImmune”) to jointly pursue the development of fully human monoclonal antibody therapeutics. MedImmune will receive milestone payments from the Company in connection with the development of any such antibodies as well as royalty payments on the Company’s net sales of such licensed product following regulatory approval. In the event of the achievement of other milestones or successful product launch, the Company would be obligated to pay MedImmune additional compensation. Since 1999, the Company has exercised one option and made certain payments. In 2006, the Company incurred and subsequently paid a milestone obligation to MedImmune of \$1,500 pursuant to the development of one product.

In 2000, the Company entered into a second agreement with CAT. The 2000 agreement provides the Company with rights to use MedImmune technology to develop and sell an unlimited number of fully human antibodies for therapeutic and diagnostic purposes. The Company will pay MedImmune clinical development milestones and royalties based on product sales. Under this same agreement, the Company paid MedImmune \$12,000 for research support and made an equity investment in CAT, which was subsequently sold. Since 2000, the Company has exercised several options and made certain payments. During 2009, the Company incurred milestone and royalty expenses to MedImmune of approximately \$8,600 associated with the sale of raxibacumab to the USG, which is included in cost of product sales on the consolidated statements of operations. No option or milestone expenses were incurred in 2008 or 2007.

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE E) — Other Financial Information

#### Collaboration Receivables

Collaboration receivables of \$10,356 includes \$9,461 in unbilled receivables from GSK in connection with the Company's cost-sharing agreements, and other billed and unbilled receivables. The \$9,461 in unbilled receivables relates to net cost reimbursements due for the three months ended December 31, 2009. In addition, the Company has non-current collaboration receivables due from Novartis and GSK. See Other Assets discussion within this Note E.

Within the December 31, 2008 consolidated balance sheet, \$2,804 has been reclassified from collaboration receivables to accounts receivable and \$67 has been reclassified from prepaid and other assets to accounts receivable to conform to current year presentation. Accounts receivable was deemed immaterial in 2008 for separate disclosure. Due to the Company's product sales and manufacturing and development services revenue in 2009, accounts receivable has become material and therefore is separately disclosed. The effect of the reclassifications is not material to the consolidated financial statements.

#### Inventory

Inventories consist of the following, which are all related to raxibacumab:

	<u>December 31,</u>	
	<u>2009</u>	<u>2008</u>
Raw materials . . . . .	\$ 4,293	\$ —
Work-in-process . . . . .	9,512	—
Finished goods . . . . .	6,344	—
	<u>\$20,149</u>	<u>\$ —</u>

#### Property, Plant and Equipment

Property, plant and equipment are stated at cost and are summarized as follows:

	<u>December 31,</u>	
	<u>2009</u>	<u>2008</u>
Building (LSM) . . . . .	\$ 204,151	\$ 204,151
Laboratory and production equipment . . . . .	94,644	88,226
Computer equipment and software . . . . .	38,793	36,249
Land and improvements . . . . .	30,521	30,521
Leasehold improvements . . . . .	25,046	23,932
Furniture and office equipment . . . . .	6,629	6,007
Construction-in-progress . . . . .	3,469	3,793
	<u>403,253</u>	<u>392,879</u>
Less: accumulated depreciation . . . . .	<u>(140,130)</u>	<u>(118,564)</u>
	<u>\$ 263,123</u>	<u>\$ 274,315</u>

Depreciation expense was \$19,960, \$19,584 and \$20,347 for the years ended December 31, 2009, 2008 and 2007, respectively.

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE E) — Other Financial Information (continued)

#### Other Assets

Other assets are comprised of the following:

	<u>December 31,</u>	
	<u>2009</u>	<u>2008</u>
Collaboration receivables, non-current . . . . .	\$ 6,920	\$ —
Deferred financing costs, net of accumulated amortization of \$6,846 and \$5,663, as of December 31, 2009 and 2008, respectively . . . . .	2,442	4,481
Other assets . . . . .	<u>1,896</u>	<u>2,264</u>
	<u>\$11,258</u>	<u>\$6,745</u>

Non-current collaboration receivables relate to amounts due to the Company by Novartis and GSK for manufacturing costs incurred to produce pre-launch commercial product. Deferred financing costs were incurred in connection with the Company's convertible subordinated debt offerings during 2005 and 2004. Debt issuance costs for the face value \$403,850 of convertible subordinated debt outstanding as of December 31, 2009 amounted to approximately \$9,288, representing primarily underwriting fees of approximately 3% of the gross amount of the convertible subordinated debt, and are being amortized on a straight-line basis to interest expense which approximates the effective interest method over the life of the convertible subordinated debt. See Note F, Long-Term Debt, for additional discussion of the Company's convertible subordinated debt.

#### Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses are comprised of the following:

	<u>December 31,</u>	
	<u>2009</u>	<u>2008</u>
Clinical trial costs . . . . .	\$23,641	\$40,212
Accrued expenses and fixed asset purchases . . . . .	5,736	6,091
Professional fees . . . . .	6,324	5,878
Accrued interest . . . . .	2,668	3,253
Collaboration payable . . . . .	<u>4,000</u>	<u>—</u>
	<u>\$42,369</u>	<u>\$55,434</u>

Accrued clinical trial costs consist primarily of investigator fees, contract research organization services and laboratory costs, primarily associated with the Company's Phase 3 studies. Collaboration payable represents cost reimbursements due to Novartis for the six months ended December 31, 2009.



# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE F) — Long-Term Debt

The components of long-term debt are as follows:

<u>Debt</u>	<u>Interest Rate</u>	<u>Maturities</u>	<u>December 31,</u>	
			<u>2009</u>	<u>2008</u>
2¼% Convertible Subordinated Notes due 2011 . . . . .	2.25%	October 2011	\$178,104	\$239,247
2¼% Convertible Subordinated Notes due 2012 . . . . .	2.25%	August 2012	171,703	178,350
			349,807	417,597
BioMed lease financing . . . . .	11.0%	May 2026	248,628	246,477
			598,435	664,074
Less current portion . . . . .			—	—
			<u>\$598,435</u>	<u>\$664,074</u>

Annual maturities of all long-term debt (representing cash to be paid) are as follows:

2010 . . . . .	\$ —
2011 . . . . .	197,100
2012 . . . . .	206,750
2013 . . . . .	—
2014 . . . . .	—
2015 and thereafter . . . . .	52,961
	<u>\$456,811</u>

The difference between the long-term debt of \$598,435 and annual maturities of \$456,811 is due to the accounting for the sale-leaseback of the LSM facility as a financing transaction and the debt discount relating to the convertible subordinated notes. During 2006, the Company entered into a purchase and sale agreement with BioMed in connection with the Company's Traville headquarters and LSM facilities. The Company accounted for the sale-leaseback of certain facilities as a financing transaction. Payments due for the BioMed debt resulting from this financing are based upon an allocation of fair value of the properties included in the transaction. Aggregate lease financing payments, including interest, over the remaining sixteen year period are approximately \$471,050 including an annual lease escalation of 2%. Interest expense associated with this debt is being calculated at approximately 11%, which approximated the Company's incremental borrowing rate at the time of the agreement. For the first nine years of the leases, the payments are less than the amount of calculated interest expense, which results in an increase in the debt balance during this period, reaching \$254,699 in 2015. Accordingly, the Company has classified the full amount of the debt outstanding as of December 31, 2009 as long-term. Beginning in 2015, the payments begin to reduce the debt balance and are reflected in the annual maturities shown herein. At the end of the twenty-year leases, the remaining debt will be approximately \$201,737.

