

Revolutionary Genetic Analysis Solutions

From Academic Research Through Translational Medicine

To Clinical Diagnostics





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2010 Annual Report

SEQUENOM®

#### Dear fellow stockholders,

The start of 2010 marked an important turning point for our organization as we continued to pursue our stated goals throughout the year, achieving one milestone after another, largely ahead of schedule. In the process, we greatly strengthened the foundation of our business in preparation for the expected growth to come.

Lead by a seasoned management team, we started 2010 with new leadership and by the beginning of 2011, we had rounded out the team with the addition of a new Senior Vice President for Diagnostics, positioning us for success as we worked to develop the commercial aspects of the company's diagnostic business.

Another important milestone was realized in the spring, when we received final approval from the Federal District Court on a settlement in the class action lawsuit filed in the prior year.

Our financial performance was strong, with revenue for 2010 up 25% over the prior year, ending at \$47.5 million, compared with \$37.9 million in 2009. We maintained gross margins in the 60% range, down only slightly from 62% in 2009, despite increased costs from our expanded diagnostic operations associated with our CAP accredited and CLIA certified diagnostic laboratory, the Sequenom Center for Molecular Medicine (Sequenom CMM).

We were successful in improving the financial profile of our core genetic analysis business showing growth in revenues with a 19% improvement from the prior year, as the launch of our next generation MassARRAY Analyzer 4 was well-received by customers in the research and translational medicine markets. During 2010, we placed a total of 51 systems, of which 27 were MassARRAY Analyzer 4s, making it one of our best years for instrument sales.

We now manufacture the new MassARRAY Analyzer 4 in-house rather than continuing to purchase analyzers from a third party equipment manufacturer. This has translated into improved gross margins for the year while reducing our investment in inventory and reducing our receivables balance to support this core aspect of the business. We continue to see promising signs of growth and expect to see additional expansion of this business throughout 2011.

It was also a very productive year for Sequenom CMM, from the increased traction gained in cystic fibrosis testing launched just prior to the start of the year, to the initiation and completion of three major studies relating to the noninvasive prenatal detection of trisomy 21. It is our hope that 2011 will be a benchmark year with the anticipated launch of two important laboratory test offerings, each with the potential to be transformative to the company and the medical community.

One key development in the molecular diagnostic segment came early in 2010, as we finalized an exclusive worldwide licensing agreement with Optherion, Inc. for a group of patents and patent applications associated with age-related macular degeneration (AMD), a common eye disorder of the elderly that sometimes leads to blindness. The addition of this licensed technology to our portfolio is an important step toward developing and commercializing a portfolio of meaningful proprietary genetic tests driven by unmet clinical needs in the field of ophthalmology.

In December of 2010, Sequenom CMM completed an analytical validation study and an *in silico* clinical validation study, and is currently on track to launch an AMD laboratory developed test (LDT) to predict genetic predisposition to late stage AMD in the third quarter of 2011, bringing this testing service to market nationwide.

2010 also marked the advancement of one of our most anticipated products in development, Sequenom CMM's noninvasive prenatal trisomy 21 (T-21) LDT to detect an overabundance of chromosome 21 in pregnant women, which is associated with fetal Down syndrome. In September, Sequenom CMM scientists completed a blinded T-21 locked-assay study, the results from which showed 100% sensitivity by accurately detecting 39 out of 39 T-21 cases and 99.7% specificity, showing that massively parallel shotgun sequencing is a viable technology for T-21 detection.

This locked-assay study manuscript was accepted and published in the March 2011 edition of the peer-reviewed American Journal of Obstetrics and Gynecology (AJOG), where it was also selected as a "report of major impact" and as Editor's Choice for that journal issue.

Another important study supporting the efficacy of this noninvasive approach was the focus of our academic collaborator and pioneer in to the field, Professor Dennis Lo, who published a ground-breaking large cohort clinical validation study early in 2011. This report, which appeared in the January 2011 edition of the British Medical Journal, utilized circulating cell-free fetal DNA isolated from maternal plasma as the analyte and massively parallel shotgun sequencing as the method of analysis.

Late in 2010, Sequenom CMM initiated a third study to provide clinical validation for the T-21 LDT. In this ongoing, larger blinded clinical validation study, Sequenom CMM is using clinical samples collected by principal investigators at the Women & Infants Hospital of Rhode Island, under an Institutional Review Board approved protocol.

Testing of the clinical specimens is taking place at the Sequenom CMM facility in San Diego, a CLIA certified laboratory licensed in the fall of 2010. Upon publication of the validation results following completion of the study, the goal is to bring the T-21 LDT to market by the end of 2011 or early 2012, through the San Diego CLIA laboratory.

Sequenom initiated discussions with the FDA in January 2011 regarding the necessary preclinical and clinical studies required to support a premarket approval (PMA) application to the FDA for an *in vitro* diagnostic device for T-21. We anticipate continuing a constructive dialog with the FDA over the coming months to define the PMA requirements.

Finally, we ended the year with a solid balance sheet due, in part, to two successful financings that raised approximately \$148 million in gross proceeds. We closed December with a balance of approximately \$135 million in cash, cash equivalents and marketable securities, which are currently expected to provide sufficient funds to finance operations through the initial commercialization phase of the AMD and T-21 LDTs and into early 2013. Going forward, we also plan to continue investing in new products, our facilities and our infrastructure.

In closing, we would like to recognize our entire team for its integrity, commitment to service, and technical excellence. Because of the exceptional team of professionals we have on staff, we have been able to grow and achieve our goals, remaining focused on the tasks at hand. We also want to thank you, our stockholders, for your continuing support and we look forward to updating you on our progress in the year ahead as we continue to position Sequenom as a leader in molecular diagnostics.

Sincerely,

Harry J Khon.k. "

Harry F. Hixson, Jr., Ph.D. Chairman and Chief Executive Officer

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Paul V. Maier Chief Financial Officer

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Ronald M. Lindsay, Ph.D. Executive Vice President, Research and Development

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

### **FORM 10-K**

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

#### (Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended December 31, 2010

OR

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

For the transition period from

d from to

**Commission File Number: 000-29101** 

APR 2 8 2011

Washington, DC 20549

## **SEQUENOM, INC.**

(Exact name of Registrant as specified in its charter)

DELAWARE (State or other jurisdiction

or incorporation or organization) 3595 John Hopkins Court San Diego, California (Address of principal executive offices) (I.R.S. Employer Identification No.) 92121

77-0365889

(Zip Code)

Registrant's telephone number, including area code: (858) 202-9000

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

Common Stock, \$.001 par value

(Title of class)

The NASDAQ Stock Market, LLC

(Name of Each Exchange on Which Registered)

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  $\square$  No  $\boxtimes$  Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  $\square$  No  $\boxtimes$ 

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  $\times$  No  $\square$ 

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

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

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.

Large accelerated filer 🗌	Accelerated filer 🔀	Non-accelerated filer		Smaller reporting company filer
		(Do not check if a smaller	;	
		reporting company)		· 1

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing sale price of the Common Stock on June 30, 2010 as reported on The NASDAQ Global Market, was approximately \$441.5 million. Shares of Common Stock held by each executive officer and director and by each person who owns 10% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. As of February 25, 2011, there were 98,972,231 shares of the registrant's Common Stock outstanding.

### DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference information from the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission (the Commission) in connection with the solicitation of proxies for the registrant's annual meeting of stockholders to be held on June 15, 2011. Such definitive proxy statement will be filed with the Commission no later than 120 days after December 31, 2010.

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#### PART I

#### Item 1. BUSINESS

All statements in this report that are not historical are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act. These forward-looking statements can generally be identified as such because the context of the statement will include words such as "may," "will," "intend," "plans," "believes," "anticipates," "expects," "estimates," "predicts," "potential," "continue," "opportunity," "goals," or "should," the negative of these words or words of similar import. Similarly, statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects are also forward-looking statements. These forward-looking statements are or will be, as applicable, based largely on our expectations and projections about future events and future trends affecting our business, and so are or will be, as applicable, subject to risks and uncertainties including but not limited to the risk factors discussed in this report, that could cause actual results to differ materially from those anticipated in the forward-looking statements. We caution investors that there can be no assurance that actual results or business conditions will not differ materially from those projected or suggested in such forward-looking statements. Our views and the events, conditions and circumstances on which these future forward-looking statements are based, may change. All forward statements are qualified in their entirety by this cautionary statement and we undertake no obligation to revise or update any such statements to reflect events or circumstances after the date hereof.

SEQUENOM<sup>®</sup>, SpectroCHIP<sup>®</sup>, iPLEX<sup>®</sup>, and MassARRAY<sup>®</sup> are registered trademarks and SEQureDx<sup>TM</sup>, iSEQ<sup>TM</sup>, AttoSense<sup>TM</sup> and SensiGene<sup>TM</sup> are trademarks of Sequenom, Inc. This report may also refer to trade names and trademarks of other organizations.

Sequenom, Inc. was incorporated in 1994 under the laws of the State of Delaware. As used in this report, the words "we," "us," "our," and "Sequenom" refer to Sequenom, Inc. and its wholly-owned subsidiaries on a consolidated basis, unless explicitly noted otherwise.

#### Overview

We are a molecular diagnostic testing and genetics analysis company committed to providing products, services, diagnostic testing, applications and genetic analysis products that translate the results of genomic science into solutions for biomedical research, translational research, molecular medicine applications, and agricultural, livestock, and other areas of research. Our development and commercialization efforts in various diagnostic areas include noninvasive women's health related and prenatal diagnostics, ophthalmology, oncology, infectious diseases, and other medical conditions, disorders and diseases.

#### **Operating Segments**

We operate our business on the basis of two reportable segments, Molecular Diagnostics and Genetic Analysis. A further description of the operations of these segments is below. The following table sets forth as of December 31, 2010 and 2009 revenues, research and development expenses, sales and marketing expenses and operating (loss) income for our Molecular Diagnostic and Genetic Analysis segments (in thousands):

	2010	2009
Revenues:		
Molecular Diagnostics	\$ 2,554	\$ 94
Genetic Analysis	44,905	37,769
	\$ 47,459	\$ 37,863
Research and development expenses:		
Molecular Diagnostics	\$ 26,000	\$ 20,935
Genetic Analysis	3,622	5,587
Unallocated (1)	13,809	10,932
Total	\$ 43,431	\$ 37,454
Sales and marketing expenses:		
Molecular Diagnostics	\$ 8,805	\$ 5,780
Genetic Analysis	14,379	13,644
Unallocated (1)	5,203	7,421
Total	\$ 28,387	\$ 26,845
Operating (loss) income:		
Molecular Diagnostics	\$ (36,216)	\$(27,034)
Genetic Analysis	11,873	4,379
Unallocated (1)	(96,676)	(48,067)
	\$(121,019)	<u>\$(70,722</u> )

(1) Management evaluates research and development expenses and sales and marketing expenses exclusive of stock-based compensation, indirect overhead expenses and allocated and absorbed costs. Operating (loss) income is evaluated by management exclusive of general and administrative expenses, net litigation settlement of \$55.4 million, stock-based compensation, indirect overhead expenses and allocated and absorbed costs. These costs are not allocated to our business segments for performance assessment by our chief operating decision maker.

We do not discretely allocate assets to our operating segments, nor does our chief operating decision maker evaluate operating segments using discrete asset information.

#### Molecular Diagnostics and SEQureDx Technology

We are committed to researching, developing and pursuing the commercialization of various noninvasive molecular diagnostic tests for prenatal genetic disorders and diseases, women's health-related disorders and diseases, ophthalmology, oncology, infectious diseases, and other medical conditions, disorders and diseases. Currently, we are primarily focused on developing and commercializing prenatal diagnostic tests using our foundational, patent-protected, noninvasive, circulating cell-free fetal, or ccff, nucleic acid-based assay technology, which we in-license from Isis Innovation Limited, or Isis. This technology uses a standard maternal blood draw for a prenatal diagnosis or risk assessment in order to provide reliable information about the presence, amount or absence of fetal genetic material early in pregnancy. We have branded our diagnostic technology for prenatal diagnostics under the trademark SEQureDx. Our efforts in molecular diagnostics are focused on developing noninvasive *in vitro* diagnostic tests using our proprietary MassARRAY system and/or nucleic acid sequencing platforms currently provided by Illumina, Inc. We plan to conduct the development,

validation, and other activities necessary to file submissions with the U.S. Food and Drug Administration, or FDA, seeking clearance or approval for commercialization of our *in vitro* diagnostic tests in the United States. To that end, we recently made a pre-investigational device exemption, or pre-IDE, submission to the FDA for an *in vitro* diagnostic test for fetal chromosome 21 aneuploidy, such as trisomy 21, and have met with the FDA to discuss our proposed preclinical and clinical study design.

Supporting our initiatives in women's health, oncology, ophthalmology and infectious disease, we completed our acquisition of the complete AttoSense portfolio of gene-based molecular tests and related assets from SensiGen, LLC, or SensiGen, in February 2009. The acquisition included highly-sensitive and specific prototype tests for the detection and monitoring of human papillomavirus, or HPV, and other tests. These tests will require further development, and we are seeking collaborative partnership opportunities with other parties for the further development and commercialization of these tests.

#### Sequenom Center for Molecular Medicine

Sequenom Center for Molecular Medicine, LLC, or Sequenom CMM, is our wholly-owned subsidiary, which operates a laboratory located in Grand Rapids, Michigan, that is accredited by the College of American Pathology, or CAP, and compliant with the certification requirements for high complexity testing under the Clinical Laboratory Improvement Amendments, or CLIA, of 1988, as amended. Sequenom CMM develops and validates laboratory developed tests, or LDTs, for use in and solely by Sequenom CMM as a testing service to physicians. Sequenom CMM utilizes our patented SEQureDx ccff technology in developing its LDTs. Sequenom CMM has validated and offers to physicians two LDTs, the SensiGene Rhesus D fetal genotyping test and a DNA-based cystic fibrosis adult carrier screening test. Patient samples are collected by physicians and submitted to Sequenom CMM for testing and the results are reported back to the ordering physician.

Sequenom CMM has established an additional laboratory in San Diego, California that complies with the California Department of Public Health Title 17 California Code of Regulations applicable regulations for clinical laboratories. A California clinical laboratory license was issued by the state and a federal CLIA certification was issued by the Centers for Medicare and Medicaid Services, or CMS, to the San Diego laboratory in late 2010. We anticipate that Sequenom CMM's San Diego laboratory will be used principally for its SensiGene Trisomy 21 LDT currently under development. We have invested substantially in Sequenom CMM's information technology infrastructure to enhance the capabilities of the laboratory to track samples and provide electronic ordering and reporting and are putting in place sample collection and transportation logistics that can be scaled as demand for Sequenom CMM's molecular diagnostic testing services increases. Sequenom CMM continues to negotiate and enter into contracts with third party payors to establish pricing for its LDTs and provide reimbursement recommendations.

Sequenom CMM is currently developing a potential LDT for assessing pregnant women who are at increased risk (by clinical indicators) of carrying a fetus with trisomy 21. The process employed in the LDT is analysis of fetal DNA extracted from maternal blood samples utilizing next generation nucleic acid sequencing, known as massively parallel shotgun sequencing, or MPSS. With technological advances and projected instrument and reagent costs of MPSS declining rapidly, Sequenom CMM believes that a trisomy 21 LDT on a MPSS platform is commercially feasible and potentially attractive compared to other platforms. The goal is to design a noninvasive test that has high specificity and sensitivity compared to currently available serum biochemical screening tests, could be used during the first and second trimesters of pregnancy, has maximum ethnic coverage of the global population, and is a direct genetic test, not a surrogate marker. There can be no assurance that Sequenom CMM will be able to achieve any of these objectives.

In November 2010, Sequenom CMM presented the results from a pilot 96 patient study of a trisomy 21 test using MPSS at a meeting of the American Society of Human Genetics. Based on the results of this small study, Sequenom CMM started and completed a larger study that analyzed 480 patient samples collected from pregnant women at increased risk for fetal chromosome 21 aneuploidy. A manuscript describing the results from this larger laboratory verification study has been published online on February 10, 2011, in the American Journal of

Obstetrics & Gynecology, or AJOG. A hard copy publication is expected to be available in the March 2011 print edition of AJOG. There can be no assurance that Sequenom CMM will be able to repeat the study results in later studies.

Based on the results from these two studies, Sequenom CMM has undertaken the next major step in the SensiGene Trisomy 21 LDT development plan, a large pivotal clinical validation study. In this study, Sequenom CMM is testing patient samples that have been collected under an institutional review board-approved clinical study conducted under the auspices of the Women and Infants Hospital in Rhode Island. We anticipate that the total number of patient samples in the clinical validation study will be approximately 2,000, of which approximately 200 will be positive for trisomy 21 based on laboratory confirmation of the diagnosis performed on samples obtained from chorionic villus sampling, or genetic amniocentesis. The study design calls for approximately 100 positive samples in each of the first and second trimesters of pregnancy. Sequenom CMM is using essentially the same assay process in the clinical validation study that was used in the 480 sample study and with the Illumina HiSeq 2000, a second generation sequencer, which was recently introduced and offers the potential for greater sample throughput than can be achieved with the first generation sequencer that Sequenom CMM used in the 96 sample study. Sequenom CMM scientists previously completed equivalency studies on the HiSeq 2000 sequencer in preparation for this large clinical validation study. Sequenom CMM anticipates that they will complete the clinical validation study by the end of the second quarter of 2011 and is planning to launch the SensiGene Trisomy 21 LDT by the end of 2011 or early 2012, after the publication of the clinical validation study results by our academic collaborators. There can be no assurance that Sequenom CMM will be able to successfully develop an LDT for trisomy 21 or that any such LDT would be successfully commercialized.

Sequenom CMM is also in the process of developing an LDT to predict genetic predisposition to late-stage age-related macular degeneration, or AMD, which is a prevalent, late onset, genetically linked vision disorder that is the most common cause of legal blindness in the elderly. Supporting this initiative, in February 2010, we entered into a license agreement with Optherion, Inc., or Optherion, under which we and our affiliated companies were granted an exclusive, worldwide, royalty-bearing license to know-how and a consolidated portfolio of patent rights that had been licensed to Optherion by a number of prominent academic institutions, for research and commercial use, including LDTs and *in vitro* diagnostic tests, in conjunction with various types of technology platforms.

#### FDA Oversight of LDTs

Historically, the FDA has exercised enforcement discretion and exempted from regulation LDTs created and used by the same laboratory. During a public meeting held in July 2010, the FDA explained that it is reconsidering its policy of enforcement discretion over LDTs. Citing a variety of safety concerns related to current LDTs, the FDA noted that the tests have become increasingly complex and utilized for significant medical decisions, sometimes in place of similar tests that have been reviewed and approved by the FDA. As part of the FDA's evolving position on the regulation of LDTs, the FDA issued letters to a number of companies in mid-2010 that primarily related to direct-to-consumer genetic testing. In these letters, the FDA expressed concern about consumers making medical decisions in reliance on genetic tests that have not undergone the FDA's premarket review. However, no formal guidance has yet been issued discussing the nature of the changes the FDA may make with respect to the regulation of LDTs, nor the scope of potential regulation.