During 2004, the Company completed the private placement of \$280,000 of 2¼% Convertible Subordinated Notes due 2011 ("2¼% Notes due 2011"), convertible into common stock at approximately \$15.55 per share. Under FASB ASC Topic 470, \$191,804 of the proceeds from the 2¼% Notes due 2011 was allocated to long-term debt and \$88,196 was allocated to equity based on the Company's non-convertible borrowing rate in effect at the time the notes were issued. Debt issuance costs for the \$191,804 of 2¼% Notes due 2011 amounted to approximately \$5,924, which are being amortized on a straight-line basis, which approximates the effective interest method, over the life of the 2¼% Notes due 2011. During 2009, the Company repurchased 2¼% Notes due 2011 with a face value of \$82,900 (as discussed below), and wrote off the related unamortized debt issuance costs and debt discount. Accumulated amortization of the debt issuance costs for the 2¼% Notes due 2011 is approximately \$4,245 and

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE F) — Long-Term Debt (continued)

\$3,596 as of December 31, 2009 and 2008, respectively. The 2¼% Notes due 2011 also contain a provision for a “make-whole” premium to be paid by the Company to holders of the 2¼% Notes due 2011 in the event of certain changes in control that could occur during the life of the 2¼% Notes due 2011. The premium is payable in the form of cash, the Company’s common stock, or the same form of consideration used to pay for the shares of the Company’s common stock in connection with the transaction constituting the change in control. The premium declines over time and is based upon the price of the Company’s stock as of the effective date of the change in control. As of December 31, 2009, the maximum premium possible is approximately \$33,753, or approximately 17% of the aggregate face value of 2¼% Notes due 2011 outstanding, in the event a qualified change in control occurs with a stock price of \$16.00 per share at such date. If the stock price on the effective date of a change in control is less than \$11.105 per share or greater than \$55.00 per share, no premium will be paid.

During 2005, the Company completed the private placement of \$230,000 of 2¼% Convertible Subordinated Notes due 2012 (“2¼% Notes due 2012”), convertible into common stock at approximately \$17.78 per share. Under FASB ASC Topic 470, \$143,266 of the proceeds from the 2¼% Notes due 2012 was allocated to long-term debt and \$86,734 was allocated to equity based on the Company’s non-convertible borrowing rate in effect at the time the notes were issued. Debt issuance costs for the \$143,266 of 2¼% Notes due 2012 amounted to approximately \$4,220, which are being amortized on a straight-line basis, which approximates the effective interest method, over the life of the 2¼% Notes due 2012. During 2009, the Company repurchased 2¼% Notes due 2012 with a face value of \$23,250 (as discussed below), and wrote off the related unamortized debt issuance costs and debt discount. Accumulated amortization of the debt issuance costs for the 2¼% Notes due 2012 is approximately \$2,601 and \$2,060 as of December 31, 2009 and 2008, respectively. The 2¼% Notes due 2012 also contain a provision for a “make-whole” premium to be paid by the Company to holders of the 2¼% Notes due 2012 in the event of certain changes in control that could occur during the life of the 2¼% Notes due 2012. The premium is payable in the form of the Company’s common stock by increasing the conversion rate to the holders of the notes who convert their notes. The premium, which is expressed as additional shares of common stock per one thousand dollars principal amount of notes, is based upon the price of the Company’s stock as of the effective date of the change in control. The maximum premium possible is approximately \$34,458, or approximately 17% of the aggregate face value of 2¼% Notes due 2012 outstanding, in the event a qualified change in control occurs with a stock price of \$14.82 per share at such date. If the stock price on the effective date of a change in control is less than \$14.82 per share or greater than \$100.00 per share, no premium will be paid.

During 2009, the Company repurchased 2¼% Notes due 2011 with a face value of \$82,900 and 2¼% Notes due 2012 with a face value of \$23,250 for an aggregate cost of approximately \$50,000 plus accrued interest. The repurchase resulted in a gain on extinguishment of debt of \$38,873, net of the related debt discount of \$16,424 and deferred financing charges of \$855.

The carrying amount and fair value of the Company’s long-term debt are as follows:

	December 31,			
	2009		2008	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
2¼% Convertible Subordinated Notes due 2011. .	\$178,104	\$ 402,084	\$239,247	\$ 86,800
2¼% Convertible Subordinated Notes due 2012. .	171,703	372,150	178,350	57,500
BioMed lease financing . . . . .	248,628	265,293	246,477	306,446
	<u>\$598,435</u>	<u>\$1,039,527</u>	<u>\$664,074</u>	<u>\$450,746</u>

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE F) — Long-Term Debt (continued)

The components of the convertible subordinated debt are as follows:

	December 31, 2009		
	Face Value	Unamortized Debt Discount	Carrying Amount
2¼% Convertible Subordinated Notes due 2011 . . . . .	\$197,100	\$(18,996)	\$178,104
2¼% Convertible Subordinated Notes due 2012 . . . . .	206,750	(35,047)	171,703
	<u>\$403,850</u>	<u>\$(54,043)</u>	<u>\$349,807</u>

	December 31, 2008		
	Face Value	Unamortized Debt Discount	Carrying Amount
2¼% Convertible Subordinated Notes due 2011 . . . . .	\$280,000	\$(40,753)	\$239,247
2¼% Convertible Subordinated Notes due 2012 . . . . .	230,000	(51,650)	178,350
	<u>\$510,000</u>	<u>\$(92,403)</u>	<u>\$417,597</u>

With respect to the Company's convertible subordinated notes (the "Notes"), the Notes are unsecured obligations of the Company and rank junior in right of payment to the Company's existing and future senior indebtedness. The Notes are not redeemable prior to maturity, but can be repurchased by the Company on the open market.

The indentures under which the Notes have been issued contain no financial covenants or any restriction on the payments of dividends, the incurrence of senior indebtedness, or other indebtedness, or the Company's issuance or repurchase of securities. There are no sinking fund requirements with respect to the Notes.