Although Sequenom CMM does not sell its testing services directly to consumers, we also received a letter from the FDA in July 2010. We responded to the FDA by letter in August 2010 and met with the FDA in September 2010. We reiterated at that meeting that Sequenom CMM's LDTs are physician-ordered and neither we nor Sequenom CMM are involved in direct-to-consumer commercialization. The FDA indicated it had no further questions on the direct-to-consumer issue at this time. We will continue to monitor potential changes as the FDA's LDT policy evolves to ensure Sequenom CMM's activities are consistent with the FDA's most current policy.

#### **Prenatal Diagnostics Licenses**

#### Isis License Agreement

We have exclusively in-licensed from Isis patent rights (including U.S. Patent No. 6,258,540 and its foreign equivalents) to use ccff nucleic acids for diagnostic testing of serum and plasma samples obtained from pregnant women. These exclusive license rights, which are platform independent and not limited to mass spectrometry, cover the general diagnostic use of ccff nucleic acids in territories that include the United States, Canada, Europe, Japan, Australia, and Hong Kong.

Subject to the license rights granted under the agreement with Isis, intellectual property rights created in connection with improvements made to the licensed technology will belong to the party developing the improvements. We also granted a perpetual royalty-free license to the University of Oxford, which is the parent of Isis, to use and publish material relating to the licensed technology and any of our improvements solely for non-commercial use. The University of Oxford's right to publish is subject to our right to delay publication of information to protect the licensed technology or our improvements.

We have agreed to make up-front payments to Isis and pay to Isis royalties on net sales of products developed or produced using the licensed patent rights, including specified minimum royalty amounts, and milestone payments upon commercial events with respect to products for particular indications.

The agreement with Isis will remain in force for the life of any patent issued in connection with the patent application covering the licensed technology, subject to earlier termination by either party upon uncured material breach or other specified circumstances. Isis may terminate the agreement if we file a petition to wind-up or dissolve or upon 30 days' written notice if we were to challenge the validity of the patent rights covering the licensed technology or fail to make the up-front payments as provided in the agreement. We may terminate the agreement for any reason with six months' advance written notice. In the event we fail to achieve certain milestone requirements with respect to particular indications, Isis may convert the exclusive license into a non-exclusive license with respect to those indications.

#### **CUHK License Agreement**

We have also exclusively in-licensed patent rights from the Chinese University of Hong Kong, or CUHK, which cover the use of cell-free fetal nucleic acids from biological samples, including plasma, serum, whole blood and urine, for prenatal diagnostic testing by MPSS. These exclusive license rights include pending United States patent application publication no. US2009/0029377A1, and its pending foreign equivalents in Australia, Brazil, Canada, China, Eurasia, Europe, Israel, India, Japan, Korea, Mexico, New Zealand, Singapore and South Africa. Certain of our license rights, which are unrelated to prenatal diagnostic testing by MPSS sequencing, are non-exclusive.

Under our license agreement with CUHK, CUHK maintains the right to use and develop any of the licensed technology solely for academic, research and publication purposes, and with respect to one of the licensed patent applications, reserves the right to use the licensed application in accordance with its agreement with the Government of the Special Administration Region of Hong Kong. In addition, CUHK has the right to grant to the Commissioner for Innovation and Technology, a non-exclusive, world-wide license to certain of our in-licensed patent rights, which do not relate to prenatal diagnostic testing by MPSS.

Under the agreement with CUHK, we paid an upfront license fee to CUHK and are required to make milestone payments upon commercial and regulatory events achieved with respect to products developed or produced using the licensed patent rights and to pay royalties on net sales of such products, including specified minimum royalty amounts. Subject to certain limited circumstances, to maintain our licensed rights under the agreement we are required to assume the financial responsibility for the prosecution, defense and maintenance of all licensed patent applications and patents and are required to provide CUHK with reasonable assistance for the prosecution, defense and maintenance of all licensed patent applications and patents at the request of CUHK. The agreement with CUHK requires us to use all reasonable efforts and diligence to exploit the licensed patent rights and to proceed with the development, manufacture and sale of products developed or produced using the licensed patent rights, and to diligently develop markets for such products. Under the terms of the agreement, we have agreed to indemnify CUHK from all losses incurred by CUHK relating to our manufacture, use, sale or any other dealing with respect to products developed or produced using the licensed patent rights. CUHK has agreed to indemnify us from all losses incurred as a result of breaches of CUHK's representations and warranties under the agreement, subject to a cap of two times the aggregate payments received by CUHK from us at the time of such breach.

The agreement with CUHK will remain effective until the later of the life of any patent issued covering the licensed technology or September 16, 2028, subject to earlier termination by either party upon an uncured material breach. CUHK may terminate the agreement if we go into liquidation or if a receiver is appointed for our assets or if we fail to make any payment as provided in the agreement or if we assign or transfer any rights under the agreement in violation of its terms or in the event of our cessation of our business relating to the commercialization of the licensed technology. If we sublicense our rights under the agreement and our sublicense fails to pay us as required under such sublicense agreement and as a result we fail to make requisite payments to CUHK within 30 days, CUHK may terminate our agreement.

We may terminate the agreement with CUHK for any reason with 30 days' advance written notice. In the event we fail to achieve certain commercial milestone requirements with respect to products developed or produced using the licensed patent rights, CUHK may terminate the licensed patent rights with respect to such specific milestone.

Under the terms of the license agreement and other agreements with CUHK, we have rights in improvements to licensed technology when such improvements are based upon and claim priority to existing patent applications that have been licensed by us. We also have a sole and exclusive option to obtain an exclusive license to research results generated by specific CUHK inventors, using a sequencing platform purchased by us for CUHK's use, and which relate to MPSS to discover and analyze plasma, serum, blood or other bodily fluid-based markers for prenatal diagnosis, prenatal prognostication, construction of a whole genome genetic map or complete genomic sequencing of the fetus or other prenatal analysis, cancer detection, cancer prognostication, or other analysis for the screening and management of cancer.

#### **Other Agreements**

We have also exclusively in-licensed patent rights from Xenomics Inc. (now known as TrovaGene, Inc.), covering the general use, on any technology platform, of fetal nucleic acids derived from maternal urine for noninvasive prenatal genetic diagnostic testing.

We also hold exclusive rights to issued patents and pending patent applications providing fundamental patent rights for digital polymerase chain reaction, or PCR, technologies and methods through a licensing agreement with Genomic Nanosystems, LLC, a wholly-owned subsidiary of the Cytonix Corporation. The issued patents are United States Patent Nos. 6,143,496; 6,391,559; and 7,459,315 and will expire in 2017. The license provides us with the exclusive right to use patented and patent pending digital PCR methods on any platform for noninvasive prenatal diagnostics and analysis for any sample (for example, fetal cells, amniotic fluid, plasma, urine, etc.). We also secured the exclusive right to use digital PCR methods in conjunction with mass spectrometry for any commercial, diagnostic or research purpose, excluding second generation sequencing.

In January 2007, as part of our platform independent commercialization strategy, we announced our first commercial partnership with Lenetix Medical Screening Laboratory, Inc., on a non-exclusive basis, which had developed a CLIA validated test for Rhesus D blood incompatibility using real-time PCR. In December 2007, Lenetix received New York State approval of a noninvasive prenatal LDT performed on a real-time PCR platform to detect fetal Rhesus D status (including male sex determination as an internal control) in the second trimester of pregnancy, based on our licensed technology and the work performed under the agreement.

Commercialization of the LDT by Lenetix commenced in January 2008. We did not derive significant revenues from our agreement with Lenetix, which expired in January 2011.

#### **Molecular Diagnostics Market**

The United States molecular diagnostics testing market represents one of the fastest growing areas of the \$51.7 billion clinical laboratory industry in the U.S. Within this market, the molecular diagnostics market segment is estimated to be \$4 billion growing at a rate of approximately 17% per year.

The total available markets for our currently marketed and planned molecular diagnostics tests are as follows:

- Each year in the U.S. there are approximately 528,000 Rhesus D negative women who are pregnant and could benefit from assessments of the RhD status of their fetuses. We estimate the total dollar size of the U.S. market to be approximately \$250 million per year.
- There are a number of tests available for cystic fibrosis carrier screening. In the U.S. about 1.1 million tests are performed annually and the average cost of these tests is between \$200 and \$400 per test. The total available market in the U.S. is estimated to be approximately \$300 million.
- We estimate the total available market for a noninvasive trisomy 21 test to be approximately \$1.5 billion in the U.S.
- AMD affects 15-20 million people in the U.S., over 2.5 million people in Canada, and more than 50 million people worldwide. In North America there are 2 million people with vision loss and more than 600,000 people that are legally blind due to the disease. The worldwide incidence of the disease increases from 1 in 10 people over the age of 60 to more than 1 in 4 people over the age of 75.

#### **Genetic Analysis**

Our proprietary MassARRAY system is comprised of hardware, software applications, consumable chips and reagents. It is a high performance (in speed, accuracy and cost efficiency) nucleic acid analysis research use only platform that quantitatively and precisely measures genetic target material and variations. Our system is widely accepted as a leading high-performance DNA analysis system for genotyping, somatic mutation analysis and fine mapping markets and continues to gain traction for applications, such as agricultural genomics and clinical research. Our research customers include premier clinical research laboratories, bio-agriculture, bio-technology and pharmaceutical companies, academic institutions, and various government agencies worldwide. To provide customer support for our expanding user base, and in an effort to maximize market penetration, we have established direct sales and support personnel serving North America, Europe and Asia, in addition to distribution partners in several major countries throughout the world.

Our MassARRAY system provides reliable results for a wide range of DNA/RNA analysis applications including single nucleotide polymorphism, or SNP, genotyping, detection of mutations, analysis of copy number variants and other structural genome variations. In addition, the system provides quantitative gene expression analysis, quantitative DNA methylation analysis, comparative sequence analysis of haploid organisms, SNP discovery, and oligonucleotide quality control. These applications are provided through proprietary research use application software that operates on the MassARRAY system and through the purchase of consumable chips and reagent sets. While the MassARRAY system is versatile across many applications, it is a robust and cost-effective genotyping and somatic mutation analysis solution enabled through our research use only iPLEX multiplexing assay, which permits multiplexed SNP and somatic mutation analysis. In April 2010 we launched our next-generation research use only mass spectrometry system, the MassARRAY Analyzer 4. This new high performance nucleic acid analysis system has been designed to meet customer demand for a bench top instrument with greater flexibility across multiple applications, improved reliability and faster performance and is designed to empower the basic and translational research community to advance findings from discovery genetic and biomarker studies toward biomarker validation and clinical utility in diagnosis, prognosis and monitoring of diseases.

Our research and development efforts in genetic analysis are committed to producing new and improved components and applications for the MassARRAY system that deliver greater system versatility and higher data quality at a competitive price per data point. These research and development activities and new applications also serve to facilitate and support our diagnostics initiatives.

#### **Genetic Analysis Markets**

#### **Oncology and Translational Research**

We provide key research tools for translational medical research targeted at oncology. These tools allow evaluation of genomic alterations and mutations, including a variety of genetic events. The genetic events that are being investigated with MassARRAY systems include the activation/inactivation of proto-oncogenes or tumor suppressor genes through single nucleotide alterations, large genomic deletions, large and small intragenic deletions, chromosomal translocations, as well as aberrant promoter methylation and other epigenetic events.

#### Pharmaceutical Research

Pharmaceutical and biotechnology companies are developing molecularly targeted therapies against a wide variety of diseases. These companies use MassARRAY systems to identify genetic alterations arising in tumors or residing in an individuals' genome. These include the identification of genetic alterations in gene pathway members targeted by particular treatments with the goal of identifying alterations affecting the efficacy of those treatments. In addition, pharmaceutical and biotechnology companies are identifying alterations that reside in subsets of individuals that may provide insights into potential drug safety considerations.

#### Academic Biomedical Research

Whole-genome population studies are conducted for general research purposes to create SNP maps and to determine allele frequencies in different ethnicities or species. Whole genome association studies and linkage studies are conducted for genetic discovery purposes. In general, these studies are high throughput studies that analyze a small number of samples against a high number of SNPs. Candidate gene and candidate region association studies typically follow whole-genome population genetics studies, whole genome association studies. Once target regions are identified and connections to disease are made, these institutions then typically perform fine mapping genotyping studies, which are conducted in an effort to apply genetics to diseases. Institutions conducting fine mapping genotyping studies use the MassARRAY system to perform candidate gene and candidate region association studies. Candidate gene association studies demonstrate that underlying genetic defects reside in specific biological pathways.

#### Agricultural: Plant Crops and Livestock

There is market demand for genetic testing as it relates to trait selection and feedlot management. There is also demand for genetic analysis of crops, including maize, rice, and others for potentially growing agricultural products with enhanced traits, such as nutritional quality, disease resistance, and crop yields.

Our MassARRAY system is widely accepted by livestock-focused service providers in the United States and Europe for genotyping, due to its suitability for routine testing of a large number of DNA samples with modest numbers of SNPs. We have provided genotyping solutions for customers in the livestock industry. Our competitive advantage in the livestock market is based upon the capability of the MassARRAY system to perform high-volume routine testing. This advantage has now been recognized by plant crop researchers who are beginning to use the MassARRAY system to identify molecular markers associated with beneficial traits. While other genetic analysis platform companies have been successful in the whole genome mapping segment of the market, the MassARRAY system is ideally suited for the evaluation of subsets of markers and for the application of genetic tests which simultaneously assess the status of tens to hundreds of markers.

#### Clinical Research, Public Health Initiatives, Biodefense

Our iSEQ Comparative Sequencing Analysis application is directed to the clinical research market (with its focus on public health issues), healthcare industries, pharmaceutical sectors and homeland defense initiatives. DNA based analyses are of increasing importance for pathogen typing and antibiotic resistance profiling. A large number of sequencing efforts in the past decade have provided reference sequences for massive parallel comparative sequencing of individuals to ascertain variations within populations and to identify informative genomic markers for routine DNA based microbial and viral typing and monitoring. This continuing effort requires accurate, reproducible, high-throughput technologies for large-scale comparative sequencing in extensive archives of microbes. The automation, throughput, accuracy, data portability and reproducibility of the MassARRAY iSEQ Comparative Sequence Analysis application serve these needs.

#### **Strategic Direction**

In our molecular diagnostics business we are focusing on developing and commercializing various noninvasive diagnostic tests. We plan to develop tests in prenatal genetic disorders and diseases, women's health-related disorders and diseases and other medical conditions, diseases and disorders in areas including ophthalmology, oncology and infectious disease. We are pursuing partnering opportunities for the development and adaptation of the MassARRAY system for commercialization of molecular diagnostics in general.

Our wholly-owned molecular diagnostic reference laboratory, Sequenom CMM is focusing on the development and validation of laboratory developed tests in prenatal, women's health and ophthalmology medical conditions for use in and solely by the laboratory. For example, in February 2010 we in-licensed AMD patent rights and currently Sequenom CMM is developing a molecular diagnostic LDT for this eye disease.

Our genetic analysis business strategy leverages our technology, intellectual property and other assets to expand deeper into and beyond the fine mapping segment of the genetic analysis market, to more aggressively target pharmaceutical companies and other for-profit institutions, particularly in areas of translational research and molecular medicine and capitalizing on our potential in molecular diagnostics markets. In our core genetic analysis business, we are focusing on prioritizing key products that we believe will drive growth and create value.

Our strategy includes:

- Investing in our genetic analysis business by developing and commercializing new biomarker panels;
- Launching and marketing a next-generation MassARRAY system for use in research applications;
- Developing and commercializing noninvasive prenatal diagnostic assays and other proprietary tests for women's health, ophthalmology, oncology, infectious disease, and other areas;
- Expanding our diagnostic offerings through in-licensing, partnering and acquisitions;
- Investing in our CAP-accredited and CLIA-certified laboratory, Sequenom CMM, enabling the laboratory to make LDTs available as a testing service to physicians.

#### **Intellectual Property**

To establish and protect our proprietary technologies and products, we rely on a combination of patent, copyright, trademark and trade secret laws, as well as confidentiality provisions in our contracts.

We have implemented a diligent patent strategy, including in-licensing, designed to facilitate our research and development and commercialization of current and future products. Our patent portfolio, including in-licensed patent rights, includes approximately 512 issued or allowed patents and approximately 333 pending patent applications, in the United States and other major industrial nations throughout the world.

Our prenatal diagnostic patent portfolio includes numerous in-licensed issued patents and in-licensed pending patent applications. The issued patents include United States Patent Nos. 6,258,540, 6,927,028, and 6,664,056, and foreign equivalents for portions of the portfolio that include Canada and Europe. These patents will expire between 2017 and 2022. Most of the patent applications that are in-licensed are in the early stages of patent prosecution and it is difficult to predict when patents will issue from those applications, if at all. These patents and patent applications cover methods of analyzing fetally-derived nucleic acids in maternal serum or plasma, methods of analyzing the methylation status of fetal nucleic acid to differentiate it from maternal nucleic acid, and various DNA and RNA markers which may be useful in detecting and diagnosing various fetal disorders, such as Down syndrome or maternal disorders, such as preeclampsia. We in-licensed United States Patent No. 6,258,540 and its foreign equivalents from ISIS in the United Kingdom. The European counterpart patent to U.S. Patent No. 6,258,540 is European Patent No. 994963. The 994963 Patent was the subject of an Opposition proceeding in the European Patent Office (the "EPO"), which was brought against ISIS by Ravgen, Inc. The Opposition concluded with the EPO's decision to affirm the grant of the European 994963 Patent, however, with amended claims consistent with the issued claims of its counterpart U.S. Patent. Ravgen has appealed the EPO's decision (Appeal No. T146/07-334) and the appeal remains currently pending before the EPO.

The majority of our issued U.S. patents pertaining to mass spectrometry-based nucleic acid analysis methods and technology will expire between 2013 and 2017. United States Patent Nos. 6,500,621, 6,300,076, 6,258,538, and 5,869,242 and European Patent No. EP 0815261 each claim nucleic acid analysis by mass spectrometry methods, including methods that may be performed using our MassARRAY system. Each of these patents expires in 2015.

Through our exclusive license agreement with Xenomics, Inc, we hold exclusive rights to patents for prenatal research and diagnostic uses and products using fetal nucleic acids found in maternal urine. The licensed patent rights include United States Patent Nos. 6,251,638; and RE 39,920, and foreign equivalents in Europe. These patents will expire between 2017 and 2018. The license provides us with exclusive rights to use transrenal fetal nucleic acids in maternal urine for noninvasive prenatal diagnostics and analysis on a platform and technology-independent basis for all uses, excluding fetal gender determination solely by the presence of Y chromosome. As described under Item 3 of this report, we are currently engaged in litigation with Xenomics regarding our rights under the license agreement.

Through our exclusive license agreement with Genomic Nanosystems, LLC, we hold exclusive rights to issued patents and pending patent applications providing fundamental rights for digital PCR technologies and methods. The issued patents are United States Patent Nos. 6,143,496; 6,391,559; and 7,459,315. These patents will expire in 2017. The license provides us with the exclusive right to use the technology on any platform for noninvasive prenatal diagnostics and analysis for any sample (for example, fetal cells, 'amniocentesis fluids, plasma, urine, etc.) and also in conjunction with mass spectrometry for any commercial, diagnostic or research purpose, excluding second generation sequencing.