The fair value of the BioMed lease financing is determined using a discounted cash flow analysis and current rates for corporate debt having similar characteristics and companies with similar credit worthiness. The Company concluded that its incremental borrowing rate as of December 31, 2009 as compared to December 31, 2008 has decreased, resulting in a decrease in the fair value of the debt to \$265,293.

### (NOTE G) — Commitments and Other Matters

#### Leases

The Company leases office and laboratory premises and equipment pursuant to operating leases expiring at various dates through 2026. Certain leases contain renewal options. Minimum annual rentals are as follows:

<u>Year Ending December 31,</u>	
2010 . . . . .	\$ 20,537
2011 . . . . .	20,886
2012 . . . . .	21,246
2013 . . . . .	21,613
2014 . . . . .	21,993
2015 and thereafter . . . . .	<u>260,876</u>
	<u>\$367,151</u>

The operating lease commitment of \$367,151 includes lease payments associated with the Company's lease with BioMed for its Traville headquarters. During 2006 the Company entered into a lease with BioMed for its Traville headquarters following the termination of the Company's Traville lease with its former lessor. Based upon an

## HUMAN GENOME SCIENCES, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

#### (NOTE G) — Commitments and Other Matters (continued)

##### Leases (continued)

allocation of fair value, the initial annual rent for Traville was approximately \$16,653. The aggregate rental payments over the remaining lease term are approximately \$343,358, including an annual escalation of 2% which is accounted for on a straight-line basis over the lease term. The Company has an option to purchase the Traville facility in 2016 for \$303,000. There are no financial covenants with respect to the BioMed lease.

As part of its agreement with BioMed, the Company committed to exercise purchase options with respect to certain equipment currently used at the Traville facility at the end of the applicable equipment lease terms. The equipment was subject to several operating leases with an unrelated party. During 2008, the Company exercised the purchase option with regard to certain leases at a cost of approximately \$4,200, and exercised the purchase option related to the remaining leases in 2009 at a cost of approximately \$5,300. The Company will transfer ownership of this facility-related equipment to BioMed at the earlier of the end of the Traville lease term or at certain other pre-specified events.

The Company has entered into two long-term leases, as amended, with MEDCO expiring January 1, 2019 for a small-scale manufacturing facility aggregating 127,000 square feet and built to the Company's specifications. The Company has accounted for these leases as operating leases. The facility was financed primarily through a combination of MEDCO Bonds and loans issued to MEDCO by certain State of Maryland agencies. The Company has no equity interest in MEDCO.

Rent is based upon MEDCO's debt service obligations. Annual base rent under the leases is currently approximately \$2,640. The MEDCO Bonds are secured by letters of credit issued for the account of MEDCO which were renewed for a two year period in December 2009. The Company has restricted investments of approximately \$34,500 and \$15,700 as of December 31, 2009 and 2008, respectively, associated with these leases which serve as security for the MEDCO letters of credit reimbursement obligation. Upon default or early lease termination, the MEDCO Bond indenture trustee can draw upon the letters of credit to pay the MEDCO Bonds as they are tendered. In such an event, the Company could lose part or all of its restricted investments and could record a charge to earnings for a corresponding amount. Alternatively, the Company has an option during or at the end of the lease term to purchase this facility for an aggregate amount that declines from approximately \$37,000 in 2010 to approximately \$21,000 in 2019. The amended leases contain no debt covenants with respect to the Company's financial condition.

See Note C, Investments, for additional discussion of the Company's restricted investments.

The Company's leases for office and laboratory space provide for certain rent escalations on each anniversary of the lease commencement date. For financial reporting purposes, rent expense is charged to operations on a straight-line basis over the term of the lease, resulting in a liability for deferred rent of \$8,664 and \$6,718 at December 31, 2009 and 2008, respectively.

The Company had entered into various sale-leaseback transactions resulting in equipment leases with rental and buy-out payments, with initial terms ranging from five to seven years. The Company accounted for these leases as operating leases. Under the leases, the Company was required to maintain minimum levels of unrestricted cash, cash equivalents and marketable securities. During 2009 and 2008, the Company exercised its remaining purchase options at the end of the initial lease terms and released the related restricted investments.

Rent expense aggregated \$22,357, \$27,588 and \$29,461 for the years ended December 31, 2009, 2008 and 2007, respectively. The decrease in rent expense in 2009 is due to the expiration of certain equipment leases.

##### Purchase Commitments

At December 31, 2009 the Company had commitments for capital expenditures, consisting primarily of manufacturing and laboratory equipment, of approximately \$1,025.

## HUMAN GENOME SCIENCES, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

#### (NOTE G) — Commitments and Other Matters (continued)

##### 401(k) Plan

The Company has a 401(k) pension plan available to eligible full-time employees. Participating employees may contribute up to 100% of their total eligible compensation to the plan, subject to Internal Revenue Service limitations. The Company currently matches a portion of the employee contributions. The Company's contribution was \$1,645, \$1,945 and \$1,740 for the years ended December 31, 2009, 2008 and 2007, respectively.

##### Contingent Liabilities

The Company is party to various claims and legal proceedings from time to time. The Company is not aware of any legal proceedings that it believes could have, individually or in the aggregate, a material adverse effect on its results of operations, financial condition or liquidity.

#### (NOTE H) — Stockholders' Equity

##### Public Offerings of Common Stock

During 2009, the Company completed two public offerings of its common stock. The Company issued 26,697,250 shares in August 2009 at a price of \$14.00 per share, resulting in net proceeds of approximately \$356,500. The Company also issued 17,825,000 shares in December 2009 at a price of \$26.75 per share, resulting in net proceeds of approximately \$456,400.

##### Stock-based Compensation Plans

The Company has two stock-based compensation plans as described below. The following is a summary of the stock-based compensation expense that has been recorded in the consolidated statements of operations for the years indicated:

	<u>Year Ended December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
Employee stock option and employee stock purchases plan compensation expense . . . . .	\$11,935	\$17,630	\$20,691
Restricted stock units . . . . .	589	647	470
Restricted stock awards . . . . .	—	316	530
Total . . . . .	<u>\$12,524</u>	<u>\$18,593</u>	<u>\$21,691</u>

No income tax benefit was recognized in the consolidated statements of operations for stock-based compensation for the years presented as realization of such benefits was not more likely than not.

##### *Stock Incentive Plan*

##### *Stock Options*

The Company has an Incentive Plan under which options to purchase new shares of the Company's common stock may be granted to employees, consultants and directors at an exercise price no less than the quoted market value on the date of grant. The Incentive Plan also provides for awards in the form of stock appreciation rights, restricted (non-vested) or unrestricted stock awards, stock-equivalent units or performance-based stock awards. The Company issues both qualified and non-qualified options under the Incentive Plan. The vesting period of the options is determined by the Board of Directors and is generally four years. Upon acquisition by a person, or group of persons, of more than 50% of the Company's outstanding common stock, outstanding options shall immediately vest in full and be exercisable. The Company recognizes compensation expense for an award with only service conditions that



# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE H) — Stockholders' Equity (continued)

#### Stock-based Compensation Plans (continued)

##### *Stock Incentive Plan (continued)*

has a graded vesting schedule on a straight-line basis over the requisite service period for the entire award. All options expire after ten years or earlier from the date of grant.

At December 31, 2009, the total authorized number of shares under the Incentive Plan, including prior plans, was 54,778,056. Options available for future grant were 7,781,289 as of December 31, 2009.

A summary of stock option activity for the year ended December 31, 2009 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value <sup>(1)</sup>
Outstanding at January 1, 2009 . . . . .	28,373,151	\$15.40	5.71	
Granted . . . . .	4,352,003	2.27		
Exercised . . . . .	(4,584,767)	10.50		\$ 51,205
Forfeited . . . . .	(691,887)	5.83		
Expired . . . . .	(2,847,326)	20.90		
Outstanding at December 31, 2009 . . . . .	<u>24,601,174</u>	13.62	5.85	476,728
Vested and expected to vest at December 31, 2009 . . . . .	<u>23,555,132</u>	14.01	4.10	448,954
Exercisable at December 31, 2009 . . . . .	<u>17,387,092</u>	17.18	4.74	292,384

(1) Aggregate intrinsic value represents only the value for those options in which the exercise price of the option is less than the market value of the Company's stock on December 31, 2009, or for exercised options, the exercise date.

The following table summarizes information about stock options outstanding at December 31, 2009:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted- Average Remaining Contractual Life (In Years)	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
\$0.52 to \$10.00 . . . . .	8,665,356	8.18	\$ 3.89	2,998,103	\$ 5.84
\$10.01 to \$12.50 . . . . .	8,522,924	5.94	10.97	7,314,130	11.02
\$12.51 to \$15.00 . . . . .	3,850,937	3.99	12.79	3,807,981	12.79
\$15.01 to \$35.00 . . . . .	975,496	4.72	21.21	680,417	20.45
\$35.01 to \$86.19 . . . . .	<u>2,586,461</u>	0.92	53.38	<u>2,586,461</u>	53.38
	<u>24,601,174</u>	5.85	13.62	<u>17,387,092</u>	17.18

During the years ended December 31, 2009, 2008 and 2007, the Company issued 4,584,767, 364,236 and 968,501 shares of common stock, respectively, in conjunction with stock option exercises. The Company received cash proceeds from the exercise of these stock options of approximately \$48,147, \$3,443 and \$7,149, respectively, for the years ended December 31, 2009, 2008 and 2007.

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE H) — Stockholders' Equity (continued)

#### Stock-based Compensation Plans (continued)

##### *Stock Incentive Plan (continued)*

As of December 31, 2009, total unrecognized compensation cost related to stock options amounted to \$15,445, which is expected to be recognized over a weighted-average period of 2.3 years as the options vest. There were non-vested stock options outstanding for 7,214,082 shares at December 31, 2009.

The total intrinsic value of stock options exercised during the years ended December 31, 2009, 2008 and 2007 was approximately \$51,205, \$720 and \$3,244, respectively. The total fair value of stock options which vested during the years ended December 31, 2009, 2008 and 2007 was approximately \$12,353, \$17,078 and \$21,420, respectively. The weighted-average grant-date fair value of stock options granted during the years ended December 31, 2009, 2008 and 2007 was \$0.91, \$2.25 and \$4.55 per share, respectively.

The fair values of employee stock options granted during the years ended December 31, 2009, 2008 and 2007 were determined based on the Black-Scholes-Merton option-pricing model using the following range of assumptions:

	Year Ended December 31,		
	2009	2008	2007
Expected life:			
Stock options . . . . .	5.5 years	5.4 years	5.0 years
Employee stock purchase plan rights . . . . .	1.0 years	1.0 years	1.0 years
Interest rate . . . . .	1.4% - 2.8%	1.2% - 3.6%	3.4% - 4.9%
Volatility . . . . .	53.0% - 83.5%	41.9% - 57.3%	40.3% - 48.0%
Dividend yield . . . . .	0%	0%	0%

An explanation of the above assumptions is as follows:

*Expected Life of Stock-based Awards* — The expected life of stock-based awards is the period of time for which the stock-based award is expected to be outstanding. This estimate is based on historical exercise data.

*Interest Rate* — The risk-free rate over the expected life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

*Volatility* — Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (implied volatility) during a period. The Company uses the implied volatility of its traded convertible notes as the sole basis for its expected volatility. The weighted average volatility used was 55.9%, 43.7% and 43.9% for 2009, 2008 and 2007, respectively.

*Dividend Yield* — The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

#### Restricted Stock

Under the Incentive Plan, the Company has granted both restricted stock awards and restricted stock units ("RSUs"). Beginning in 2007, employees of the Company could elect to receive RSUs in lieu of a portion of their stock option grants. RSUs have service conditions and vest ratably on an annual basis over a four-year period. During 2009, the Company awarded 65,587 RSUs at a weighted-average grant date fair value of \$0.52 per share. During 2008, 36,500 previously granted restricted stock awards vested and the remaining 48,000 were cancelled. The Company incurred \$589, \$963 and \$1,000 of compensation expense for the years ended December 31, 2009, 2008 and 2007, respectively, related to both RSUs and restricted stock awards.

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### **(NOTE H) — Stockholders' Equity (continued)**

#### **Stock-based Compensation Plans (continued)**

##### *Stock Incentive Plan (continued)*

A summary of the status of the Company's restricted stock as of December 31, 2009 and changes during the year ended December 31, 2009, is presented below:

	<u>Shares</u>	<u>Weighted-Average Grant-Date Fair Value</u>
Restricted stock at January 1, 2009 . . . . .	237,976	\$8.87
Granted . . . . .	65,587	0.52
Vested . . . . .	(73,066)	9.20
Forfeited . . . . .	<u>(24,760)</u>	6.38
Restricted stock at December 31, 2009 . . . . .	<u>205,737</u>	6.39
Expected to vest at December 31, 2009 . . . . .	<u>174,876</u>	6.39

Stock-based compensation expense under FASB ASC Topic 718, *Compensation — Stock Compensation*, for the years ended December 31, 2009, 2008 and 2007 is not necessarily representative of the level of stock-based compensation expense in future years due to, among other things, (1) the vesting period of the stock-based compensation and (2) the number and fair value of additional stock-based grants in future years.