Our success depends to a significant degree upon our ability to continue to develop proprietary products and technologies, to identify and validate useful genetic markers and to thoroughly understand their associations with disease, and to in-license desirable or necessary intellectual property as appropriate. We intend to continue to file patent applications as we develop new products and methods for nucleic acid analysis, and as we develop diagnostic and molecular medicine related technology and products. Patents provide some degree of protection for our intellectual property. However, the assertion of patent protection involves complex legal and factual determinations and is therefore uncertain. The laws governing patentability and the scope of patent coverage continue to evolve, particularly in the areas of genetics, molecular biology, and prenatal and molecular diagnostics that are of interest to us. There can be no assurance that patents will issue from any of our patent applications. The scope of any of our issued patents, including U.S. Patent No. 6,258,540, may not be sufficiently broad to offer meaningful protection.

Our issued patents may be successfully challenged, invalidated, circumvented or declared unenforceable so that our patent rights would not create an effective competitive barrier. The laws of some foreign countries may not permit such assignments or may not protect our proprietary rights to the same extent, as do the laws of the United States. In view of these factors, our intellectual property positions bear some degree of uncertainty. We also rely in part on trade secret protection and confidentiality agreements for protection of our intellectual property. We attempt to protect our trade secrets and confidential information by entering into confidentiality agreements with outside parties and with our employees and consultants. Our employees also sign agreements requiring that they assign to us their intellectual property interests in work performed for us as a part of their employment. The laws of some foreign countries may not permit such assignments or may not protect our proprietary rights to the same extent, as do the laws of the United States. All employees sign an agreement not to compete unfairly with us during their employment and upon termination of their employment, through the misuse of confidential information, soliciting employees, soliciting customers, and the like. It is possible that these agreements may be breached or invalidated and if so, there may not be an adequate corrective remedy available. Parties may breach the confidentiality provisions in our contracts or infringe or misappropriate our patents, copyrights, trademarks, trade secrets, confidential information, and other proprietary rights. Outside parties may independently discover or invent competing technologies or reverse engineer our trade secrets or other technology. The measures we are taking to protect our proprietary rights may not be adequate due to factors beyond our control.

In the future, parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether parties will assert such claims against us, or whether those claims will harm our business. For example, on February 15, 2011, Stanford University was issued United States Patent No. 7,888,017 titled "Non-invasive Fetal Genetic Screening by Digital Analysis" which includes patent claims purportedly covering methods for the noninvasive detection of fetal aneuploidy, or the '017 patent. We believe a competitor may have licensed rights to the '017 patent. If we challenge the validity of the '017 patent or defend against claims of infringement of that patent, or if we have to defend against any other asserted intellectual property right, we will face costly litigation and diversion of management's attention and resources. As a result of such disputes, we may have to develop costly non-infringing technology or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, which could seriously harm our business and financial condition.

#### Competition

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We face competition from various companies offering nucleic acid analysis systems and services, from various companies developing and commercializing diagnostic assays, and from various companies researching and developing prenatal diagnostic technology.

In the molecular diagnostic business, including the noninvasive prenatal diagnostic market, our tests are based on detection of circulating cell-free fetal nucleic acid in maternal plasma. Our exclusive license to the intellectual property surrounding the use of circulating cell-free fetal nucleic acids in maternal serum or plasma, and also the precision and accuracy of our MassARRAY system provide us with competitive advantages in this space. Our competition arises from alternative methods of noninvasive prenatal diagnostics such as fetal cell purification from maternal blood and trophoblast purification from cervical swabs, fetal cell approaches, and potentially from sequencing approaches. Competitors potentially include Ikonysis, Inc., Artemis Health, Inc., Celula Inc., Fluidigm Corp., Tandem Diagnostics, Inc. and others.

In the genetic analysis marketplace, our MassARRAY system competes with alternative technology platforms that differ in cost per data point, throughput, sample amplification, analysis process, sample separation or method of DNA detection, turnaround time and quality of results. Most competitive technologies do not rely on direct detection methods such as mass spectrometry, but instead use indirect sample detection methods, such as hybridization or labeling. Competitive technologies are offered by Life Technologies, Corp. (formerly Applied Biosystems, Inc.), Beckman Coulter, Inc., Illumina Inc., Biotage AB, Fluidigm Corp., Ibis Biosciences, Inc. (now Abbott), Luminex, KBiosystems and others.

#### **Research and Development**

We believe that investment in research and development is essential to establishing a long-term competitive position as a provider of genetic analysis tools and as a provider or an enabler of diagnostic tests. Our research and development expenses for the years ended December 31, 2010, 2009, and 2008, were \$43.4 million, \$37.5 million, and \$27.5 million, respectively.

During 2010, we conducted most of our research and development activities at our facilities in the United States. Our research and development is augmented by advisory and collaborative relationships with others.

During 2010, we reviewed our research and development initiatives and determined to focus our research and development efforts on our key initiatives. Our efforts were primarily focused on our continuing efforts to develop a noninvasive ccff prenatal test for trisomy 21, a new initiative to develop a noninvasive test for age-related macular degeneration, the completion of the launch of a next-generation MassARRAY system with improved performance and reliability, expansion of the applications for our MassARRAY technology and the introduction of new panels for our research and translational medicine customers.

#### Government Regulation

Regulation by governmental authorities in the United States and other countries will be a significant factor in the development, testing, production and marketing of diagnostic products, including tests that may be developed by us or our corporate partners, collaborators or licensees. Certain diagnostic products developed by us or our collaborators may require regulatory approval by governmental agencies prior to commercialization. Products that we develop in the diagnostic markets, depending on their intended use, will be regulated as medical devices by the FDA and regulatory agencies or bodies of other countries. In the United States, our diagnostic products will require either premarket approval, or PMA, or premarket notification, or 510(k), from the FDA prior to marketing in the U.S. The 510(k) notification process usually takes from three to six months from submission to clearance, but can take significantly longer. The PMA process is much more costly, lengthy, and uncertain and generally takes from nine to eighteen months or longer from submission to approval. The receipt and timing of regulatory clearances or approvals for the marketing of such products may have a significant effect on our future revenues. Human diagnostic products are subject to rigorous testing and other approval procedures by the FDA and similar regulatory agencies or bodies of other countries. Various federal and state regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of diagnostic products.

Obtaining these approvals and the subsequent compliance with these regulations require the expenditure of substantial resources over a significant period of time, and there can be no assurance that any clearance or approvals will be granted. Any such delay in obtaining or failure to obtain such clearance or approvals could adversely affect our ability to earn sales revenues, royalties or other license-based fees. Current governmental regulations may change as a result of future legislation or administrative action and cannot be predicted.

As mentioned above, our strategy focuses on capitalizing on our potential in molecular diagnostics markets with various noninvasive diagnostic tests and laboratory platform systems. Sequenom CMM's approach involves the development and launch of LDTs as a testing service to physicians. Sequenom CMM is responsible for the development, validation and commercialization of the testing service. Such laboratory developed tests are under the purview of CMS and State agencies that provide oversight of all laboratory testing (except research) performed on humans in the United States to ensure the accuracy and reliability of all laboratory testing. To date, the FDA has exercised its regulatory discretion not to regulate LDTs, as LDTs are developed and used by a single laboratory. The FDA has been reviewing their approach to regulation in the area of genetic testing, most notably direct-to-consumer genetic tests, and LDTs more broadly, and the laws and regulations may undergo change in the near future and these changes may have an impact to our business.

Further, Sequenom CMM and any other CLIA certified laboratories that we may partner with are subject to CLIA regulations, which are designed to ensure the quality and reliability of clinical laboratories by mandating specific standards in the areas of personnel qualifications, administration and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. Laboratories must undergo on-site surveys at least every two years, which may be conducted by the Federal CLIA program or by a private CMS approved accrediting agency, such as the College of American Pathologists, or CAP, among others. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. Sequenom CMM is also subject to regulation of laboratory operations under state clinical laboratory laws. State clinical laboratory laws may require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. Certain states, such as California, Florida, Maryland, New York, Pennsylvania and Rhode Island, each require that we obtain licenses to test specimens from patients residing in those states and additional states may require similar licenses in the future. Only Washington and New York State are exempt under CLIA, as these states have established laboratory quality standards at least as stringent as CLIA's. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations.

Our research and development activities involve the controlled use of hazardous materials and chemicals, however, the concentration and volumes of these chemicals are limited. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of such materials and chemicals, as well as certain waste products.

#### **Employees**

As of February 18, 2011, we employed 237 persons, of whom 46 hold Ph.D. or M.D. degrees and 46 hold other advanced degrees. Our success will depend in large part upon our ability to attract and retain employees. We face competition in this regard from other companies, research and academic institutions, government entities, and other organizations.

#### **Executive Officers**

Our executive officers, their positions with us, and their ages as of March 8, 2011 are as follows:

Name	Age	Position
Executive Officers		
Harry F. Hixson, Jr., Ph.D	72	Chief Executive Officer and Director
Ronald M. Lindsay, Ph.D.	63	Executive Vice President, Research and Development and Director
Paul V. Maier, M.B.A.	63	Chief Financial Officer
Allan Bombard, M.D., M.B.A.	58	Chief Medical Officer
Charles R. Cantor, Ph.D.	68	Chief Scientific Officer
Alisa Judge	55	Vice President, Human Resources
Michael Monko, M.B.A.	51	Senior Vice President, Sales and Marketing
Larry Myres	52	Vice President, Operations
Clarke Neumann, J.D.	47	Vice President and General Counsel
Dirk van den Boom, Ph.D	40	Senior Vice President, Research and Development
Robin Weiner, M.B.A.	55	Senior Vice President, Quality and Regulatory Affairs
William Welch, M.B.A	49	Senior Vice President, Diagnostics

*Harry F. Hixson, Jr., Ph.D.* Dr. Hixson has served as our chief executive officer since September 2009. Dr. Hixson has served as chairman of the board of directors since 2003. He recently served as a director of BrainCells, Inc., from December 2003 to February 2011, where he also served as chief executive officer from July 2004 until September 2005. Dr. Hixson served as chief executive officer of Elitra Pharmaceuticals, Inc., a

biopharmaceutical company focused on anti-infective drug development, from February 1998 until May 2003. He served as president and chief operating officer of Amgen Inc., and as a member of its board of directors from 1988 to 1991. Prior to Amgen, Dr. Hixson held various management positions with Abbott Laboratories, including vice president, diagnostic products business group, and vice president, research and development, in the Diagnostics Division. Dr. Hixson also is a director of Arena Pharmaceuticals, Inc., and from September 2006 until May 2010 served as a director of Infinity Pharmaceuticals, Inc., and from February 2009 until September 2010 served as a director of Novabay Pharmaceuticals. Dr. Hixson received his Ph.D. in Physical Biochemistry from Purdue University and an M.B.A. from the University of Chicago.

Ronald M. Lindsay, Ph.D. Dr. Lindsay has served as our executive vice president of research and development since August 2010 and previously served as our interim senior vice president of research and development from September 2009 until August 2010. Dr. Lindsay has served as a member of our board of directors since 2003. He currently operates Milestone Consulting, a biopharmaceutical consulting firm. Dr. Lindsay served as vice president, research and development, and chief science officer of diaDexus Inc., a biotechnology company, from 2000 to January 2004. From 1997 through 2000, Dr. Lindsay served in various senior management roles with Millennium Pharmaceuticals, Inc., a biopharmaceutical company. From 1989 to 1997, Dr. Lindsay served in various roles with Regeneron Pharmaceuticals Inc., of which he was a founding scientist. He is a director of Arque Inc., and HistoRx Inc. Dr. Lindsay received his Ph.D. in Biochemistry from the University of Calgary.

*Paul V. Maier, M.B.A.* Mr. Maier has served as our chief financial officer since November 2009. Mr. Maier served as senior vice president and chief financial officer of Ligand Pharmaceuticals Incorporated from 1992 until January 2007, where he helped build Ligand from a venture stage company to a commercial, integrated biopharmaceutical organization. Prior to Ligand, Mr. Maier spent six years in various management and finance positions at ICN Pharmaceuticals. Mr. Maier currently serves as a director of Talon Therapeutics (formerly Hana Biosciences, Inc.), Pure Bioscience, and International Stem Cell Corporation. Mr. Maier received his M.B.A. from Harvard University.

Allan Bombard, M.D., M.B.A. Dr. Bombard has served as our chief medical officer since January 2009. From October 2008 to January 2009, Dr. Bombard was the chief executive officer of Lenetix Medical Laboratory, which provided genetic screening and diagnostic testing for obstetricians, gynecologists, family practitioners, nurse midwives, laboratories, diagnostic facilities and other healthcare providers. From April 2005 to October 2008, Dr. Bombard was chief medical officer of Sharp Mary Birch Hospital for Women. From 2002 to 2005, Dr. Bombard served as senior vice president, chair, and residency program director of the Department of Obstetrics and Gynecology at Lutheran Medical Center. Prior to Lutheran Medical Center, he served as the western United States medical director for women's health at Aetna. Dr. Bombard is currently clinical professor in the Department of Reproductive Medicine at the University of California San Diego. Dr. Bombard received his M.D. from the George Washington University and his M.B.A. from the University of San Diego.

*Charles R. Cantor, Ph.D.* Dr. Cantor has served as our chief scientific officer and chairman of the scientific advisory board since August 1998 and served as a member of our board of directors from 1998 to 2009. Dr. Cantor is also a director of DiThera, Inc., a biotechnology company that he founded in 2007. Since 1992, Dr. Cantor has served as a professor in the Department of Biomedical Engineering and co-director of the Center for Advanced Biotechnology at Boston University. Prior to that time, Dr. Cantor held positions at Columbia University and the University of California, Berkeley. He was also director of the Human Genome Center of the Department of Energy at Lawrence Berkeley Laboratory. Dr. Cantor published the first textbook on genomics, *The Science and Technology of the Human Genome Project*, and remains active in the Human Genome Project through his membership in a number of the project's advisory committees and review boards. Dr. Cantor is a member of the National Academy of Sciences. He is also a scientific advisor to 12 biotechnology and life science companies and one venture capital firm. Dr. Cantor currently serves as a director of ExSAR, Inc., Human BioMolecular Research Institute, and Retrotrope, Inc. Dr. Cantor received his Ph.D. in Chemistry from the University of California, Berkeley.

Alisa Judge. Ms. Judge has served as our vice president, human resources, since June 2007, and brings over 20 years of human resources experience having previously served as vice president of human resources, from April 2005 to June 2007, at Claritas, a division of the Nielsen Company, a provider of marketing information and audience measurement. Prior to Claritas, Ms. Judge held the same role, from February 2003 to February 2005 for GKN Aerospace Chem-tronics, a supplier to automotive and aerospace manufacturers. Ms. Judge holds a B.S. in Business from Humboldt State University.

*Michael Monko, M.B.A.* Mr. Monko has served as our senior vice president, sales and marketing since August 2006. Mr. Monko served as vice president of sales for the organization that is now the diagnostics strategic business unit of Millipore, a bioscience research and biopharmaceutical manufacturing supplier, from 2005 to July 2006. Previously, he served 19 years in various sales roles at Invitrogen Corporation (now Life Technologies, Corp.), a biotechnology tools company. Mr. Monko received his M.B.A. from Babson College.

*Larry Myres*. Mr. Myres has served as our vicé president, operations since November 2005. Mr. Myres was vice president of operations for DexCom, Inc., a medical device company, from 2000 to 2005 and Precision Vascular Systems, a medical device company, from 1997 to 2000. Mr. Myres received his Bachelor of Science degree from Westminster College of Salt Lake City.

*Clarke Neumann, J.D.* Mr. Neumann has served as our vice president, general counsel, and assistant secretary since May 1999 and served as our corporate counsel from July 1999 to May 2001. Prior to joining us, Mr. Neumann was an attorney at Lyon & Lyon, LLP, specializing in intellectual property litigation, strategic counseling, business litigation and transactional matters. Mr. Neumann holds a J.D. from Loyola Law School, Los Angeles and a B.S. in chemical engineering from Pennsylvania State University.

*Dirk van den Boom, Ph.D.* Dr. van den Boom has served as our senior vice president of research and development since August 2010 and previously served as our vice president, research and development from October 2009 to August 2010. Dr. van den Boom joined Sequenom in 1998 in the company's Hamburg offices, subsequently serving in various management roles within our research and development department. Dr. van den Boom has co-authored more than 50 scientific articles and is inventor on 48 patents/patent applications. He received his Ph.D. in Biochemistry/Molecular Biology from the University of Hamburg where he focused on various aspects of nucleic acid analysis with mass spectrometry.

*Robin Weiner, M.B.A.* Ms. Weiner has served as our senior vice president of quality and regulatory affairs since October 2010. Prior to joining us, Ms. Weiner was an independent regulatory consultant to biotechnology companies, focusing on regulatory strategy, product submissions and quality management systems. From 2004 to 2007, Ms. Weiner served as vice president regulatory and government affairs at Biosite Incorporated, a medical device company, and was responsible for leading Biosite's worldwide product approvals and regulatory compliance activities. Ms. Weiner holds a bachelor's degree from the University of California, San Diego and a master's degree in business administration from National University.

*William Welch, M.B.A.* Mr. Welch has served as our senior vice president, diagnostic, since January 2011. Prior to joining us, Mr. Welch was a consultant to molecular diagnostic companies in the personalized medicine sector. From August 2005 to September 2009 Mr. Welch was senior vice president and chief commercial officer at Monogram Biosciences, a bioscience laboratory services company, where he led sales, marketing, commercial operations and pharma alliances for its oncology and virology businesses. Prior to Monogram, Mr. Welch was vice president of sales and marketing from September 2001 to August 2005 at La Jolla Pharmaceuticals, a biopharmaceutical company. Mr. Welch holds a B.S. in chemical engineering from the University of California at Berkeley and received his M.B.A. from Harvard University.

#### **Available Information**

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, amendments to those reports, and other information with the SEC. We will supply a copy of any document we file with the SEC, without charge. To request a copy, please contact Investor Relations, Sequenom, Inc., 3595 John Hopkins Court, San Diego, CA, 92121, USA. The public may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street NE, Washington, D.C. 20549, or by calling the SEC at 1-800-SEC-0330, or by accessing the SEC's website at *www.sec.gov*, where the SEC maintains reports, proxy and information statements and other information regarding us and other issuers that file electronically with the SEC. In addition, as soon as reasonably practicable after such materials are filed with or furnished to the SEC, we make copies available to the public free of charge through our website at *www.sequenom.com*. We also regularly post on our corporate website copies of our press releases as well as additional information about us. Interested persons can subscribe on our website to email alerts that are sent automatically when we issue press releases, when we file our reports with the SEC, or when certain other information becomes available.

#### Item 1A. RISK FACTORS

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Before deciding to invest in us or deciding to maintain or increase your investment, you should carefully consider the risks described below, in addition to the other information contained in this report and in our other filings with the SEC. The risks and uncertainties described below and in our other filings are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business. If any of these known or unknown risks or uncertainties actually occurs, our business, financial condition and results of operations could be seriously harmed. In that event, the market price for our common stock could decline and you may lose your investment.

If we fail to obtain the capital necessary to fund our operations, our financial results, financial condition and our ability to continue as a going concern will be adversely affected and we will have to delay or terminate some or all of our product development programs.