#### *Employee Stock Purchase Plan*

The Company has an Employee Stock Purchase Plan (the "Purchase Plan"), as amended, registering 2,000,000 shares of \$0.01 par value common stock for issuance under this plan. Under the Purchase Plan, eligible employees may purchase shares of common stock on certain dates and at certain prices as set forth in the plan. The common stock is purchased under the Purchase Plan at a discounted rate, currently at 15%, which results in this plan qualifying as compensatory. The first purchase period for the Purchase Plan began January 1, 2001. During 2009, the Company issued 308,112 shares of common stock pursuant to the Purchase Plan and recorded compensation cost of approximately \$163. The weighted-average fair value of the employee stock purchase plan rights granted during 2009, 2008 and 2007 was \$0.53, \$0.84 and \$2.19 per share, respectively. Common stock reserved for future employee purchase under the Purchase Plan aggregated 736,447 shares as of December 31, 2009. There are no other investment options for participants.

### **(NOTE I) — Preferred Share Purchase Rights**

On May 20, 1998, the Company adopted a Shareholder Rights Plan, which provided for the issuance of rights to purchase shares of Junior Participating Preferred Stock, par value \$0.01 per share (the "Preferred Shares"), of the Company. Under the Shareholder Rights Plan, the Company distributed one preferred share purchase right (a "Right") for each outstanding share of common stock, par value \$0.01 (the "Common Shares"), of the Company. The Rights were distributed on June 26, 1998 to stockholders of record on May 27, 1998. The Rights expired on May 20, 2008.

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE J) — Income Taxes

The Company provides for income taxes using the liability method. The difference between the tax provision and the amount that would be computed by applying the statutory Federal income tax rate to income before taxes is attributable to the following:

	Year Ended December 31,		
	2009	2008	2007
Federal income tax provision (benefit) at 34% . . . . .	\$ 1,491	\$ (91,416)	\$ (96,693)
Change in state income tax rate . . . . .	—	—	(14,798)
State taxes, net of federal tax benefit . . . . .	185	(14,161)	(12,652)
Tax credits, principally for research and development . . . . .	(1,813)	(3,500)	(2,911)
Research and development credit refunds . . . . .	(1,274)	—	—
Other . . . . .	(3,303)	3,447	3,585
Increase in valuation allowance on deferred tax asset . . . . .	<u>3,440</u>	<u>105,630</u>	<u>123,469</u>
	<u><u>\$ (1,274)</u></u>	<u><u>\$ —</u></u>	<u><u>\$ —</u></u>

The change in valuation allowance as reported above excludes the change in valuation allowance associated with the net deferred tax asset recorded in connection with the net unrealized (gains) losses on investments, as such amounts are recorded as a component of other comprehensive income (loss).

Temporary differences and carryforwards that give rise to a significant portion of deferred tax assets and liabilities are as follows:

	Current Asset	Long-Term Asset (Liability)
December 31, 2009		
Net operating loss carryforward . . . . .	\$ —	\$ 739,900
Research and development and other tax credit carryforwards . . . . .	—	35,282
Deferred revenue . . . . .	34,935	781
Facility exit charge . . . . .	—	3,957
Net unrealized gains on investments . . . . .	—	(2,885)
Intangible assets . . . . .	394	4,602
Equity-based compensation . . . . .	—	11,561
Depreciation . . . . .	—	14,154
Unamortized debt discount . . . . .	—	(21,317)
Reserves and accruals . . . . .	11,687	10,068
Other . . . . .	<u>—</u>	<u>726</u>
	47,016	796,829
Less valuation allowance . . . . .	<u>(47,016)</u>	<u>(796,829)</u>
	<u><u>\$ —</u></u>	<u><u>\$ —</u></u>

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE J) — Income Taxes (continued)

	Current Asset	Long-Term Asset (Liability)
December 31, 2008		
Net operating loss carryforward . . . . .	\$ —	\$ 768,037
Research and development and other tax credit carryforwards . . . . .	—	33,469
Capital loss carryforward . . . . .	—	289
Deferred revenue . . . . .	17,256	11,661
Facility exit charge . . . . .	—	4,518
Net unrealized losses on investments . . . . .	—	1,805
Intangible assets . . . . .	394	4,996
Equity-based compensation . . . . .	—	11,864
Depreciation . . . . .	—	8,352
Unamortized debt discount . . . . .	—	(36,448)
Reserves and accruals . . . . .	7,964	10,555
Other . . . . .	—	296
	25,614	819,394
Less valuation allowance . . . . .	(25,614)	(819,394)
	<u>\$ —</u>	<u>\$ —</u>

The Company recognized a valuation allowance to the full extent of its deferred tax assets since the likelihood of realization of the benefit cannot be determined. The valuation allowance decreased by \$1,163 during 2009 to \$843,845 at December 31, 2009. The decrease is primarily related to the reversal of valuation allowance against net operating loss carryforwards that were utilized in the current year.

Provision for income taxes is comprised of the following:

	<u>Year Ended December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
Current:			
Federal . . . . .	\$(1,274)	\$—	\$—
State . . . . .	—	—	—
Foreign taxes . . . . .	—	—	—
Deferred . . . . .	—	—	—
	<u>\$(1,274)</u>	<u>\$—</u>	<u>\$—</u>

Income tax benefit of \$1,274 represents a credit received in 2009 for 2008 of approximately \$491 and an accrued income tax benefit of approximately \$783 for 2009. The Company elected to accelerate recognition of research and development tax credits by electing out of bonus depreciation pursuant to regulations passed in 2008.

The Company has available tax credit carryforwards of approximately \$35,044 which expire, if unused, from the year 2010 through the year 2029. The Company has net operating loss (“NOL”) carryforwards for federal income tax purposes of approximately \$1,632,941, excluding stock-based compensation NOLs, which expire, if unused, from the year 2010 through the year 2029. The Company’s ability to utilize these NOLs may be limited under Internal Revenue Code Section 382 (“Section 382”). In connection with the adoption of stock-based compensation guidance in 2006, the Company elected to follow the with-and-without approach to determine the sequence in

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE J) — Income Taxes (continued)

which deductions and NOL carryforwards are utilized. Accordingly, no tax benefit related to stock options was recognized in the current year as a result of the utilization of approximately \$26,500 of NOL carryforwards. At December 31, 2009, the Company has approximately \$287,053 of NOL carryforwards that relate to stock-based compensation for which future tax benefits will be credited to equity.

Section 382 imposes annual limitations on the utilization of NOL carryforwards and other tax attributes upon an ownership change. In general terms, an ownership change may result from transactions that increase the aggregate ownership of certain stockholders in the Company's stock by more than 50 percentage points over a testing period (generally three years).

The Company completed a Section 382 analysis during 2009. Based on this analysis, the Company's NOLs and other tax attributes should not be limited under Section 382. The Company's future utilization of all of the Company's NOLs and other tax attributes is dependent upon the Company's ability to generate sufficient income during the carryforward periods and no future significant changes in ownership. When tax attributes are used, NOLs are used before tax credits and this will likely result in expiration of the tax credits.