We expect to continue to incur losses for the foreseeable future and may have to raise substantial cash to fund our planned operations.

Our cash, cash equivalents and current marketable securities were \$135.5 million as of December 31, 2010. Based on our current plans, we believe our cash, cash equivalents and current marketable securities will be sufficient to fund our operating expenses and capital requirements into early 2013. Our announced plans for research and development activities to expand our diagnostic test menu can only be implemented if we are successful in raising significant funds. In addition, there can be no assurances that our research and development activities will be successful. We need to collect a large number of patient samples in a timely manner in order to execute our molecular diagnostic research and development activities. If we do not make sufficient research and development progress, this could adversely impact our ability to raise significant additional funds, which could adversely impact our ability to continue as a going concern. The actual amount of funds that we will need and the timing of any such investment will be determined by many factors, some of which are beyond our control.

In September 2010, we filed a shelf registration statement with the SEC providing for the sale by us of up to \$150 million of our equity and debt securities from time to time in one or more transactions. This registration statement was declared effective by the SEC in October 2010 and is intended to provide us with the flexibility to take advantage of potential financing opportunities when and if deemed appropriate by our management. In December 2010, pursuant to this registration statement, we issued and sold 16,100,000 shares of our common stock at a price of \$6.00 per share in a public offering that raised net proceeds of approximately \$90.6 million. In addition to the capital we raised in December 2010, we anticipate that we may need to raise additional funds in the future for the continued development and commercialization of our molecular diagnostic technology. We may need to sell equity or debt securities to raise significant additional funds. However, it may be difficult for us to raise additional capital through the sale of equity or debt securities. The sale of additional securities will likely

result in dilution to our stockholders. Additional financing may not be available in amounts or on terms satisfactory to us or at all. We may be unable to raise additional funds due to a variety of factors, including our financial condition, the status of our research and development programs, the status of ongoing litigation and pending governmental investigations and the general condition of the financial markets. If we fail to raise additional funds, we will have to delay or terminate some or all of our research and development programs, our financial condition and operating results will be adversely affected and we may have to cease our operations.

The amount of additional funds we will need depends on many factors, including:

• the size of our future operating losses;

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- our success and our distributors' success in selling our MassARRAY system, ancillary reagents, software and services;
- Sequenom CMM's success in making available its testing service for cystic fibrosis carrier screening and fetal Rhesus D genotyping and the level of reimbursement it receives and its collections for those tests;
- the terms and conditions of sales contracts, including extended payment terms;
- our ability to introduce and sell new MassARRAY system, ancillary reagents, software and services, including the MassARRAY Analyzer 4;
- the level of our selling, general and administrative expenses;
- our success and the extent of our investment in the research, development and commercialization of diagnostic technology, including genetic analysis technology, molecular diagnostics and noninvasive prenatal diagnostic technology;
- our success in obtaining sufficient quantities and quality of patient samples;
- our success in obtaining regulatory clearance or approval to market our diagnostic products in various countries, including the United States;
- our success in validating our diagnostic tests and the levels of clinical performance achieved;
- our success either alone or in collaboration with our partners in launching and selling additional diagnostic products or services;
- our success and the extent of our investment in the research and development in our genetic analysis business;
- the extent to which we enter into, maintain, and derive revenues from licensing agreements, including agreements to out-license our noninvasive prenatal analysis technology, research and other collaborations, joint ventures and other business arrangements;
- the amount of our legal expenses and any fines or damages arising out of the matters that were the subject of an investigation by a special committee of our board of directors in 2009, including such amounts associated with the investigations by the SEC, the Office of the U.S. Attorney for the Southern District of California and the FBI, and the claims asserted by TrovaGene (formerly Xenomics), none of which are currently covered by insurance;
- the level of our legal expenses and any damages or settlement payments arising from the lawsuit filed by our former chief financial officer to the extent our insurance coverage is insufficient;
- the amount of any legal expenses, settlement payments, fines or damages arising from any future investigation or litigation and the extent to which any of the foregoing is covered by insurance;
- the dilution from any issuance of securities, whether in connection with future capital-raising or acquisition transactions, the settlement of litigation, or otherwise;
- the extent to which we acquire, and our success in integrating, technologies or companies;

- the level of our expenses associated with the audit of our consolidated financial statements as well as compliance with other corporate governance and regulatory developments or initiatives;
- regulatory changes by the FDA and other worldwide regulatory authorities; or
- technological developments in our markets.

General market conditions, the market price of our common stock, uncertainty about the successful development and validation of the trisomy 21 test and other LDTs and diagnostic tests, the uncertainty regarding the results of ongoing litigation matters and the investigations by the SEC, the U.S. Attorney and the FBI or other factors may not support capital raising transactions. In addition, our ability to raise additional capital may depend upon obtaining stockholder approval. There can be no assurance that we will be able to obtain stockholder approval if it is necessary. If we are unable to obtain sufficient additional funds on a timely basis or on terms favorable to us, we may be required to cease or reduce further commercialization of our products, to cease or reduce certain research and development projects, to sell, license or otherwise dispose of some or all of our technology or assets or business units, to merge all or a portion of our business with another entity or we may not be able to continue as a going concern. If we raise additional funds by selling shares of our capital stock (or otherwise issue shares of our capital stock or rights to acquire share of our capital stock), the ownership interest of our current stockholders will be diluted.

## Uncertainty regarding the SensiGene Trisomy 21 Test and other planned tests could materially adversely affect our business, financial condition and results of operations.

We announced in April 2009 that previously reported test data and results for the noninvasive prenatal test for trisomy 21 then under development could not be relied upon. As a result, the launch of the test did not occur. While Sequenom CMM is continuing its research and development program for a noninvasive prenatal test for trisomy 21, it is no longer trying to develop a test that analyzes RNA samples. Sequenom CMM is now focusing its research and development efforts on a noninvasive trisomy 21 test that analyzes DNA samples utilizing MPSS instead of our proprietary MassARRAY system. We and Sequenom CMM have limited experience developing and no experience commercializing sequencing-based technology and would need to rely on collaborative partners and sequencing technology provided by others in order to commercialize a test utilizing sequencing. We have no control over the manufacture of the sequencers and consumables that Sequenom CMM expects to use for the SensiGene Trisomy 21 Test, including whether such sequencers will meet our quality system requirements to ensure quality and reliability for the sequencers and consumables, and can give no assurance that we will be able to obtain a reliable supply of the sequencers and consumables that we will need for such a test.

The launch of any diagnostic test will require the completion of certain clinical development and commercialization activities, including the efforts of collaborative partners on which we rely, and the expenditure of additional cash resources. We can give no assurance that we will be able to successfully complete the clinical development of any test or that we will be able to establish or maintain the collaborative relationships that are essential to our clinical development and commercialization efforts. We also can give no assurance that we will be able to reduce our expenditures sufficiently or otherwise mitigate the risks associated with our business to raise enough capital to complete clinical development or commercialization activities. Clinical development requires large numbers of patient samples and we may not be able to use prior collected samples or collect a sufficient number of appropriate samples in a timely manner in the future to complete clinical development for a trisomy 21 test or any other planned molecular diagnostic test. Failure to possess or to collect a sufficient number of appropriate samples in a timely manner or significantly delay our ability to research, develop, complete clinical development and validation, obtain FDA approval as may be necessary, and launch, any of the planned tests. Our inability to use prior collected samples or any failure to complete our on-going clinical studies or commercialization of the trisomy 21 test, as well as other planned screening and diagnostic tests could have material adverse effects on our business, operating results or financial condition.

# We are the subject of investigations by the SEC, the Office of the U.S. Attorney for the Southern District of California and the FBI, each of which could further adversely affect our reputation, business prospects, operating results, or financial condition.

In June 2009, we received written notification that the staff of the SEC has initiated an investigation relating to our April 29, 2009 announcement regarding the trisomy 21 test then under development. As part of this investigation, the SEC staff has also required us to produce information with respect to our announcements relating to our offer to acquire EXACT Sciences, Inc. in January 2009. We intend to continue to cooperate fully with the SEC in its investigation. Following our announcement on September 28, 2009 regarding the completion of the independent investigation by the special committee of our board of directors, the Office of the U.S. Attorney for the Southern District of California and the FBI contacted us to inquire about our announcement. We intend to continue to cooperate fully with the U.S. Attorney and the FBI.

In June 2010, the SEC filed a complaint against Elizabeth Dragon, who was formerly our senior vice president, research and development. The complaint alleges that between June 2008 and January 2009 Dr. Dragon made or allowed for the dissemination of materially false and misleading statements regarding the trisomy 21 test then under development, thereby inflating the price of our stock. The SEC sought a permanent injunction against any future violations of the federal securities laws by Dr. Dragon, civil penalties, and imposition of an officer and director bar against her. On the same day, Dr. Dragon filed a consent to judgment of permanent injunction and other relief. In the consent to judgment, Dr. Dragon, without admitting or denying the allegations in the SEC's complaint, agreed to the permanent injunction against future violations of federal securities laws, the director and officer bar, and civil penalties to be determined by the court.

In June 2010, the U.S. Attorney filed a criminal information against Dr. Dragon. The criminal information charges Dr. Dragon with one count of conspiracy to commit securities fraud by conspiring to disseminate materially false and misleading statements regarding the trisomy 21 test then under development. On the same day, Dr. Dragon pled guilty to the criminal information, and the magistrate judge assigned to this matter recommended that the district court judge accept Dr. Dragon's guilty plea. Prior to sentencing, Dr. Dragon passed away in February 2011.

On March 7, 2011, the staff of the SEC advised us that it is considering recommending that the SEC bring a civil injunctive action against us alleging that we violated Sections 10(b) and 13(a) of the Exchange Act of 1934 and Rules 10b-5, 12b-20, 13a-1 and 13a-11 thereunder. We have cooperated fully with the SEC in its investigation and will endeavor to negotiate an acceptable injunctive resolution with the staff, but any resolution that we may negotiate with the staff will be subject to the approval of the SEC. There can be no assurance that such resolution will be limited to injunctive relief or that such resolution will not have a material adverse effect on our business, results of operation or financial condition.

The investigations by the SEC, the U.S. Attorney and the FBI have had an adverse impact on our reputation, and if they continue for a prolonged period of time, they may have a further adverse impact on our reputation, business prospects, operating results or financial condition. There can be no assurance that we will be able to negotiate an acceptable injunctive resolution with the staff of the SEC or that the SEC will approve any resolution that we negotiate with the staff or that any resolution of this matter will not have a material adverse effect on our reputation, business prospects, operating results or financial condition. In the event that the investigations by the SEC, the U.S. Attorney or the FBI lead to action against us or additional action against any current or former officer or director, our reputation, business prospects, operating results or our current and former officers and directors, which require that we advance the expenses they incur, including the fees and costs of their attorneys' in connection with these matters. These matters are likely to result in the continued incurrence of significant legal expenses, which have exceeded our available insurance policy limits. These matters may result in the diversion of management's attention from our business and may have a negative effect on employee morale.

# We and certain of our current executive officers and directors have been named as defendants in litigation that could result in substantial costs, divert management's attention and otherwise result in dilution to our stockholders.

On September 24, 2010, we were served with a complaint in a lawsuit filed by our former chief financial officer. He has asserted various claims against us, our chief executive officer, our executive vice president and one of our directors arising out of his resignation in September 2009. Although we intend to continue to vigorously defend such claims, there is no guarantee that we will be successful and we may be have to pay damages awards or otherwise may enter into settlement arrangements in connection with such other claims. Any such payments or settlement arrangements could have material adverse effects on our business, operating results or financial condition. We may be required to issue additional shares of our common stock or other securities convertible into or exchangeable for our common stock in connection with future settlements, which would result in additional dilution to our stockholders. Even if the pending claims are not successful, litigation with respect to such claims could result in substantial costs and significant adverse impact on our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

#### We have limited experience.

Sequenom CMM's noninvasive prenatal and other molecular diagnostic laboratory developed tests are at an early stage of discovery and development or have just recently been launched. Additionally, we continue to develop new products and create new applications for our products. We are also researching, developing and pursuing the commercialization of additional noninvasive molecular diagnostic tests for prenatal genetic disorders and other diseases and disorders for use on our MassARRAY system and other platforms, and we have limited or no experience in these applications of our technology and operating and selling in these markets. We have limited experience developing and no experience commercializing sequencing-based technology and would need to rely on collaborative partners and sequencing technology provided by others in order to commercialize any test utilizing sequencing, including a noninvasive prenatal test for trisomy 21. Among other risks, using a platform provided by another party presents potential manufacturing supply and reliability, FDA quality compliance, and intellectual property infringement risks. Sequenom CMM has limited knowledge and experience regarding AMD and its associated genetics and genetic factors and as a result, may be unable to conduct and complete adequate research and development activities in order to develop a commercially viable LDT for AMD. You should evaluate us in the context of the uncertainties and complexities affecting an early stage company developing products and applications for the life science industries and experiencing the challenges associated with entering into new markets that are highly competitive. Based on our limited experience in developing new products and applications, we may not:

- effectively execute on or focus our research and development efforts;
- properly model new opportunities to ensure appropriate resource allocation;
- create products that are appropriately developed to meet customer needs;
- perform adequate and timely validation testing of such products and applications;
- effectively assess and meet regulatory requirements in the United States and other countries;
- ensure appropriate communication between different departments responsible for commercialization activities;
- implement effective product launch or sales strategies;
- effectively design and manufacture products that achieve commercial success; or
- take other actions that ultimately lead to commercial success of any new products or applications that we develop.

Sequenom CMM may face setbacks in the development and validation of noninvasive prenatal and other molecular diagnostic laboratory developed tests. As previously announced, Sequenom CMM is no longer relying on prior studies related to the trisomy 21 LDT previously under development. While Sequenom CMM is continuing its research and development program for a noninvasive prenatal test for trisomy 21, it is no longer trying to develop a LDT that analyzes RNA samples. Sequenom CMM is now focusing its research and development efforts on a noninvasive trisomy 21 test that analyzes DNA samples utilizing MPSS instead of Sequenom's proprietary MassARRAY system.

We need to make significant investments to ensure our diagnostic tests as well as our genetic analysis products and applications perform properly and are cost-effective. We or our partners will likely need to apply for and obtain certain regulatory approvals to sell certain of our products under development for diagnostic applications, and it is uncertain whether such approvals will be granted. Even if we develop products for commercial use and obtain all necessary regulatory approvals, we may not be able to develop products that are accepted or satisfy customers in the genomic, diagnostic, noninvasive prenatal, clinical research, pharmaceutical, or other markets or the emerging field of molecular medicine and that can be marketed and sold successfully.

### We may not be able to generate significant revenue from noninvasive prenatal diagnostic tests or any other tests we may develop.

Our business is substantially dependent on our ability to develop and launch our diagnostic tests and Sequenom CMM laboratory developed tests. Sequenom CMM has committed significant research and development resources for the development and validation of laboratory developed tests and Sequenom has likewise invested significant research and development resources. There is no guarantee that Sequenom CMM will successfully generate significant revenues from any of its testing services that Sequenom CMM has launched or plans to launch in the future. In September 2009, Sequenom CMM launched a testing service for cystic fibrosis carrier screening. In early 2010, Sequenom CMM launched a testing service for noninvasive prenatal Rhesus D. Sequenom CMM is pursuing the development and launch of a testing service for assessment of risk for progressing from early to late AMD, as well as a testing service for noninvasive prenatal risk assessment for trisomy 21 and additional testing services in the future. However, there is no guarantee that Sequenom CMM will be able to successfully launch any of these or any other diagnostic testing services on anticipated timelines or at all. We have limited experience in licensing, manufacturing, selling, marketing or distributing our SEQureDx technology, or diagnostic or other tests. If we, or our partners, are not able to successfully market or sell noninvasive prenatal diagnostic tests or other tests we may develop for any reason, including the failure to obtain any required regulatory approvals, we will not generate any revenue from the sale of such tests or Sequenom CMM's laboratory developed testing services. Even if we are able to develop noninvasive prenatal diagnostic or other tests for sale in the marketplace, a number of factors could impact our ability to sell such tests or generate any significant revenue from the sale of such tests or testing services, including the following:

- the outcome of the investigations by the SEC, the Office of the U.S. Attorney for the Southern District of California and the FBI and private litigation;
- the effectiveness of the remedial measures recommended by the special committee following its independent investigation and our ability to implement additional controls and risk management measures as appropriate;
- our ability to establish and maintain sufficient intellectual property rights in our products;
- intellectual property rights held by others, including United States Patent No. 7,888,017 titled "Noninvasive Fetal Genetic Screening by Digital Analysis" assigned to Stanford University, or others infringing our intellectual property rights;
- the availability of adequate study samples for validation studies for any diagnostic tests we develop;
- reliance on Sequenom CMM, which is subject to routine governmental oversight and inspections for continued operation pursuant to CLIA, to process tests ordered by physicians;

- Sequenom CMM's ability to establish and maintain adequate infrastructure to support the commercial launch of its testing services of its LDTs, including establishing adequate laboratory space, information technology infrastructure, sample collection and tracking systems, electronic ordering and reporting systems and other infrastructure and hiring adequate laboratory and other personnel;
- Sequenom CMM's success of the validation studies for its LDTs under development and its ability to continue to publish study results in peer-reviewed journals;
- the availability of alternative and competing tests or products and technological innovations or other advances in medicine that cause our technologies to be less competitive;
- compliance with federal, state and foreign regulations governing laboratory testing on human specimens;
- the sale and marketing of research use only or other tests, including noninvasive prenatal tests;
- the accuracy rates of such tests, including rates of false negatives and/or false positives;
- concerns regarding the safety and effectiveness or clinical validity of noninvasive prenatal or other tests;
- changes in the regulatory environment affecting health care and health care providers, including changes in laws regulating laboratory testing and/or device manufacturers and any laws regulating prenatal testing;
- the extent and success of Sequenom CMM's sales and marketing efforts and ability to drive adoption of its diagnostic testing services;
- coverage and reimbursement levels by government payors and private insurers;
- the level of physician adoption of any diagnostic tests we or Sequenom CMM develops;
- pricing pressures and changes in third-party payor reimbursement policies;
- general changes or developments in the market for women's and/or prenatal health diagnostics, or diagnostics in general;
- ethical and legal issues concerning the appropriate use of the information resulting from noninvasive prenatal diagnostic tests or other tests;
- the refusal by women to undergo such tests for moral, religious or other reasons, or based on perceptions about the safety or reliability of such tests;
- our ability to provide effective customer support; or
- our ability to promote and protect our SEQureDx brand and patented technology and our other brands and technologies.

#### Our operating results may fluctuate significantly.

Our revenues and results of operations may fluctuate significantly, depending on a variety of factors, including the following:

- our ability to manage costs and expenses and effectively implement our business strategy;
- our ability to raise additional capital and continue as a going concern;
- our success and our distributors' success in marketing and selling, and changes in the demand for, our products and services, including our MassARRAY system and iPLEX multiplex genotyping application and other applications and related consumables, and demand for products and services for genotyping, DNA methylation (epigenetic analysis) and QGE (gene expression analysis) applications;

- Sequenom CMM's success in providing its cystic fibrosis carrier screening and fetal Rhesus D genotyping testing services and the level of reimbursement Sequenom CMM receives and its collections for those tests;
- our success in manufacturing, marketing and selling the MassARRAY Analyzer 4;
- the pricing of our products and services and those of our competitors;
- our success in collecting payments from customers and collaborative partners, variations in the timing of these payments and the recognition of these payments as revenues;
- our success in responding to customer complaints effectively and managing relationships with our customers;
- the timing and cost of any new product or service offerings by us;
- our ability to identify and develop in a cost-efficient manner new applications and products, such as
  noninvasive prenatal or other diagnostic assays and other diagnostic technologies, our ability to
  improve current products to increase demand for such products and the success of such applications,
  products and improvements;
- our ability to establish and maintain sufficient intellectual property rights in our products;
- the potential need to acquire licenses to new technology, including genetic markers that may be useful in diagnostic applications, or to use our technology in new markets, which could require us to pay unanticipated license fees and royalties in connection with licenses we may need to acquire;
- our research and development progress and how rapidly we are able to achieve technical milestones;
- the cost, quality and availability of the MassARRAY Analyzer 4, consumable chips, also known as SpectroCHIP bioarrays, oligonucleotides, DNA samples, tissue samples, reagents and related components and technologies;
- material developments in our customer and supplier relationships, including our ability to successfully transition to new technologies;
- Sequenom CMM's ability to validate any potential noninvasive prenatal or other LDTs;
- our ability to obtain regulatory clearance or approval of any potential diagnostic product;
- the level of our legal expenses and any fines or damages arising out of the matters that were the subject of an investigation by a special committee of our board of directors in 2009, including the investigations by the SEC, the Office of the U.S. Attorney for the Southern District of California and the FBI, and the claims asserted by TrovaGene (formerly Xenomics), none of which are covered any longer by insurance; or
- the level of our legal expenses and any fines, damages or settlement payments arising from the lawsuit filed by our former chief financial officer any future investigation or litigation and the extent to which any of the foregoing is covered by insurance.

Further, our revenues and operating results are difficult to predict because Sequenom CMM's testing services have only recently been launched and we do not have sufficient history to forecast revenues reliably for those tests, and also because our revenues and operating results depend on the number, timing, and type of MassARRAY system placements that we make during the year and the quantity and timing of consumables sales for the installed base of systems. Changes in the relative mix of our MassARRAY system and consumables sales, as well as service agreements can have a significant impact on our gross margin, as consumable sales and service agreements typically have margins significantly different than MassARRAY system sales. Our international revenues and operating results are also difficult to predict because they depend upon the activities of our distributors in some countries. The absence of or delay in generating revenues will have a significant adverse effect on our operating results from period to period and result in increased operating losses.

We believe that period-to-period comparisons of our financial results will not necessarily be meaningful. You should not rely on these comparisons as an indication of our future performance. If our operating results in any future period fall below the expectations of securities analysts and investors, our stock price will likely fall.

#### A reduction in revenues from sales of MassARRAY products would harm our business.

We expect that sales of MassARRAY systems and consumables will account for most of our total revenues throughout 2011 and perhaps thereafter, unless and until our noninvasive prenatal or Sequenom CMM's testing services begin to generate significant revenues. The following factors, among others, would reduce the demand for MassARRAY products and services:

- our success in manufacturing, marketing and selling the MassARRAY Analyzer 4;
- our ability to maintain necessary quality standards and specifications for the MassARRAY Analyzer 4;
- unstable, weak, or deteriorating economic conditions and fiscal policies or changes in fiscal policies that negatively impact customer buying decisions;
- uncertainty about our ability to continue as a going concern and supply products and services to customers;
- competition from other products and service providers or failure of our products or applications or services; or
- negative publicity or evaluations, particularly with respect to product warranty and repair and troubleshooting services provided to existing customers, or with respect to the investigations by the SEC, the Office of the U.S. Attorney for the Southern District of California or the FBI, or the lawsuit filed by our former chief financial officer or other private litigation, developments or events in our prenatal diagnostic and other programs.

#### Our revenues are subject to risks faced by our customers and potential customers.

We expect that our revenues throughout 2011 and perhaps thereafter, unless and until our noninvasive prenatal and Sequenom CMM's testing services begin to generate significant revenues, will be derived primarily from MassARRAY system products provided to academic institutions and other research institutions. Our operating results could fluctuate substantially due to reductions and delays in research and development expenditures by these customers. These reductions and delays could result from factors such as:

- changes in economic conditions and possible country-based boycotts;
- changes in government programs that provide funding for these customers;
- other factors affecting research and development spending; or
- uncertainty about our ability to continue as a going concern and fund operations and supply products and services to customers.

None of these factors are within our control. We have broadened the markets to which we sell our products and applications and continue to develop new applications and products for use in new markets. We are targeting customers in clinical research and clinical marker validation, the emerging field of molecular medicine, genetic service laboratories, and animal testing laboratories and diagnostic testing markets. We have limited or no experience operating in certain of these potential markets and, as a result, may be unable to develop products and applications that allow us to penetrate these markets or successfully generate any revenue from sales in these markets. We have limited ability to forecast demand for our products and applications in these markets.

## We depend on sales of our consumable chips and other MassARRAY consumables for a significant portion of our revenues.

Sales of our consumable chips and other consumables for the MassARRAY system are an important source of revenue. Revenues from MassARRAY consumables totaled approximately 46% of our total revenues for the year ended December 31, 2010, compared to 54% of our total revenues for the year ended December 31, 2009. Factors which may limit the use of our consumable chips and other consumables or otherwise adversely affect our revenues from consumables include:

- the extent of our customers' level of utilization of their MassARRAY systems;
- our ability to provide timely repair services and our ability to secure replacement parts, such as lasers, for our MassARRAY systems;
- our ability to successfully transition to the MassARRAY Analyzer 4;
- the extent to which customers increase multiplexing levels using iPLEX applications;
- the availability and adoption of new technologies and applications provided by our competitors;
- a failure to sell additional MassARRAY systems;

- the termination of contracts with or adverse developments in our relations with suppliers of our consumables;
- the training of customer personnel in the use of our products;
- the acceptance of our technology by our customers;
- any negative publicity with respect to the investigations by the SEC, the Office of the U.S. Attorney for the Southern District of California or the FBI, the lawsuit filed by our former chief financial officer or other private litigation or developments or events in our prenatal diagnostic and other programs;
- uncertainty about our ability to continue as a going concern and fund operations and supply products and services to customers;
- our ability to maintain necessary quality standards and specifications for our SpectroCHIP products; or
- our ability to transition to new suppliers for components for the MassARRAY Analyzer 4 and to maintain such relationships.

# Our wholly-owned subsidiary, Sequenom CMM, has limited experience operating a CLIA-certified laboratory. Its ability to successfully develop and commercialize LDTs will depend on its ability to successfully operate its CLIA-certified laboratory and maintain required regulatory licensures.

Sequenom CMM, our wholly-owned CLIA-certified laboratory located in Grand Rapids, Michigan, has developed, validated and commercialized three LDTs. We acquired Sequenom CMM in 2008 and as a result have limited experience operating a CLIA-certified laboratory. For future tests, if Sequenom CMM is unable to successfully develop and validate any new LDTs or other testing services that it intends to commercialize it may not be able to successfully commercialize such tests on the anticipated timelines or at all. Although we have invested substantially in Sequenom CMM's infrastructure, it is possible that they may not have adequate infrastructure in place to meet demand for its currently launched testing services or for the demand of future LDTs that it develops. In 2010 we established an additional Sequenom CMM laboratory in San Diego and a California clinical laboratory license was issued by the state to the San Diego laboratory in October 2010. A federal CLIA certification was issued by CMS. Sequenom CMM's ability to successfully develop and validate LDTs will depend on its ability to successfully operate and maintain required regulatory licensure. We cannot provide assurances that we or Sequenom CMM will have sufficient resources to successfully build or qualify an additional CLIA-certified laboratory.

CLIA is designed to ensure the quality and reliability of clinical laboratories by mandating specific standards in the areas of personnel qualifications, administration and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. Laboratories must undergo on-site surveys at least every two years, which may be conducted by the Federal CLIA program or by a private CMS approved accrediting agency such as the College of American Pathologists, or CAP, among others. Sequenom CMM is also subject to regulation of laboratory operations under state clinical laboratory laws as will be any new CLIA-certified laboratory that we establish or acquire. State clinical laboratory laws may require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. Certain states, such as California, Florida, Maryland, New York, Pennsylvania and Rhode Island, each requires that laboratories obtain licenses to test specimens from patients residing in those states and additional states may require similar licenses in the future. If we are unable to obtain and maintain a license from these states, we will not be able to process any samples from patients located in those states. Only Washington and New York States are exempt under CLIA, as these states have established laboratory quality standards at least as stringent as CLIA's. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations, which could adversely affect our business and results of operations.

#### We may not successfully obtain regulatory approval of any noninvasive prenatal or other diagnostic product or other product which we or our licensing or collaborative partners develop.

Products that we or our collaborators develop in the molecular medicine, diagnostic, noninvasive prenatal diagnostic, or other markets, depending on their intended use, may be regulated as medical devices by the FDA and other worldwide regulatory authorities. In the United States our products may require either a premarket approval application, or PMA, or a premarket notification, or 510(k), from the FDA, prior to marketing. The 510(k) notification process usually takes from three to six months from submission to clearance, but can take significantly longer. The premarket approval process is much more costly, lengthy, uncertain, and generally takes from nine to eighteen months or longer from submission to approval. In addition, commercialization of any diagnostic or other product that we or our licensees or collaborators develop would depend upon successful completion of non-clinical testing and clinical studies. Preclinical and clinical studies can be long, expensive, and uncertain processes and we do not know whether we, our licensees, or any of our collaborators, would be permitted or able to undertake clinical studies of any potential products. It may take us or our licensees or collaborators many years to complete any such testing, and failure could occur at any stage. Results from preliminary studies do not necessarily predict final results, and acceptable results in early studies may not be repeated in later studies. A number of companies in the diagnostics industry, including biotechnology companies, have suffered significant setbacks in clinical studies, even after promising results in earlier studies. Delays or rejections of potential products may be encountered based on changes in regulatory policy for product approval during the period of product development and regulatory agency review. If our projects reach clinical studies, we or our licensees or collaborators could decide to discontinue development of any or all of these projects at any time for commercial, scientific, or other reasons.

The FDA currently regulates *in vitro* diagnostic devices, or IVDs, as products that assess human specimens and are intended for use in the diagnosis of diseases or other conditions, under the authority of Section 321(h) of the Federal Food, Drug, and Cosmetic Act, or FD&C Act. Historically the FDA has exercised enforcement discretion and exempted from regulation LDTs created and used within a single laboratory. LDTs have included a broad range of test types, from routine blood tests to complex genomic assays that seek to predict disease risk or a patient's response to treatment. The FDA has emphasized that its policy was to regulate LDTs in a way that would not inhibit the development of such tests or diminish the contribution they make to public health. Although LDTs to date have not been subject to FDA regulation, certification of the laboratory is required under CLIA to ensure the accuracy and reliability of all laboratory testing through a quality assurance program, which includes standards in the areas of personnel qualifications, administration and participation in proficiency testing, patient test management and quality control procedures. In addition, state laboratory licensing and inspection

requirements may also apply. Although LDT testing is currently solely under the purview of CMS and state agencies who provide oversight of laboratories, the FDA has been reviewing their approach to the oversight of LDTs, and the regulations may undergo change in the future.

In July 2010, the FDA held a two day public meeting to discuss the regulatory oversight of LDTs, which may result in new oversight in the future. We and Sequenom CMM may not be able to meet such new regulatory oversight requirements and Sequenom CMM may be forced to stop offering LDTs until any such new regulatory requirements have been met, which would have a material adverse effect on our business. We cannot predict the extent of the FDA's future regulation and policies with respect to LDTs in general or our diagnostic tests in particular. If Sequenom CMM is unable to successfully launch any LDTs or if it is otherwise required to obtain FDA premarket clearance or approval prior to commercializing any testing service, its ability to generate revenue from the sale of such testing services may be delayed and it may never be able to generate significant revenues from sales of diagnostic products.

## The FDA has recently expressed specific concern regarding direct-to-consumer genetic tests, and may require that such tests be offered only under 510(k) clearance or PMA and not as laboratory developed tests.

As part of the FDA's evolving position on the regulation of LDTs, the FDA issued letters to a number of companies in mid-2010 that primarily related to direct-to-consumer genetic testing. In these letters, the FDA expressed concern about consumers making medical decisions in reliance on genetic tests that have not undergone the FDA's premarket review. However, no formal guidance has yet been issued discussing the nature of the changes the FDA may make with respect to the regulation of LDTs, nor the scope of potential regulation.

Although Sequenom CMM does not sell its testing services directly to consumers, we also received a letter from the FDA in July 2010. We responded to the FDA by letter in August 2010 and met with the FDA in September 2010. We reiterated at that meeting that Sequenom CMM's LDTs are physician ordered and neither we nor Sequenom CMM are involved in any direct-to-consumer commercialization of any kind. The FDA indicated it had no further questions on the direct-to-consumer issue at this time. We will continue to monitor potential changes as the FDA's LDT policy evolves to ensure Sequenom CMM's activities are consistent with the FDA's most current policy. Although the FDA has exercised enforcement discretion in the past for LDTs, we cannot assure you that the FDA will abstain from such action in the future against us, which would have material adverse effects on our business.

## The results of preclinical and clinical studies are not necessarily predictive of future results, and our current diagnostic products and product candidates may not have favorable results in later studies.

We intend to publish results of certain of our studies, including studies of Sequenom CMM's SensiGene Trisomy 21 LDT currently under development, and there can be no assurance that such results will be viewed favorably by clinicians, patients or investors when published. For example, in February 2011 the American Journal of Obstetrics and Gynecology announced the publication of a manuscript describing results from the research and development locked-assay verification study by Sequenom CMM. In addition, Sequenom CMM's scientific collaborators and other third parties may also publish results relating to their own studies. There can be no assurance that the results of their studies when published will be viewed favorably. If such results are not viewed favorably after publication, it could have a negative impact on the perception of our technology and prospects. Additionally, there can be no assurance that the results of others' studies are indicative of our own future study results or of our ability to develop and commercialize noninvasive molecular diagnostic tests.

To date performance data has not yet been demonstrated in large clinical validation studies for any of our diagnostic products. Favorable results in early studies may not be repeated in later studies that would be required to obtain either PMA approval or 510(k) clearance from the FDA. Our diagnostic products may fail to demonstrate positive results in clinical studies despite having progressed through earlier-stage validation studies. Limited results from earlier-stage studies may not predict results from studies in larger numbers of subjects

drawn from more diverse populations over a longer period of time. Unfavorable results from ongoing preclinical and clinical studies could result in delays, modifications or abandonment of ongoing or future clinical studies, or abandonment of a product development program or may delay, limit or prevent regulatory approvals or commercialization.

## Because we exclusively licensed our noninvasive prenatal diagnostic and gender determination testing rights from Isis any dispute with Isis may adversely affect our and Sequenom CMM's ability to develop and commercialize diagnostic tests based on these licensed rights.

In October 2005, we entered into an exclusive license to noninvasive prenatal diagnostic rights (United States Patent No. 6,258,540 and foreign equivalents) with Isis, which we amended in October 2006 and in November 2007 to also include exclusive rights to intellectual property for noninvasive prenatal gender determination testing for social and lifestyle purposes. In November 2009, we entered into a third amendment to modify certain time-based commercial launch milestones relating to aneuploidy and other products. We and Sequenom CMM are using and intend to continue to use the rights that we acquired under the license to develop and commercialize noninvasive prenatal nucleic acid based tests. If there is any dispute between us and Isis regarding our rights under the license agreement, or we do not achieve the commercial launch milestones, as modified, in a timely manner, our and Sequenom CMM's ability to exclusively commercialize these diagnostic tests and LDTs may be adversely affected and could delay or completely terminate our product development and commercialization efforts for these tests.

# We, Sequenom CMM and our licensees and collaborators may not be successful in developing or commercializing diagnostic products, and LDTs, diagnostic assays including noninvasive prenatal diagnostic products, or other products using our products, services, or discoveries.

Development of diagnostic or other products by us or LDTs developed by Sequenom CMM, our licensees, or our collaborators are subject to risks of failure inherent in the development and commercial viability of any such product, such as demand for such product. These risks further include the possibility that such product would:

- be found to be ineffective, unreliable, inadequate or otherwise fail to receive regulatory approval;
- be difficult or impossible to manufacture on a commercial scale;
- be uneconomical to market or otherwise not be effectively marketed;
- fail to be successfully commercialized if adequate reimbursement from government health administration authorities, private health insurers, and other organizations for the costs of such product is unavailable;
- be impossible to commercialize because such product infringes on the proprietary rights of others or competes with products marketed by others that are superior; or
- fail to be commercialized prior to the successful marketing of similar products by competitors.

If a licensee discovers or develops diagnostic or other products or we or Sequenom CMM or a collaborator, discover or develop diagnostic or other products using our technology, products, services, or discoveries, we may rely on that licensee or collaborator (hereafter referred to as "partner") for product development, regulatory approval, manufacturing, and marketing of those products before we can realize revenue and some or all of the milestone payments, royalties, or other payments we may be entitled to under the terms of the licensing or collaboration agreement. If we are unable to successfully achieve milestones or our partners fail to develop successful products, we will not earn the revenues contemplated and we may also lose exclusive (as in the case of our license agreement with Isis, under which we in-license our fundamental noninvasive prenatal diagnostic technology, and our license agreement with the Chinese University of Hong Kong) or non-exclusive license rights to intellectual property that are required to commercialize such products. We cannot control the amount

and timing of resources our partners may devote to our programs or potential products. As a result, we cannot be certain that our partners will choose to develop or commercialize any products or will be successful in doing so. In addition, if a partner is involved in a business combination, such as a merger or acquisition, or changes its business focus, its performance under its agreement with us may suffer and, as a result, we may not generate any revenues or only limited revenues from the royalty, milestone, and similar payment provisions contained in our agreement with that partner.

## Our ability to compete in the market may decline if we lose some of our intellectual property rights or are unable to obtain other intellectual property rights.

Our success will depend on our ability to obtain and protect patents on our technology, to protect our trade secrets, and to maintain our rights to licensed intellectual property or technologies, including United States Patent No. 6,258,540 and foreign equivalents, which we have licensed from Isis for noninvasive prenatal diagnostics and noninvasive prenatal gender determination testing for social and lifestyle purposes. Our patent applications or those of our licensors may not result in the issue'of patents in the United States or other countries. Our patents or those of our licensors may not afford meaningful protection for our technology and products. Others may challenge our patents or those of our licensors in litigation or by proceedings such as interference, oppositions and reexaminations, as is the case with the appeal pending before the European Patent Office with respect to the European patent equivalent of United States Patent No. 6,258,540 (European Patent No. 994963). As a result, our patents or those of our licensors could be narrowed or invalidated or become unenforceable or lose priority to other patents, which could adversely affect our ability to successfully commercialize any of our diagnostic products that are dependent upon such patents. With respect to the SensiGene Trisomy 21 test under development, Sequenom CMM is currently focusing its efforts on a test that analyzes DNA samples utilizing MPSS instead of our proprietary MassARRAY system. While we believe our exclusive license to United States Patent No. 6,258,540 provides us substantial rights with respect to prenatal diagnostic products independent of platform and we are also the licensee of a patent application that contains claims regarding the use of MPSS in prenatal diagnostics, we are also aware of other patent applications that contain the same claims and similar claims and are owned or controlled by a potential competitor. The issuance by the U.S. Patent and Trademark Office of a patent with respect to any of these applications could result in an interference proceeding, which would be expensive and there can be no assurance that we would prevail in such a proceeding. If we do not prevail in any such proceeding, the prevailing party may obtain superior rights to our claimed inventions and technology, which could adversely affect our ability to successfully commercialize the SensiGene Trisomy 21 test under development. For example, on February 15, 2011, Stanford University was issued United States Patent No. 7,888,017 titled "Non-invasive Fetal Genetic Screening by Digital Analysis" which includes patent claims purportedly covering methods for the noninvasive detection of fetal aneuploidy. We believe a competitor may have licensed rights to the '017 patent. If we are forced to challenge the validity of the '017 patent and defend against claims of infringement of that patent, or if we are forced to defend against any other asserted intellectual property right, we will face costly litigation and diversion of management's attention and resources. As a result of such disputes, we may have to develop costly non-infringing technology or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, which could seriously harm our business and financial condition.