The Company adopted the uncertain tax positions guidance of FASB ASC Topic 740, *Income Taxes*, on January 1, 2007. The Company had no unrecognized tax benefits as of January 1, 2007 and provides a full valuation allowance on the net deferred tax asset recognized in the consolidated financial statements. As a result, the adoption of FASB ASC Topic 740 effective January 1, 2007 had no effect on the Company's financial position as of such date, or on net operating losses available to offset future taxable income.

The Company recognizes interest and penalties related to uncertain tax positions, if any, in income tax expense. As of December 31, 2009 and 2008, the Company did not accrue any interest related to uncertain tax positions. The Company's income taxes have not been subject to examination by any tax jurisdictions since its inception. Due to NOL and tax credit carryforwards, all income tax returns filed by the Company are subject to examination by the taxing jurisdictions.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

	<u>2009</u>	<u>2008</u>	<u>2007</u>
Balance as of January 1 . . . . .	\$30,282	\$29,611	\$28,641
Gross increases related to prior year tax positions . . . . .	—	62	—
Gross decreases related to prior year tax positions . . . . .	(1,108)	(558)	—
Gross increases related to current year tax positions . . . . .	<u>848</u>	<u>1,167</u>	<u>970</u>
Balance as of December 31 . . . . .	<u>\$30,022</u>	<u>\$30,282</u>	<u>\$29,611</u>

The Company believes that any of its uncertain tax positions would not result in adjustments to its effective income tax rate because likely corresponding adjustments to deferred tax assets would be offset by adjustments to recorded valuation allowances.

### (NOTE K) — Facility-Related Exit Charges (Credits)

During 2006, the Company exited certain headquarters space ("Wing C") and recorded a charge of \$9,156, net of estimated sublease income, pursuant to FASB ASC Topic 420, *Exit or Disposal Cost Obligations*. The charge of \$9,156 represented the present value of the excess of future payments for Wing C over estimated sublease income and an impairment charge on certain fixed assets and leasehold improvements. The impairment charge was based on the net book value, which approximated fair value, of the assets and leasehold improvements at the time the Company exited the space. During 2007, the Company entered into an agreement to sublease a portion of Wing C to MedImmune, Inc. Upon execution of the sublease, no adjustment to the 2006 estimates of facility-related exit



## HUMAN GENOME SCIENCES, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

#### **(NOTE K) — Facility-Related Exit Charges (Credits) (continued)**

charges was required as the sublease income approximated the initial estimated sublease income. During the second quarter of 2009, MedImmune, Inc. terminated its sublease, which resulted in an exit charge of approximately \$11,400, comprised of an increase of \$10,585 in accrued exit expenses and \$850 in additional fixed asset impairments. During the fourth quarter of 2009, the Company decided to resume production activities in Wing C in order to support increased contract manufacturing services and increased early-stage clinical development and reversed approximately \$10,675 of the exit reserve, representing the portion of the Wing C exit reserve related to the production space. The Company's exit reserve is approximately \$4,206 at December 31, 2009.

In 2006, the Company consolidated certain of its operations from a laboratory building to its Traville headquarters space and the LSM and subleased the laboratory building. In conjunction with this exit, the Company recorded a charge of \$3,514 relating to the estimated sublease loss and an impairment charge on certain fixed assets and leasehold improvements relating to this space. The impairment charge was based on the net book value, which approximated fair value, of the assets and leasehold improvements at the time the Company exited the space. During 2007, the Company purchased the building from the landlord and subsequently sold it to BioMed. In conjunction with this purchase and sale, the Company reversed the remaining accrual related to its exit from the building of \$1,969 and recognized a net gain on the purchase and sale of \$1,704. The total gain of \$3,673 is reflected as Facility-related exit charges (credits) in the consolidated statement of operations.

The following table summarizes the activity related to the reserve for exit charges for the year ended December 31, 2009, all of which is facilities-related:

Balance as of January 1, 2009 . . . . .	\$ 5,027
Accretion recorded . . . . .	<u>1,384</u>
Subtotal . . . . .	6,411
Cash items . . . . .	(2,115)
Accrual adjustment, net. . . . .	<u>(90)</u>
Balance as of December 31, 2009 . . . . .	4,206
Less current portion . . . . .	<u>(2,227)</u>
	<u><u>\$ 1,979</u></u>

#### **(NOTE L) — Fair Value Measurements**

The FASB guidance regarding the fair value of all assets and liabilities defines fair value, provides guidance for measuring fair value and requires certain disclosures. This guidance does not require any new fair value measurements, but rather applies to all other accounting pronouncements that require or permit fair value measurements. This guidance does not apply to measurements related to share-based payments.

The FASB Codification discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow), and the cost approach (cost to replace the service capacity of an asset or replacement cost). The guidance utilizes a fair value hierarchy that prioritizes the inputs to

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE L) — Fair Value Measurements (continued)

valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- Level 3: Unobservable inputs that reflect the reporting entity's own assumptions.

Active markets are those in which transactions occur with sufficient frequency and volume to provide pricing information on an ongoing basis. Inactive markets are those in which there are few transactions for the asset, prices are not current, or price quotations vary substantially either over time or among market makers, or in which little information is released publicly. With regard to the Company's financial assets subject to fair value measurements, the Company believes that all of the assets it holds are actively traded because there is sufficient frequency and volume to obtain pricing information on an ongoing basis.

The Company's assets and liabilities subject to fair value measurements on a recurring basis and the related fair value hierarchy are as follows:

<u>Description</u>	<u>Fair Value as of December 31, 2009</u>	<u>Fair Value Measurements as of December 31, 2009 Using Fair Value Hierarchy</u>		
		<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Cash and cash equivalents . . . . .	\$ 567,667	\$567,667	\$ —	\$—
Short-term investments . . . . .	151,528	8,029	143,499	—
Marketable securities . . . . .	384,028	—	384,028	—
Long-term equity investment . . . . .	21	21	—	—
Restricted investments . . . . .	88,437	6,693	81,744	—
Total . . . . .	<u>\$1,191,681</u>	<u>\$582,410</u>	<u>\$609,271</u>	<u>\$—</u>

The Company evaluates the types of securities in its investment portfolios to determine the proper classification in the fair value hierarchy based on trading activity and the observability of market inputs. The Company's Level 1 assets include cash, money market instruments and U.S. Treasury securities. Level 2 assets include government-sponsored enterprise securities, commercial paper, corporate bonds, asset-backed securities, and mortgage-backed securities. The Company's privately-held equity investment is carried at cost and is not included in the table above, and is reviewed for impairment at each reporting date.

The Company generally obtains a single quote or price per instrument from independent third parties to help it determine the fair value of securities in Level 1 and Level 2 of the fair value hierarchy. The Company's Level 1 cash and money market instruments are valued based on quoted prices from third parties, and the Company's Level 1 U.S. Treasury securities are valued based on broker quotes. The Company's Level 2 assets are valued using a multi-dimensional pricing model that includes a variety of inputs including actual trade data, benchmark yield data, non-binding broker/dealer quotes, issuer spread data, monthly payment information, collateral performance and other reference information. These are all observable inputs. The Company reviews the values generated by the multi-dimensional pricing model for reasonableness, which could include reviewing other publicly available information.