AND CONTRACTORS

Competitors may develop products similar to ours that do not conflict with our patents or patent rights. Others may develop products, technologies or methods, including noninvasive prenatal tests or other diagnostic tests in violation of our patents or those of our licensors, or by operating around our patents or license agreements, which could reduce sales of our consumables or reduce or remove our noninvasive prenatal and other diagnostic commercialization opportunities. To protect or enforce our patent rights, we may initiate interference proceedings, oppositions, reexaminations or litigation against others. However, these activities are expensive, take significant time and divert management's attention from other business concerns. We may not prevail in these activities. If we are not successful in these activities, the prevailing party may obtain superior rights to our claimed inventions and technology, which could adversely affect our ability to successfully commercialize any of our diagnostic products that are dependent upon such technologies. The patent position of biotechnology companies generally is highly uncertain and involves complex legal and factual questions that are

often the subject of litigation. No consistent policy has emerged from the U.S. Patent and Trademark Office, the offices of foreign countries or the courts regarding the breadth of claims allowed or the degree of protection afforded under biotechnology patents. There is a substantial backlog of biotechnology patent applications at the U.S. Patent and Trademark Office and of the equivalent offices around the world and the approval or rejection of patent applications may take several years.

## Claims by other companies that we infringe their intellectual property rights or that patents on which we rely are invalid could adversely affect our business.

From time to time, companies have asserted, and may again assert, patent, copyright and other intellectual proprietary rights against our products or products using our technologies. These claims have resulted and may in the future result in lawsuits being brought against us. We may not prevail in any lawsuits alleging patent infringement given the complex technical issues and inherent uncertainties in intellectual property litigation. If any of our products, technologies or activities, in particular our iPLEX products and our MassARRAY system (including the MassARRAY Analyzer 4), from which we derive a substantial portion of our revenues, or Sequenom CMM's SensiGene Trisomy 21 or AMD LDTs under development, were found to infringe on another company's intellectual property rights, we could be subject to an injunction that would force the removal of such product from the market or we could be required to redesign such product, which could be costly. We could also be ordered to pay damages or other compensation, including punitive damages and attorneys' fees to such other company. A negative outcome in any such litigation could also severely disrupt the sales of our marketed products to our customers or their customers, which in turn could harm our relationships with our customers, our market share and our product revenues. Even if we are ultimately successful in defending any intellectual property litigation, such litigation is expensive and time consuming to address, will divert our management's attention from our business and may harm our reputation.

Other companies or entities also may commence actions seeking to establish the invalidity of our patents. In the event that one or more of our patents are challenged, a court may invalidate the patent(s) or determine that the patent(s) is not enforceable, which could harm our competitive position. If one or more of our patents are invalidated or found to be unenforceable, or if the scope of the claims in any of these patents is limited by a court decision, we could lose certain market exclusivity afforded by patents owned or in-licensed by us and potential competitors could more easily bring products to the market that directly compete with our own. Such adverse decisions may negatively impact our revenues.

## The rights we rely upon to protect the intellectual property underlying our products may not be adequate, which could enable others to use our technology and reduce our ability to compete with them.

We require our employees, consultants, advisors, and collaborators to execute confidentiality agreements and in certain cases, assignment or license agreements. We cannot guarantee that these agreements will provide us with adequate intellectual property ownership or protection against improper or unauthorized use or disclosure of confidential information or inventions. In some situations, these agreements may conflict with or be subject to the rights of others with whom our employees, consultants, advisors, or collaborators have prior employment or consulting relationships. In some situations, as is the case with our employees in Germany, these types of agreements or relationships are subject to foreign law, which provides us with less favorable rights or treatment than under United States law. Others may gain access to our inventions, trade secrets or independently develop substantially equivalent proprietary materials, products, information, and techniques.

# Our business and industry are subject to complex and costly regulation and if government regulations are interpreted or enforced in a manner adverse to us, we may be subject to enforcement actions, penalties, exclusion, and other material limitations on our operations.

We are subject to various federal, state and local laws targeting fraud and abuse in the health care industry, including anti-kickback and false claims laws. The Federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in

exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program, such as Medicare or Medicaid. The definition of "remuneration" has been broadly interpreted to include anything of value, including, for example, gifts, discounts, the furnishing of free supplies, equipment or services, credit arrangements, payments of cash and waivers of payment. The recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "PPACA"), among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the health care industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the U.S. Department of Health & Human Services Office of Inspector General (OIG) to issue a series of regulations, known as "safe harbors." These safe harbors set forth requirements that, if met in their entirety, will assure health care providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal, or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG. Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for health care items or services reimbursed by any payor, not only the Medicare and Medicaid programs, and do not contain identical safe harbors. Government officials have focused their enforcement efforts on marketing of health care services and products, among other activities, and have brought cases against numerous companies and certain sales and marketing personnel for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Another development affecting the health care industry is the increased use of the federal civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claim laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal health care program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of \$5,500 to \$11,000 for each separate false claim. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improper use of Medicare numbers when detailing the provider of services, and allegations as to misrepresentations with respect to the services rendered. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly adversely affect our financial performance.

Federal law prohibits any entity from offering or transferring to a Medicare or Medicaid beneficiary any remuneration that the entity knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services, including waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. Entities found in violation may be liable for civil monetary penalties of up to \$10,000 for

each wrongful act. Although we believe that our sales and marketing practices are in material compliance with all applicable federal and state laws and regulations, relevant regulatory authorities may disagree and violation of these laws, or, our exclusion from such programs as Medicaid and other governmental programs as a result of a violation of such laws, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

## We have a history of generating a large percentage of our revenue at the end of each quarterly accounting period.

Due to the manner in which many customers in target markets for our MassARRAY system products allocate and spend their budgeted funds for acquisition of our products, a large percentage of our sales are booked at the end of each quarterly accounting period. Because of this timing of our sales, we may not be able to reliably predict order volumes and our quarterly revenues. A sales delay of only a few days may significantly impact our quarter-to-quarter comparisons. If our quarterly or year-end revenues fall below the expectations of securities analysts and investors, our stock price may decline. Similarly, if we are unable to ship our customer orders on time, or if extended payment terms are required, there could be a material adverse effect on revenues for a given quarter.

## If our customers are unable to adequately prepare samples for our MassARRAY system, the overall market demand for our products may decline.

Before using the MassARRAY system, customers must prepare samples by following several steps that are subject to human error, including DNA isolation and DNA amplification. If DNA samples are not prepared appropriately, or the proposed assays are too complex, the MassARRAY system may not generate a reading or a correct reading. If our customers experience these difficulties, they might achieve lower throughput levels than specified for the system. If our customers are unable to generate expected levels of throughput, they might not continue to purchase our consumables, they could express their discontent with our products to others, or they could collaborate with others to jointly benefit from the use of our products. Any or all of these actions would reduce the overall market demand for our products. From time to time, we have experienced customer complaints regarding data quality and difficulty in processing more complex assays.

## The sales cycles for our MassARRAY system products are lengthy, and we may expend substantial funds and management effort with no assurance of successfully selling our products or services.

The sales cycles for our MassARRAY system products are typically lengthy. Our sales and licensing efforts require the effective demonstration of the benefits, value, and differentiation and validation of our products and services, and significant education and training of multiple personnel and departments within a customer organization. We may be required to negotiate agreements containing terms unique to each prospective customer or licensee which would lengthen the sales cycle. We may expend substantial funds and management effort with no assurance that we will sell our products or services. In addition, this lengthy sales cycle makes it more difficult for us to accurately forecast revenue in future periods and may cause revenues and operating results to vary significantly in such periods.

### We may not be able to successfully adapt or maintain our products for commercial applications.

A number of potential applications of our MassARRAY technology and potential products, including research use only and diagnostic applications for noninvasive prenatal and other molecular testing, may require significant enhancements in our core technology or the in-licensing of intellectual property rights or technologies. In connection with developing new products and applications, we may not effectively deploy our research and development efforts in a cost-efficient manner or otherwise in a manner that leads to the successful commercialization and scale-up of such products and applications. If we are unable to complete the development, introduction, or scale-up of any product, or if any of our products or applications, such as gene expression analysis, epigenetic analysis or iPLEX multiplexing, do not achieve a significant level of market acceptance, our

business, financial condition and results of operations could be seriously harmed. Achieving market acceptance will depend on many factors, including demonstrating to customers that our technology and products are cost competitive or superior to other technologies and products that are available now or that may become available in the future. We believe that our revenue growth and profitability will substantially depend on our ability to overcome significant technological and other challenges and successfully introduce our newly developed products, applications, and services into the marketplace.

## We have limited commercial production capability and experience and may encounter production problems or delays, which could result in lower revenue.

We partially assemble the MassARRAY system and partially manufacture our consumable chips and MassARRAY kits. The MassARRAY Analyzer 4, requires more outsourcing of component manufacturing and more internal assembly. To date, we have only produced our current products in moderate quantities. We may not be able to maintain acceptable quality standards as we ramp up production of the MassARRAY Analyzer 4. To achieve anticipated customer demand levels, we will need to transition and scale-up our production capability and maintain adequate levels of inventory while manufacturing our products at a reasonable cost. We may not be able to produce sufficient quantities to meet market demand or manufacture our product at a reasonable cost. If we cannot achieve the required level and quality of production, we may need to abandon or reduce our internal efforts and fully outsource production or rely on licensing and other arrangements with third parties. This reliance could reduce our gross margins and expose us to the risks inherent in relying on others. We might not be able to successfully outsource our production or enter into licensing or other arrangements with these third parties, which would adversely affect our business. Also, from time to time we have experienced quality issues on some of our chips. We may not be able to maintain acceptable quality standards for production of our chips, which could harm our business and result in lower revenue.

## We depend on third-party products and services and limited sources of supply to develop and manufacture our products.

We rely on outside vendors to supply certain products and the components and materials used in our products. Many of these products, components and materials are obtained from a single supplier or a limited group of suppliers and some have lead-times of several months. The MassARRAY Analyzer 4 is comprised of numerous components each provided to us from a single source and some of which have lead times of several months. Regarding other elements of our MassARRAY system, we also have sole suppliers for our chips, our pins for our nanodispenser and our liquid handling device. Our consumables also include components provided by sole suppliers. In the event of any adverse developments with these vendors, our product supply may be interrupted and obtaining substitute components could be difficult or require us to re-design our products and assays which would have an adverse impact on our business. In the past, we have experienced quality problems with and delays in receiving components used to produce our consumable chips and quality issues with our chips, and also had technical difficulties with our pin-tool nanoliter dispenser device. We have also experienced software and operational difficulties with our MassARRAY system. Our reliance on outside vendors generally, and a sole or a limited group of suppliers in particular, involves several risks, including:

- the inability to obtain an adequate supply of properly functioning, required products, components, and materials due to capacity constraints, product defects, a discontinuance of a product by a supplier, or other supply constraints;
- reduced control over quality and pricing of products, components, and materials; or

• delays and long lead times in receiving products, components, or materials from vendors.

## We depend on third-party products and services for our current and planned laboratory developed tests.

We rely on outside vendors to supply certain products and the components and materials used for laboratory developed tests currently provided by Sequenom CMM and we will also rely on outside vendors for laboratory developed tests that Sequenom CMM plans to offer in the future. Many of these products, components and

materials are obtained from a single supplier or a limited group of suppliers and some have lead times of several months. For example, we are relying solely on Illumina, Inc. for sequencers and reagents for Sequenom CMM's planned laboratory developed tests for trisomy 21. Also, the MassARRAY Analyzer 4 mass spectrometry system that is currently used for Sequenom CMM's cystic fibrosis carrier screen and fetal Rhesus D tests, is comprised of numerous components, each provided to us from a single source and some of which have lead times of several months. Regarding other elements of our MassARRAY system, we also have sole suppliers for our chips, our pins for our nanodispenser and our liquid handling device.

Our consumables also include components provided by sole suppliers. In the event of any adverse developments with these vendors, our product supply may be interrupted and obtaining substitute components could be difficult or require Sequenom CMM to re-design and/or re-validate its laboratory developed tests, which would have an adverse impact on our business, including Sequenom CMM's ability to offer or to continue to offer laboratory developed tests. In the past, we have experienced quality problems with and delays in receiving components used to produce our consumable chips and quality issues with our chips, and also had technical difficulties with our pin-tool nanoliter dispenser device. We have also experienced software and operational difficulties with our MassARRAY system. Our reliance on outside vendors generally, and a sole or a limited group of suppliers in particular, involves several risks, including:

- the inability to obtain an adequate supply of properly functioning, required products, components, and materials due to capacity constraints, product defects, a discontinuance of a product by a supplier, or other supply constraints;
- reduced control over quality and pricing of products, components, and materials;
- delays and long lead times in receiving products, components, or materials from vendors; and
- Sequenom CMM's inability to provide laboratory developed tests or to maintain or increase its capacity to do so.

# If the validity of an informed consent from a subject was to be challenged, we could be forced to stop using some of our resources, which would hinder our gene discovery out licensing efforts and our diagnostic product development efforts.

We have measures in place to ensure that all clinical data and genetic and other biological samples that we receive from our clinical collaborators have been collected from subjects who have provided appropriate informed consent for the data and samples provided for purposes which extend to include commercial diagnostic product development activities. We have measures in place to ensure that data and samples that have been collected by our clinical collaborators are provided to us on a subject de-identified basis. We also have measures in place to ensure that the subjects from whom our data and samples are collected do not retain or have conferred on them any proprietary or commercial rights to the data or any discoveries derived from them. Our clinical collaborators are based in a number of different countries, and, to a large extent, we rely upon our clinical collaborators for appropriate compliance with the subject's informed consent provided and with local law and international regulation. That our data and samples come from and are collected by entities based in different countries results in complex legal questions regarding the adequacy of informed consent and the status of genetic material under a large number of different legal systems. The subject's informed consent obtained in any particular country could be challenged in the future, and those informed consent could prove invalid, unlawful or otherwise inadequate for our purposes. Any findings against us, or our clinical collaborators, could deny us access to or force us to stop using some of our clinical or genetic resources, which would hinder our diagnostic product development efforts. We could become involved in legal challenges, which could consume a substantial proportion of our management and financial resources.

## If we cannot obtain licenses to patented SNPs and genes relevant to our diagnostic areas of interest, we could be prevented from obtaining significant revenue or becoming profitable.

The U.S. Patent and Trademark Office has issued and continues to issue patents claiming single SNP and gene discoveries and their related associations and functions. If certain SNPs and genes are patented, we will

need to obtain rights to those SNPs and genes to develop, use, and sell related assays and other types of products or services utilizing such SNPs and genes. Required licenses may not be available on commercially acceptable terms. If we were to fail to obtain licenses to certain patented SNPs and genes, we might never achieve significant revenue from our diagnostic product development.

# If the medical relevance of SNPs is not demonstrated or is not recognized by others, we may have less demand for our products and services and may have less opportunity to enter into diagnostic product development and commercialization collaborations with others.

Some of the products we hope to develop involve new and unproven approaches or involve applications in markets that we are only beginning to explore. They are based on the assumption that information about genes and SNPs may help scientists better understand conditions or complex disease processes. Scientists generally have a limited understanding of the role of genes and SNPs in diseases, and few products based on gene discoveries have been developed. We cannot be certain that genetic information will play a key role in the development of diagnostics or other products in the future, or that any genetic-based findings would be accepted by diagnostic, pharmaceutical, or biotechnology companies or by any other potential market or industry segment. If we or our customers or collaborators are unable to generate valuable information that can be used to develop diagnostics or other products, the demand for our products, applications, and services will be reduced and our business will be harmed.

# We may not be able to form and maintain the collaborative relationships or the rights to third-party intellectual property and technologies that our business strategy requires and such relationships may lead to disputes over technology rights or product revenue, royalties, or other payments.

We form research collaborations and licensing arrangements with collaborators to operate our business successfully. To succeed, we will have to maintain our existing relationships and establish additional collaborations and licensing arrangements. Our current strategy includes pursuing partnering opportunities with larger companies interested in or involved in the development of pharmaceutical and diagnostic products. Our strategy also includes obtaining licenses to third-party intellectual property rights and technologies, such as our exclusive license to noninvasive prenatal analysis rights that we acquired from Isis (United States Patent No. 6,258,540 and foreign equivalents) and other rights we have acquired for the use of fetal nucleic acids obtained from maternal urine for noninvasive prenatal diagnostics and to pursue development of a test for assessment of risk for developing AMD, to potentially expand our product portfolio and generate additional sources of revenue. If we do not achieve certain milestones in a timely manner, particularly with respect to the planned test for trisomy 21, we risk losing our exclusive license rights from Isis and may also lose rights under our other licenses if we do not adequately pursue commercialization in the manner specified in those licenses. In the case of the Isis license, we have satisfied all milestone obligations under the license agreement regarding Sequenom CMM's development of a fetal Rhesus D genotyping LDT and a fetal sex determination LDT, and provided Sequenom CMM meets its anticipated launch for a trisomy 21 LDT and we meet our U.S. FDA submission date for a trisomy 21 test, we will have satisfied all milestone obligations under the license agreement regarding that test and the license would no longer be convertible to a non-exclusive license. Disputes may also arise in connection with these collaborations and licensing arrangements, which may result in liability to us or may result in the loss of acquired technology that may adversely affect our business. For example, as described elsewhere in this report, TrovaGene (formerly Xenomics) has asserted claims regarding our rights under the license agreement.

We cannot be sure that we will be able to establish any additional research collaborations, licensing arrangements, or other partnerships necessary to develop and commercialize products or that we can do so on terms favorable to us. If we are unable to establish these collaborations or licensing arrangements, we may not be able to successfully develop any diagnostic or other products or applications including the Sequenom CMM SensiGene Trisomy 21 Test under development, or generate any milestone, royalty, or other revenue from sales of these products or applications. If our collaborations or licensing arrangements are not successful or we are not able to manage multiple collaborations successfully, our programs will suffer and we may never generate any

revenue from sales of products based on licensed rights or technologies or under these collaborative or licensing arrangements. If we increase the number of collaborations or licensing agreements, it will become more difficult to manage the various relationships successfully and the potential for conflicts among the collaborators and licensees or licensors will increase. Conflicts with our collaborators, licensees or licensors, or other factors may lead to disputes over technology or intellectual property rights or product revenue, royalties, or other payments, which may adversely affect our business.

In addition, our government grants provide the government certain license rights to inventions resulting from funded work. Our business could be harmed if the government exercises those rights.

## If we do not succeed in obtaining development and marketing rights for products developed in collaboration with others, our revenue and profitability prospects could be substantially harmed.

Our business strategy includes, in part, the development of noninvasive prenatal diagnostic and other products in collaboration with others, or utilizing the technology of others, and we intend to obtain commercialization or royalty rights to those products or technologies. If we are unable to obtain such rights, or are unable to do so on favorable financial terms, our revenue and profitability prospects could be substantially harmed. To date, we have initiated limited activities towards commercializing products developed in collaboration with, or utilizing the technology of, others. Even if we obtain commercialization rights, commercialization of products may require resources that we do not currently possess and may not be able to develop or obtain, or commercialization may be financially unattractive based upon the revenue-sharing terms offered by potential licensors or provided for in the relevant agreement.

## Ethical, privacy, or other concerns about the use of genetic information could reduce demand for our products and services.

Genetic testing, including gender determination and trisomy 21 testing, has raised ethical issues regarding privacy and the appropriate uses of the resulting information. For these reasons, governmental authorities may limit or otherwise regulate the use of genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Such concerns may lead individuals to refuse to use genetics tests even if permitted. Any of these scenarios could reduce the potential markets for our products and services, which would seriously harm our business, financial condition, and results of operations.

## If we breach any of the terms of our license or supply agreements, or these agreements are otherwise terminated or modified, the termination or modification of such agreements could result in our loss of access to critical components and could delay or suspend our commercialization efforts.

We have sourced or licensed components of our technology from other parties. Our failure to maintain continued supply of such components, particularly in the case of sole suppliers, or the right to use these components would seriously harm our business, financial condition, and results of operations. As a result, in the event that demand for our products declines or does not meet our forecasts, we could have excess inventory or increased expenses or our margins could decrease which could have an adverse impact on our financial condition and business. In the event of any adverse developments with these vendors, our product supply may be interrupted, which would have an adverse impact on our business. Changes to or termination of our agreements or inability to renew our agreements with these parties or enter into new agreements with other suppliers could result in the loss of access to these aspects of our technology or other intellectual property rights or technologies that we may acquire from time to time and could impair, delay, or suspend our commercialization efforts. While we negotiate for agreement periods or notice of termination periods that provide us reasonable periods of time to secure alternative supplies, and require that such agreements may not be terminated without advance notice arbitrarily or without good reason, such as uncured breach or insolvency, these negotiations are often unsuccessful or such provisions may not provide us with adequate time to secure alternative supplies, provide us with access to alternative technologies on commercially acceptable terms, or otherwise provide us with adequate protection.

## We may not successfully complete the acquisition of businesses or technologies that we desire to acquire.

We may acquire additional businesses or technologies, or enter into other strategic transactions.

Managing future acquisitions entails numerous operational and financial risks, including:

- the inability to retain key employees of any acquired businesses or hire enough qualified personnel to staff any new or expanded operations;
- the impairment of relationships with key customers of acquired businesses due to changes in management and ownership of the acquired businesses;
- the inability to sublease on financially acceptable terms excess leased space or terminate lease obligations of acquired businesses that are not necessary or useful for the operation of our business;
- the exposure to federal, state, local and foreign tax liabilities in connection with any acquisition or the integration of any acquired businesses;
- the exposure to unknown liabilities or disputes with the former stakeholders or management or employees of acquired businesses;
- higher than expected acquisition and integration expenses that would cause our quarterly and annual operating results to fluctuate;
- increased amortization expenses if an acquisition results in significant intangible assets;
- combining the operations and personnel of acquired businesses with our own, which would be difficult and costly;
- · disputes over rights to acquired technologies or with licensors or licensees of those technologies; or
- integrating or completing the development and application of any acquired technologies, which would disrupt our business and divert management's time and attention.

We may also attempt to acquire businesses or technologies or attempt to enter into strategic transactions that we are unable to complete. If we are unable to complete such transactions, we may expend substantial resources and ultimately not successfully complete the transaction. Such transactions may also distract management and result in other adverse effects on our business and operations. These transactions may also involve the issuance of shares of our capital stock, which may result in dilution to our stockholders.

## We may not be able to successfully compete in the biotechnology and diagnostic industries.

The biotechnology and diagnostic industries are highly competitive. We expect to compete with a broad range of companies in the United States and other countries that are engaged in the development and production of products, applications, services, and strategies to analyze genetic information and strategies to develop and commercialize diagnostic, noninvasive prenatal diagnostic, and other products for customers in the clinical research and clinical marker validation and molecular medicine fields as well as diagnostic service laboratories, animal testing and food safety labs, and customers in other markets. They include:

- biotechnology, pharmaceutical, diagnostic, chemical, and other companies;
- academic and scientific institutions;
- governmental agencies; or
- public and private research organizations.

Many of our competitors have much greater financial, technical, research, marketing, sales, distribution, service, and other resources than we do. Our competitors may offer broader product lines and services and have greater name recognition than we do. Several companies are currently making or developing products that compete with our products. Our competitors may develop or market technologies or products that are more

effective or commercially attractive than our current or future products that may render our technologies or products obsolete or that have superior intellectual property rights. The delay in the development and launch of a trisomy 21 test, as well as developments in the investigations by the SEC, the Office of the U.S. Attorney for the Southern District of California and the FBI, and the lawsuit filed by our former chief financial officer or other pending private litigation may adversely affect our competitive position and the market acceptance of any tests that we may commercialize and may affect our ability to maintain and recruit key personnel.

## We may potentially compete with our customers, which may adversely affect our business.

We have sold MassARRAY systems worldwide to pharmaceutical and biotechnology companies, academic research centers, and government laboratories. Some of our customers use our DNA analysis products to perform contract research services, or to perform genetics studies on their own disease populations for potential diagnostic applications and drug target identification in the same or similar manner as we have done. Although there are many potential contract research services 'opportunities and disease areas and diagnostic applications, our customers may seek service work or develop diagnostic assays or may target diseases areas that may overlap with those that we have chosen to pursue. In such cases we may potentially compete against our customers. Competition from our customers may adversely affect our services business or our ability to successfully commercialize diagnostic products.

## If we cannot attract and retain highly-skilled personnel, our growth might not proceed as rapidly as we intend and our business may be adversely affected.

The success of our business will depend on our ability to identify, attract, hire, train, retain, maintain, and motivate highly skilled personnel, particularly sales, scientific, medical, and technical personnel, for our future success. Competition for highly skilled personnel is intense, and we might not succeed in attracting and retaining these employees. If we cannot attract and retain the personnel we require, we would not be able to expand our business as rapidly as we intend. Our announcements in 2009 of the delay in the launch of the trisomy 21 test then under development and the results of the investigation by the special committee may have had a negative effect on employee morale and may have affected our ability to retain and recruit key personnel. When we seek to hire personnel to fill open positions, we may be unable to hire qualified replacements for the positions that we need to fill, and there may be significant costs associated with the recruiting, hiring and retention of officers and employees for the open positions. If we lose additional key employees, scientists, physician collaborators or if our management team is not able to effectively manage us through these events, our business, financial condition, and results of operations may be adversely affected. We do not carry "key person" insurance covering any of our officers or other employees.

## If we do not effectively manage our business as it evolves, it could affect our ability to pursue opportunities and expand our business.

Evolution in our business, particularly our attempted transition to developing and commercializing molecular diagnostic tests, has placed and may continue to place a significant strain on our personnel, facilities, management systems, information technology infrastructure, disclosure controls, internal controls and resources. We have implemented the remedial measures recommended by the special committee of our board of directors following its independent investigation, including:

- the introduction of a number of standard operating procedures regarding study design planning and review, including clear identification of whether a study is blinded or unblinded, raw data storage at multiple locations, independent third-party review of blinded clinical data, and a redundancy review of clinical study design by our oversight committee and of blinded clinical data by the science committee of our board of directors, our clinical group and our biostatistician;
- the creation of the science committee to oversee our research and development strategy and activities, including our evaluation of cross-functional training for personnel in all areas associated with research

and development, covering: (i) the proper conduct of test studies, (ii) the proper and timely disclosure of any problems with test studies, and (iii) the proper handling of data and results of test studies;

- the hiring of a full-time biostatistician and engagement of an external consultant on an "as needed" basis as a clinical biostatistician;
- the formalization of the role of our oversight committee and the appointment of project leaders to oversee and manage each of our products in development;
- the amendment of our new hire orientation program, employee handbook and code of business conduct and ethics and enhancement of our training programs concerning ethics, scientific processes, public disclosures and professional e-mail conduct;
- the revision of our policy concerning the storage of clinical samples, including requiring that samples be stored in third-party storage facilities, bar-coding samples for electronic tracking and auditing, creating formal procedures for obtaining a sample, and limiting access to our sample storage freezer;
- the requirement that the known outcomes of all samples to be used in any blinded experiment must be conveyed to the third party storage provider and are only revealed to us after the results of the blinded experiment have been finalized;
- the amendment and restatement of our disclosure committee's charter;
- the adoption of a comprehensive new policy on corporate disclosure controls and procedures, a set of disclosure controls and procedures and a corporate disclosure policy;
- the reduction in the number of direct reports to our chief executive officer; or
- the engagement of an external consultant to assist and advise the audit committee in developing an enterprise risk management process.

These remedial measures are designed to prevent the use of inadequate protocols and controls in our clinical studies and the recurrence of the other errors discovered in the special committee's investigation by:

- establishing a procedural framework for the conduct of future clinical studies;
- inserting internal controls consistent with that framework;
- augmenting our company's expertise in conducting clinical studies;
- reinforcing management oversight of the conduct of clinical studies;
- educating employees on the proper conduct of clinical studies and their responsibilities in such activities;
- establishing control over the samples used in our clinical studies;
- establishing additional levels of responsibility for the development of new products;
- enhancing our organizational structure to distribute management responsibility appropriately;
- reinforcing our disclosure controls and procedures to prevent the dissemination of inadequately vetted information by our company; or
- improving our risk assessment and management in general.

While we feel that the remedial measures that we have implemented have made our controls and procedures more effective, any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and no evaluation of controls and procedures can provide absolute assurance that all control issues have been detected. We will need to continue to improve our operational and financial systems and managerial controls and procedures and train and manage our workforce and transition our business to execute on the commercialization of molecular diagnostic tests. If we fail to effectively manage the evolution of our business and the transition to also being a provider of diagnostic products, including the effective implementation these remedial measures and additional changes to our corporate governance policies, protocols and practices, or fail to take other necessary action to maintain close coordination among our various departments, our ability to execute on our business plan, rebuild credibility, pursue business opportunities, expand our business, and sell our products and applications in new markets may be adversely affected.

## Certain of our molecular diagnostic tests may not be eligible for reimbursement by payors which may limit the demand for these tests by physicians and their patients. We may incur additional financial risk related to collections and reimbursement in connection with the commercialization of our molecular diagnostic tests.

In September 2009, Sequenom CMM commercially launched its testing service for cystic fibrosis carrier screening and in early 2010 it launched its testing service for noninvasive fetal Rhesus D genotyping, and it intends to continue launching additional molecular diagnostic testing services in the future. Because these LDTs have only recently been launched, demand for and reimbursement by payors of these tests is uncertain. Because certain of the molecular diagnostic LDTs Sequenom CMM has launched or intends to launch as a testing service may not be medically necessary or may otherwise not be subject to reimbursement by payors, it is difficult to know how much demand there will be for such tests by physicians. Sequenom CMM generally bills third-party payors for its testing services and pursues case-by-case reimbursement where policies are not in place for a particular test it has very limited experience in billing and pursuing reimbursement and payment for molecular diagnostic tests. As a result of this lack of experience and uncertainty with respect to reimbursement, Sequenom CMM may also face an increased risk in its collection efforts, including potential write-offs of doubtful accounts and long collection cycles for accounts receivable related to its testing service, which could adversely affect our business, results of operations and financial condition.

# We must be in compliance with security and privacy regulations under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and other state regulations, which may increase our operational costs.

The HIPAA privacy and security regulations establish comprehensive federal standards with respect to the uses and disclosures of protected health information, or PHI, by health plans and health care providers, in addition to setting standards to protect the confidentiality, integrity and availability of electronic PHI. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, to obtain payments for services and health care operations activities;
- a patient's rights to access, amend and receive an accounting of certain disclosures of PHI;
- the content of notices of privacy practices for PHI; or
- administrative, technical and physical safeguards required of entities that use or receive PHI electronically.

As Sequenom CMM launches additional commercial diagnostic tests, they must continue to implement policies and procedures related to compliance with the HIPAA privacy and security regulations, as required by law, which may increase their operational costs. Furthermore, the privacy and security regulations provide for significant fines and other penalties for wrongful use or disclosure of PHI, including potential civil and criminal fines and penalties. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, Sequenom CMM also could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

## We incur significant costs as a result of operating as a public company and our management expects to continue to devote substantial time to public company compliance programs.

As a public company, we incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC and The NASDAQ Stock Market. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and as a result of the new corporate governance and executive compensation related rules, regulations and guidelines prompted by the Dodd- Frank Act and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will continue to cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

## The U.S. health care reform law could adversely affect our business, profitability and stock price.

Comprehensive health care reform legislation has been signed into law in the United States. Although we cannot fully predict the many ways that health care reform might affect our business, the law imposes a 2.3% excise tax on certain transactions, including many U.S. sales of medical devices, which we expect will include U.S. sales of Sequenom's systems and consumables. This tax is scheduled to take effect in 2013. It is unclear whether and to what extent, if at all, other anticipated developments resulting from health care reform, such as an increase in the number of people with health insurance and an increased focus on preventive medicine, may provide us additional revenue to offset this increased tax. If additional revenue does not materialize, or if our efforts to offset the excise tax through price increases, spending cuts or other actions are unsuccessful, the increased tax burden would adversely affect our financial performance, which in turn could cause the price of our stock to decline.

## We are subject to risks associated with our foreign operations.

We expect that a significant portion of our sales will continue to be made outside the United States. Approximately 54% of our sales were made outside of the United States during the year ended December 31, 2010, compared to 52% for the year ended December 31, 2009. A successful international effort will require us to develop relationships with international customers and collaborators, including distributors. We may not be able to identify, attract, retain, or maintain suitable international customers or collaborators. Expansion into international markets will require us to establish and grow foreign operations, hire additional personnel to run these operations, and maintain good relations with our foreign customers and collaborators or distributors. International operations including many of the same risks to our business that affect our domestic operations, but also involve a number of risks not typically present in domestic operations, including:

currency fluctuation risks;

- changes in regulatory requirements;
- costs and risks of deploying systems in foreign countries;
- licenses, tariffs, and other trade barriers;
- political and economic instability and possible country-based boycotts;

- difficulties in staffing and managing foreign operations;
- potentially adverse tax consequences;
- the burden of complying with a wide variety of complex foreign laws and treaties; or
- · different rules, regulations, and policies governing intellectual property protection and enforcement.

Our international operations are also subject to the risks associated with the imposition of legislation and regulations relating to the import or export of high technology products. We cannot predict whether tariffs or restrictions upon the importation or exportation of our products will be implemented by the United States or other countries.

## If our production and laboratory facilities are damaged, our business would be seriously harmed.

Our only manufacturing facility for research use only genetic analysis products is located in San Diego, California, where we also have laboratories. Sequenom CMM also has laboratory facilities in San Diego, California and Grand Rapids, Michigan. Damage to our facilities due to war, fire, natural disaster, power loss, communications failure, terrorism, unauthorized entry, or other events could prevent us from conducting our business for an indefinite period, could result in a loss of important data or cause us to cease development and production of our products. We cannot be certain that our limited insurance to protect against business interruption would be adequate or would continue to be available to us on commercially reasonable terms, or at all.

## Responding to claims relating to improper handling, storage or disposal of hazardous chemicals, and radioactive and biological materials which we use could be time consuming and costly.

We use controlled hazardous and radioactive materials in the conduct of our business, as well as biological materials that have the potential to transmit disease. The risk of accidental contamination or injury from these materials cannot be completely eliminated. If an accident with these substances occurs, we could be liable for any damages that result, which could seriously harm our business. Additionally, an accident could damage our research and manufacturing facilities and operations, resulting in delays and increased costs. Such damage and any expense resulting from delays, disruptions, or any claims may not be covered by our insurance policies.

## We may not have adequate insurance if we become subject to product liability or other claims.

Our business exposes us to potential product liability and other types of claims and our exposure will increase as we and Sequenom CMM and our partners and collaborators prepare to commercialize research use only or other molecular tests, including LDTs and diagnostics for prenatal and other diseases, disorders and medical conditions. We have product and general liability insurance that covers us against specific product liability and other claims up to an annual aggregate limit of \$20.0 million and \$2.0 million, respectively. Any claim in excess of our insurance coverage would have to be paid out of our cash reserves, which would have a detrimental effect on our financial condition. It is difficult to determine whether we have obtained sufficient insurance to cover potential claims. Also, we cannot assure you that we can or will maintain our insurance policies on commercially acceptable terms, or at all.

## The uncertainty of the current economic and political conditions could harm our revenues and operating results.

Current domestic and global economic conditions are uncertain and have continued to be volatile over the past few years. The recent turmoil in the economic environment in many parts of the world may continue to put pressure on global economic conditions. Our revenues and operating results may be affected by uncertain or changing economic and market conditions. If global economic and market conditions, or economic conditions in the United States or other key markets, remain uncertain or persist, spread, or deteriorate further, we may experience material impacts on our business, operating results, and financial condition.

## Our stock price has been and may continue to be volatile, and your investment could suffer a decline in value.

The trading price of our common stock has been volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including but not limited to:

- our ability to raise additional capital and continue as a going concern;
- actual or anticipated variations in quarterly and annual operating results;
- announcements regarding technological innovations, intellectual property rtghts, research and development progress or setbacks, or product launches by us or our competitors;
- our success in entering into, and the success in performing under, licensing and product development and commercialization agreements with others;
- the success of the validation studies for Sequenom CMM's LDTs under development and its ability to continue to publish study results in peer-reviewed journals;
- our success in and the expenses associated with researching, developing and commercializing diagnostic products, alone or in collaboration with our partners and obtaining any required regulatory approval for those products and services;
- the status of litigation against us and certain of our former executive officers and directors;
- the dilution from the issuance of securities in connection with the settlement of litigation;
- our ability to successfully implement the remedial measures recommended by the special committee following our independent investigation and the effectiveness of those measures;
- the status, duration, scope and outcome of the investigations by the SEC, the Office of the U.S. Attorney for the Southern District of California and the FBI;
- securities analysts' earnings projections or securities analysts' recommendations; or general market conditions, including the recent crisis in global financial markets.

The stock market in general, and The NASDAQ Global Market and the market for life sciences companies in particular, have experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of the listed companies. There have been dramatic fluctuations in the market prices of securities of biotechnology companies. These price fluctuations may be rapid and severe and may leave investors little time to react. Broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Sharp drops in the market price of our common stock expose us to further securities class-action litigation.