The Company does not hold auction rate securities, loans held for sale, mortgage-backed securities backed by sub-prime or Alt-A collateral or any other investments which require the Company to determine fair value using a

**HUMAN GENOME SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(dollars in thousands, except per share data)**

**(NOTE L) — Fair Value Measurements (continued)**

discounted cash flow approach. Therefore, the Company does not need to adjust its analysis or change its assumptions specifically to factor illiquidity in the markets into its fair values.

The fair value of the Company's collaboration receivables, other assets, accounts payable, accrued expenses and collaboration payable approximate their carrying amount due to the relatively short maturity of these items. The fair value of the Company's convertible subordinated debt is based on quoted market prices. The quoted market price of the Company's convertible subordinated debt was approximately \$774,234 as of December 31, 2009. With respect to its lease financing, the Company evaluated its incremental borrowing rate as of December 31, 2009, based on the current interest rate environment and the Company's credit risk. The fair value of the BioMed lease financing was approximately \$265,293 as of December 31, 2009 based on a discounted cash flow analysis, and current rates for corporate debt having similar characteristics and companies with similar creditworthiness.

**(NOTE M) — Teva Biopharmaceuticals USA, Inc. (formerly CoGenesys)**

In 2008, Teva acquired all of the outstanding stock of CoGenesys, which became Teva Bio. CoGenesys had been a division of the Company until 2006, when the Company completed the sale of assets and concurrently entered into a license agreement and manufacturing services agreement.

As consideration for the assets conveyed, liabilities assumed and intellectual property licensed, the Company obtained a 14% equity interest in CoGenesys. As part of this transaction, \$7,575 was allocated to the intellectual property license and manufacturing services agreement and was recognized ratably over the term of the manufacturing services agreement, as amended, which ended in 2009.

Under the license agreement, as amended, the Company is entitled to various milestone and royalty rights on certain products, if they are developed and commercialized. Teva Bio can obtain additional product rights by extending the initial seven-year research term upon the payment of additional consideration.

As a result of Teva's acquisition of CoGenesys in 2008, the Company received \$47,336 as partial payment for its equity investment in CoGenesys and recorded a gain on sale of long-term equity investment of \$32,518 in 2008. The terms of the agreement between Teva and CoGenesys required an escrow account be established for 10% of the purchase price as security for CoGenesys' representations, warranties, and covenants. Because the Company had no information concerning the likelihood of the terms of the escrow agreement being satisfied, the Company did not include any potential proceeds from escrow in the calculation of the gain on the sale of its investment in 2008. During 2009, the Company received the final payment for its equity investment in CoGenesys and recorded a gain of \$5,259.

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE N) — Earnings Per Share

Diluted net income (loss) per share was determined as follows:

	December 31,		
	2009	2008	2007
Numerator:			
Net income used for diluted net income (loss) per share . . . . .	\$ 5,659	\$ (268,891)	\$ (284,371)
Denominator:			
Weighted average shares outstanding . . . . .	149,334,426	135,406,642	134,333,418
Effect of dilutive securities:			
Employee stock options and restricted stock units . . . . .	5,719,047	—	—
Weighted average shares used for diluted net income (loss) per share . . . . .	155,053,473	135,406,642	134,333,418
Diluted net income (loss) per share . . . . .	\$ 0.04	\$ (1.99)	\$ (2.12)

Common stock issued in connection with the Company's Purchase Plan and through exercised options granted pursuant to the Incentive Plan are included in the Company's weighted average share balance based upon the issuance date of the related shares. As of December 31, 2009, 2008 and 2007, the Company had 24,601,174, 28,373,151 and 28,121,529, respectively, stock options outstanding. As of December 31, 2009, the Company had 24,303,304 shares issuable upon the conversion of the Company's convertible subordinated debt. As of December 31, 2008 and 2007 the Company had 30,942,877 shares issuable upon the conversion of the Company's convertible subordinated debt. The shares issuable upon the conversion of the Company's convertible subordinated debt are excluded from the weighted average shares as they are anti-dilutive.

### (NOTE O) — Related Parties

Prior to the sale of the Company's equity investment in CoGenesys, CoGenesys was a related party of the Company. For the year ended December 31, 2007 the Company recognized revenue of \$2,803, under the 2006 license agreement and manufacturing services agreement with CoGenesys. Effective February 2008, CoGenesys is no longer a related party of the Company, as a result of the Teva acquisition of all the outstanding shares of CoGenesys.

The Company owns approximately one percent of VIA Pharmaceuticals, Inc. ("VIA"). During 2007, the Company and VIA mutually terminated a 1997 License Agreement between the parties. Accordingly, the Company no longer deems VIA to be a related party.

# HUMAN GENOME SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands, except per share data)

### (NOTE P) — Quarterly Financial Information (unaudited)

Quarterly financial information for 2009 and 2008 is presented in the following table:

	<u>1<sup>st</sup> Quarter</u>	<u>2<sup>nd</sup> Quarter</u>	<u>3<sup>rd</sup> Quarter</u>	<u>4<sup>th</sup> Quarter</u>
<b>2009</b>				
Revenue . . . . .	\$177,277	\$ 26,681	\$ 18,834	\$ 52,957
Income (loss) from operations . . . . .	97,795	(53,414)	(37,964)	(229)
Net income (loss) . . . . .	129,813	(65,411)	(49,003)	(9,740)
Net income (loss) per share, basic . . . . .	0.96	(0.48)	(0.32)	(0.06)
Net income (loss) per share, diluted . . . . .	0.85	(0.48)	(0.32)	(0.06)
<b>2008</b>				
Revenue . . . . .	\$ 12,275	\$ 11,567	\$ 11,674	\$ 12,906
Income (loss) from operations . . . . .	(76,427)	(70,357)	(58,310)	(50,606)
Net income (loss) . . . . .	(52,719)	(80,107)	(74,181)	(61,884)
Net income (loss) per share, basic and diluted . .	(0.39)	(0.59)	(0.55)	(0.46)

The Company's results for the first quarter of 2009 include a gain on extinguishment of debt of \$38,873, or \$0.29 per basic share and \$0.24 per diluted share and a gain on the sale of an equity investment of \$5,259, or \$0.04 per basic share and \$0.03 per diluted share.

The Company's results for the first quarter of 2008 include a gain on the sale of an equity investment of \$32,518, or \$0.24 per basic and diluted share.

The Company's results for the third quarter of 2008 include a charge for impaired investments of \$6,049, or \$0.04 per basic and diluted share.

I, H. Thomas Watkins, certify that:

1. I have reviewed this Annual Report on Form 10-K for the period ended December 31, 2009 of Human Genome Sciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ H. Thomas Watkins

H. Thomas Watkins  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: March 2, 2010



I, Timothy C. Barabe, certify that:

1. I have reviewed this Annual Report on Form 10-K for the period ended December 31, 2009 of Human Genome Sciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Timothy C. Barabe

Timothy C. Barabe  
Senior Vice President and Chief Financial Officer  
(Principal Financial Officer)

Date: March 2, 2010

**Certification of Principal Executive Officer  
Pursuant to 18 U.S.C. 1350  
(Section 906 of the Sarbanes-Oxley Act of 2002)**

I, H. Thomas Watkins, President and Chief Executive Officer (principal executive officer) of Human Genome Sciences, Inc. (the "Registrant"), certify, to the best of my knowledge, based upon a review of the Annual Report on Form 10-K for the period ended December 31, 2009 of the Registrant (the "Report"), that:

- (1) The Report fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ H. Thomas Watkins

\_\_\_\_\_  
Name: H. Thomas Watkins

Date: March 2, 2010

**Certification of Principal Financial Officer  
Pursuant to 18 U.S.C. 1350  
(Section 906 of the Sarbanes-Oxley Act of 2002)**

I, Timothy C. Barabe, Senior Vice President and Chief Financial Officer (principal financial officer) of Human Genome Sciences, Inc. (the “Registrant”), certify, to the best of my knowledge, based upon a review of the Annual Report on Form 10-K for the period ended December 31, 2009 of the Registrant (the “Report”), that:

- (1) The Report fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ Timothy C. Barabe

\_\_\_\_\_  
Name: Timothy C. Barabe

Date: March 2, 2010

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## BOARD OF DIRECTORS

### **Argeris (Jerry) N. Karabelas, Ph.D.**

*Chairman of the Board, Human Genome Sciences, Inc.  
Partner, Care Capital LLC  
Former Head of Healthcare and Chief Executive Officer,  
Worldwide Pharmaceuticals, Novartis, AG*

### **H. Thomas Watkins**

*President and Chief Executive Officer  
Human Genome Sciences, Inc.*

### **Richard J. Danzig**

*Chairman, Center for a New American Security  
Consultant, U.S. Government Departments and  
Agencies on Biological Terrorism  
Senior Fellow, Center for Strategic and International Studies  
and Center for Naval Analyses  
Former Secretary of the Navy*

### **Jürgen Drews, M.D.**

*Member of the Executive Committee of the Roche Group (Retired)  
Former Chairman and Partner, International Biomedicine  
Management Partners  
Former Managing Partner, Bear Stearns Health Innoventures*

### **Maxine Gowen, Ph.D.**

*President and Chief Executive Officer, Trevena, Inc.  
Former Senior Vice President, Center of Excellence  
for External Drug Discovery, GlaxoSmithKline  
Former Senior Lecturer and Head, Bone Cell Biology Group,  
Department of Bone and Joint Medicine, University of Bath, U.K.*

### **Tuan Ha-Ngoc**

*President and Chief Executive Officer, AVEO Pharmaceuticals, Inc.  
Former Executive Vice President, Corporate Development,  
Commercial Operations, European and Japanese Operations,  
Genetics Institute*

### **John L. LaMattina, Ph.D.**

*Senior Partner, PureTech Ventures  
Former Senior Vice President, Pfizer Inc., and President,  
Pfizer Global Research & Development*

### **Augustine Lawlor**

*Managing Partner, HealthCare Ventures LLC  
Former Chief Operating Officer, LeukoSite*

### **Robert C. Young, M.D.**

*President, RCY Medicine  
Former Chancellor, Fox Chase Cancer Center  
Former Chairman, Board of Scientific Advisors of the  
National Cancer Institute*

## CORPORATE HEADQUARTERS

Human Genome Sciences, Inc.  
14200 Shady Grove Road  
Rockville, MD 20850  
Phone: (301) 309-8504  
[www.hgsi.com](http://www.hgsi.com)

## TRANSFER AGENT

American Stock Transfer & Trust Company  
59 Maiden Lane  
New York, NY 10038  
Phone: (800) 937-5449  
or (212) 936-5100  
[www.amstock.com](http://www.amstock.com)

## OFFICERS

### **H. Thomas Watkins**

*President and Chief Executive Officer*

### **James H. Davis, Ph.D., J.D.**

*Executive Vice President, General Counsel and Secretary*

### **Barry A. Labinger**

*Executive Vice President and Chief Commercial Officer*

### **David P. Southwell**

*Executive Vice President and Chief Financial Officer*

### **David C. Stump, M.D.**

*Executive Vice President, Research and Development*

### **Susan Bateson**

*Senior Vice President, Human Resources*

### **Curran M. Simpson**

*Senior Vice President, Operations*

### **Sally D. Bolmer, Ph.D.**

*Senior Vice President, Development and Regulatory Affairs*

### **William W. Freimuth, M.D., Ph.D.**

*Vice President, Clinical Research—Immunology, Rheumatology  
and Infectious Diseases*

### **Gilles Gallant, B.Pharm, Ph.D.**

*Vice President, Clinical Research—Oncology*

### **Scott Habig**

*Vice President, Sales*

### **Randy J. Maddux**

*Vice President, Manufacturing Operations*

### **Kevin P. McRaith**

*Vice President, Sales and Marketing*

### **Joseph A. Morin**

*Vice President, Engineering*

### **Daniel J. Odenheimer, Ph.D.**

*Vice President, Clinical Research—General Medicine*

### **Jerry Parrott**

*Vice President, Corporate Communications and Public Policy*

### **Thomas M. Spitznagel, Ph.D.**

*Vice President, BioPharmaceutical Development*

### **Sarah Thomas**

*Vice President, Quality*

### **Michele M. Wales, Ph.D., J.D.**

*Vice President, Intellectual Property*

### **Ann L. Wang**

*Vice President, Clinical Operations*

## ANNUAL MEETING

Thursday, May 20, 2010 at 9:30 am  
Marriott Gaithersburg Washingtonian Center  
9751 Washingtonian Boulevard  
Gaithersburg, MD 20878

## SEC FILINGS

Copies of the Company's filings with the Securities and Exchange Commission are available without charge on the HGS website at [www.hgsi.com/sec-filings.html](http://www.hgsi.com/sec-filings.html) as soon as is reasonably practicable after filing.

## OTHER INFORMATION

Health professionals and patients interested in clinical trials of HGS products may inquire via e-mail to [medinfo@hgsi.com](mailto:medinfo@hgsi.com) or by calling HGS at (877) 822-8472.



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Rockville, MD 20850-3338  
Phone: (301) 309-8504

[www.hgsi.com](http://www.hgsi.com)