## Item 1B. UNRESOLVED STAFF COMMENTS

None.

## Item 2. PROPERTIES

We are headquartered in San Diego, California, with wholly-owned subsidiaries located in Hamburg, Germany, Cambridge, England, Hong Kong, Grand Rapids, Michigan and Tokyo, Japan. We also have offices in Queensland, Australia and Beijing, China. Collectively, we lease approximately 114,000 square feet under leases that expire at various dates through September 2015, each of which contains laboratory, office, manufacturing, or storage facilities.

The San Diego site is our company headquarters and houses our selling, general, and administrative offices, research and development facilities, manufacturing operations, as well as a CLIA-certified molecular diagnostics

laboratory operated by Sequenom CMM. The site in Hamburg, Germany, is used to support sales and distribution in Europe. The site in Hong Kong is used for sales and support activities performed in Asia. The site in Cambridge, England is used for sales and support activities performed in Europe. Sequenom CMM's site in Grand Rapids, Michigan, house their CLIA-certified, CAP accredited molecular diagnostics laboratory and selling, general and administrative offices. The site in Tokyo, Japan, is used for sales and support activities performed in Japan. We believe our facilities are adequate for our current needs.

## Item 3. LEGAL PROCEEDINGS

## IPO Litigation

In November 2001, we and certain of our current or former officers and directors were named as defendants in a class action shareholder complaint filed by Collegeware USA in the U.S. District Court for the Southern District of New York (now captioned In re Sequenom, Inc. IPO Securities Litigation) Case No. 01-CV-10831. In the complaint, the plaintiffs allege that our underwriters, certain of our officers and directors and we violated the federal securities laws because our registration statement and prospectus contained untrue statements of material fact or omitted material facts regarding the compensation to be received by and the stock allocation practices of the underwriters. The plaintiffs seek unspecified monetary damages and other relief. Similar complaints were filed in the same District Court against hundreds of other public companies that conducted initial public offerings of their common stock in the late 1990s and 2000 (the IPO Cases).

In October 2002, our officers and directors were dismissed without prejudice pursuant to a stipulated dismissal and tolling agreement with the plaintiffs. In February 2003, the District Court dismissed the claim against us brought under Section 10(b) of the Exchange Act, without giving the plaintiffs leave to amend the complaint with respect to that claim. The District Court declined to dismiss the claim against us brought under Section 11 of the Securities Act of 1933, as amended (the Securities Act).

In September 2003, pursuant to the authorization of a special litigation committee of our board of directors, we approved in principle a settlement offer by the plaintiffs. In September 2004, we entered into a settlement agreement with the plaintiffs. In February 2005, the District Court issued a decision certifying a class action for settlement purposes and granting preliminary approval of the settlement subject to modification of certain bar orders contemplated by the settlement. In August 2005, the District Court reaffirmed class certification and preliminary approval of the modified settlement. In December 2006, the U.S. Court of Appeals for the Second Circuit vacated the District Court's decision certifying as class actions the six lawsuits designated as "focus cases." Thereafter the District Court ordered a stay of all proceedings in all of the lawsuits pending the outcome of plaintiffs' petition to the Second Circuit for rehearing en banc. In April 2007, the Second Circuit denied plaintiffs' rehearing petition, but clarified that the plaintiffs may seek to certify a more limited class in the District Court. Accordingly, the settlement as originally negotiated was terminated pursuant to stipulation and will not receive final approval.

In February 2009, liaison counsel for plaintiffs informed the District Court that a new settlement of all IPO Cases had been agreed to in principle, subject to formal approval by the parties and preliminary and final approval by the District Court. In April 2009, the parties submitted a tentative settlement agreement to the District Court and moved for preliminary approval thereof. In June 2009, the District Court granted preliminary approval of the tentative settlement and ordered that notice of the settlement be published and mailed to class members. In September 2009, the District Court held a final fairness hearing. In October 2009, the District Court certified the settlement class in each IPO Case and granted final approval to the settlement. Thereafter, three shareholders filed a Petition for Permission to Appeal Class Certification Order, asserting that the District Court's certification of the settlement classes violates the Second Circuit's earlier class certification decisions in the IPO Cases and a number of shareholders also filed direct appeals, objecting to final approval of the settlement is affirmed on appeal, the settlement will result in the dismissal of all claims against us and our officers and directors with prejudice, and our pro rata share of the settlement fund will be fully funded by insurance.

### Securities and Shareholder Derivative Litigation

In April 2009, we announced that the expected launch of a test for trisomy 21 then under development by Sequenom CMM had been delayed and that we were no longer relying on the previously announced test data and results for that test, as a result of inadequately substantiated claims, inconsistencies and errors and inadequate protocols and controls, which included: the mischaracterization of tests as having been conducted in a blinded manner (i.e., that the tests had been performed by scientists who did not know the true outcomes for the samples tested before the test results had been determined); the improper unblinding of true outcomes for samples being tested; the use of the unblinded true outcomes to alter and improve reported test results, the unsubstantiated reporting of test results for low-risk samples (i.e., samples from expectant mothers who were less likely to be carrying a fetus with trisomy 21) without knowing the true outcomes for such samples; the failure to perform testing on those low-risk samples; the inadequate storage of serum samples resulting in breakdown of nucleic acids: and other improper practices. Following the April 2009 announcement, several complaints were filed in the U.S. District Court for the Southern District of California against us and certain of our current and former officers and directors on behalf of certain purchasers of our common stock. The complaints included claims asserted under Sections 10 and 20(a) of the Exchange Act and Sections 11 and 12(a)(2) of the Securities Act and were brought as shareholder class actions. In general, the complaints alleged that we and certain of our officers and directors violated federal securities laws by making materially false and misleading statements regarding the test, thereby artificially inflating the price of our common stock. In September 2009 the complaints were consolidated under the caption In re Sequenom, Inc. Securities Litigation, Master File No. 3:09-cv-00921 LAB-WMC and a lead plaintiff was appointed. In December 2009 we entered into a stipulation of settlement with the lead plaintiff on behalf of the plaintiffs' class. Pursuant to the terms of the stipulation, we paid \$14 million, which was funded by insurance proceeds. We also agreed to issue to the plaintiffs' class approximately 6.8 million shares of our common stock, and to adopt or continue our implementation of changes and additions to certain corporate governance policies, protocols and practices. The court held a final settlement approval hearing in May 2010, following which the court approved the final settlement. The time for appeals lapsed without any appeal. Of the 6.8 million shares of common stock to be issued in the settlement, 409,005 shares were issued in June 2010 to counsel for the plaintiffs' class in accordance with the stipulation of settlement. Following completion of the class action claim procedures, we issued the balance of 6,407,738 shares as of December 31, 2010.

In May 2009, a shareholder derivative complaint was filed in the Superior Court of California for the County of San Diego against certain of our current and former directors and officers. Thereafter, a number of similar actions, also styled as shareholder derivative suits, were filed in state court and were consolidated in a single court. In July 2009 the first of three shareholder derivative suits were filed in the U.S. District Court for the Southern District of California. The federal shareholder derivative actions were consolidated before a single court under the caption In re Sequenom, Inc. Derivative Litigation, S.D. Cal. Case No. 09-CV-1341 LAB (WMc) and plaintiffs filed a single consolidated complaint. A separate federal derivative compliant, Ries, et al. v. Stylli, et al, case no. 09-CV-2517 LAB (WMc), was filed thereafter and it was coordinated with the consolidated federal derivative action. The state and federal shareholder derivative actions are hereinafter collectively referred to as the "Derivative Actions." The complaints in the Derivative Actions allege breaches of fiduciary duties by the defendants and other violations of law. In general, the complaints allege that our directors and certain of our officers caused or allowed for the dissemination of materially false and misleading statements regarding the trisomy 21 test then under development, thereby artificially inflating the price of our common stock. In May 2010, we entered into a stipulation of settlement to resolve the Derivative Actions. The current and former directors and officers named as individual defendants in the Derivative Actions also entered into the stipulation of settlement. In exchange for a release of all claims by the plaintiffs and a dismissal of the Derivative Actions, we agreed (i) to adopt or continue certain corporate governance measures and (ii) to pay the plaintiffs' attorneys a total of \$2.5 million, of which \$1.0 million has been funded by insurance proceeds. The U.S. District Court issued its final approval of the settlement in accordance with the terms of the stipulation of settlement and entered an order dismissing the federal shareholder derivative actions in July 2010. In accordance with the terms of the stipulation of settlement, the parties in the state shareholder derivative actions filed a joint stipulation to dismiss the actions with prejudice in San Diego Superior Court in July 2010. In connection with the final

approval of settlement, we remitted a cash payment of \$338,000 and issued 200,000 shares of our common stock at a fair value of \$5.81 per share in payment of the portion of the plaintiffs' attorneys' fees not funded by insurance proceeds.

### SEC Investigation

In June 2009, we received written notification that the Enforcement staff of the SEC has initiated an investigation following our April 2009 announcement regarding the trisomy 21 test then under development. As part of this investigation, the SEC staff has also required us to produce information with respect to our announcement relating to our offer to acquire EXACT Sciences, Inc. in January 2009. On March 7, 2011, the staff of the SEC advised us that it is considering recommending that the SEC bring a civil injunctive action against us alleging that we violated Sections 10(b) and 13(a) of the Securities Exchange Act of 1934 and Rules 10b-5, 12b-20, 13a-1 and 13a-11 thereunder. We have cooperated fully with the SEC in its investigation and will endeavor to negotiate an acceptable injunctive resolution with the staff, but any resolution that we may negotiate with the staff will be subject to the approval of the SEC. There can be no assurance that such resolution will be limited to injunctive relief or that such resolution will not have a material adverse effect on our business, results of operation or financial condition.

In June 2010, the SEC filed a complaint against Elizabeth Dragon, who was formerly our Senior Vice President, Research and Development. The complaint alleged that between June 2008 and January 2009 Dr. Dragon made or allowed for the dissemination of materially false and misleading statements regarding the trisomy 21 test then under development, thereby inflating the price of our stock. The SEC sought a permanent injunction against any future violations of the federal securities laws by Dr. Dragon, civil penalties, and imposition of an officer and director bar against her. On the same day, Dr. Dragon filed a consent to judgment of permanent injunction and other relief. In the consent to judgment, Dr. Dragon, without admitting or denying the allegations in the SEC's complaint, agreed to the permanent injunction against future violations of federal securities laws, the director and officer bar, and civil penalties to be determined by the court.

## DOJ and FBI Investigation

Following our September 2009 announcement regarding the work and recommendations of a special committee of independent directors after it had completed its independent investigation of activity related to the trisomy 21 test, representatives of the Office of the U.S. Attorney for the Southern District of California contacted us to inquire about the announcement. We intend to continue to cooperate fully with the U.S. Attorney and the Federal Bureau of Investigation (FBI) in this matter.

In June 2010, the U.S. Attorney filed a criminal information against Dr. Dragon.' The criminal information charged Dr. Dragon with one count of conspiracy to commit securities fraud by conspiring to disseminate materially false and misleading statements regarding the trisomy 21 test then under development. On the same day, Dr. Dragon pled guilty to the criminal information, and the magistrate judge assigned to this matter recommended that the district court judge accept Dr. Dragon's guilty plea. Prior to sentencing, Dr. Dragon passed away in February 2011.

#### Xenomics Litigation

In October 2009, plaintiff Xenomics, Inc. (now known as TrovaGene) filed a complaint in the Supreme Court of the State of New York naming us as the defendant. In the complaint, the plaintiff alleged that due to materially false and misleading statements regarding the trisomy 21 test under development, we had breached the license agreement entered into by the parties on October 29, 2008, which provides us with exclusively licensed patent rights for the use of fetal nucleic acids obtained from maternal urine, and that the plaintiff has suffered damages as a result. The plaintiff sought equitable relief and \$300 million in damages. In December 2009, we removed the case to the U.S. District Court for the Southern District of New York. In May 2010, the district court granted our motion to dismiss the action because the license agreement specifically provides that if TrovaGene seeks to resolve a dispute arising under the agreement, it must do so by commencing an arbitration in San Diego. As of the date of this report, TrovaGene has not commenced arbitration proceedings in San Diego.

## Paul Hawran Litigation

In August 2010, Paul Hawran, our former chief financial officer, sued the three directors who comprised the special committee that conducted the investigation of activity related to the trisomy 21 test, alleging that they had defamed him, invaded his privacy, negligently and intentionally interfered with his prospective economic advantage, and committed unfair business practices under California Business and Professions Code Section 17200. Mr. Hawran alleged in his complaint that he was asked to resign because he had raised concerns about the conduct of certain of our directors. The lawsuit, Hawran v. Hixson et al, case no. 37-2010-00058632-CU-DF-NC, was filed in the Superior Court of California for the North County of San Diego. In September 2010, we were served with an amended complaint in this lawsuit, in which Mr. Hawran named us as a defendant in addition to the three individuals previously named and added claims of breach of contract and intentional and negligent misrepresentation. October 2010, the defendants filed a motion to strike the complaint under California Code of Civil Procedure Section 425.16 on the grounds that Mr. Hawran's claims arise from acts in furtherance of the defendants' right of petition or free speech under the United States or California Constitution in connection with a public issue and filed a demurrer to each and every cause of action in the complaint. On January 3, 2011, the court issued a minute order dismissing some, but not all, of the claims alleged in the amended complaint. The defendants filed a notice of appeal regarding the minute order on January 11, 2011 and Mr. Hawran filed a cross-appeal regarding the same on January 31, 2011. The individual defendants and we intend to vigorously defend ourselves against the claims advanced.

In addition, from time to time, we may be involved in litigation that is not material relating to claims arising out of our operations in the normal course of business.

Claim estimates that are probable and can be reasonably estimated are reflected as liabilities of the Company. Because of the uncertainties related to the incurrence, amount and range of loss on any pending litigation, investigation, inquiry or claim, management is currently unable to predict the ultimate outcome of any litigation, investigation, inquiry or claim, determine whether a liability has been incurred or make an estimate of the reasonably possible liability that could result from an unfavorable outcome. It is reasonably possible that some of the matters, which are pending or may be asserted, could be decided unfavorably to the Company. An adverse ruling or outcome in any lawsuit involving us could materially affect our business, liquidity, consolidated financial position or results of operations ability to sell one or more of our products or could result in additional competition. In view of the unpredictable nature of such matters, we cannot provide any assurances regarding the outcome of any litigation, investigation, inquiry or claim to which we are a party or the impact on us of an adverse ruling of such matters.

## Item 4. (REMOVED AND RESERVED)

## PART II

## Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

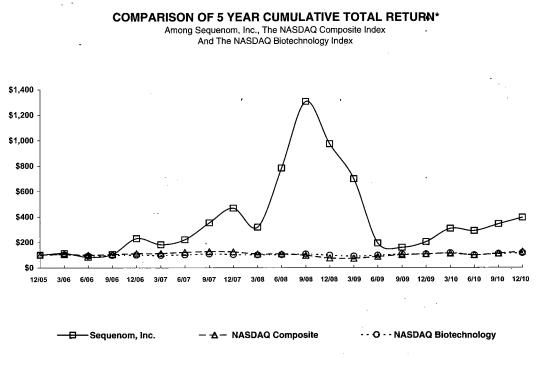
(a) Our common stock is traded on The NASDAQ Global Market under the symbol "SQNM." The following tables set forth the high and low sales prices for the Company's common stock as reported on The NASDAQ Global Market for the periods indicated.

	High	Low
Year Ended December 31, 2010:		
Fourth Quarter	\$ 8.14	\$ 6.32
Third Quarter	\$ 7.05	\$ 5.37
Second Quarter	\$ 6.63	\$ 4.74
First Quarter	\$ 8.20	\$ 3.95
Year Ended December 31, 2009		
Fourth Quarter	\$ 4.49	\$ 2.76
Third Quarter	\$ 6.61	\$ 3.23
Second Quarter	\$16.27	\$ 2.93
First Quarter	\$25.54	\$12.68

There were approximately 765 holders of record of our common stock as of February 25, 2011. We have not paid any cash dividends to date and do not anticipate any being paid in the foreseeable future.

## **Performance Measurement Comparison\***

The following graph compares the cumulative total stockholder return on our common stock between December 31, 2005 and December 31, 2010 with the cumulative total return of (i) the NASDAQ Composite Index (NASDAQ Index) and (ii) the NASDAQ Biotechnology Index (the NASDAQ Biotech Index), over the same period. This graph assumes the investment of \$100.00 on December 31, 2005 in common stock, the NASDAQ Index and the NASDAQ Biotech Index, and assumes the reinvestment of any dividends.



\*\$100 invested on 12/31/05 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

\* This Section is not "soliciting material" is not deemed "filed" with the SEC and is not to be incorporated by reference in any of our filing under the Securities Act of 1933 or the Securities Exchange Act of 1934 whether made before or after the date hereof without regard to any general incorporation language in any such filing.

## Item 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data is derived from our audited consolidated financial statements and should be read in conjunction with the consolidated financial statements and the notes to such statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this report. Historical results are not necessarily indicative of the results to be expected in the future.

	Years ended December 31,				
	2010	2009	2008	2007	2006
	(In thousands, except per share data)				
Consolidated statements of operations data Revenues:					
Consumables, MassARRAY and other product				-	
related	\$ 42.422	\$ 35,533	\$ 42,259	\$ 37,365	¢ 07.051
Contract research services	2,483	2,209	\$ 42,239 4,817	\$ 57,505 3,524	\$ 27,051 1,023
Diagnostic	2,554	94	-,017	5,524	1,02.
Research and other		27	73	113	422
Total revenues	47,459	37,863	47,149	41,002	28,496
Costs and expenses:	,	,	,		20,190
Cost of consumables, product, services and					
diagnostic revenue	18,996	14,570	19,590	18,077	11,887
Research and development	43,431	37,454	27,455	14,352	11,939
Selling and marketing, general and					
administrative	50,667	54,972	42,735	31,148	22,425
Litigation settlement, net	55,384	-		-	_
charge		1,589			10
Amortization of acquired intangibles					1,511
Total costs and expenses	168,478	108,585	89,780	63,577	47,772
Loss from operations Other income (expense):	(121,019)	(70,722)	(42,631)	(22,575)	(19,276
Interest income	162	440	1 500	1 701	0.04
Gain (loss) on marketable securities	102	442 (1,914)	1,592 (2,584)	1,781	906
Interest expense	(190)	(1,914)	(2,384)	(1,071) (17)	(20
Other income (expense), net	82	1,560	(137) (181)	(101)	191
Loss before income taxes	(120,854)	(70,895)	´		
Income tax benefit (expense)	(120,854)	(117)	(43,943) (211)	(21,983)	(18,199 622
Net loss	\$(120,844)	$\frac{(117)}{(71,012)}$	$\frac{7(211)}{$(44,154)}$	<u> </u>	\$(17,577
Net loss per share, basic and diluted	<u>(1.69)</u>	<u>\$ (1.16)</u>	<u>\$ (0.83)</u>	<u>(0.57)</u>	\$ (0.71
Weighted average shares outstanding, basic and					
diluted	71,697	61,171	53,129	38,865	24,842

	As of December 31,				
•••	2010	2009	2008	2007	2006
Consolidated balance sheet data		(	In thousands)		
Cash, cash equivalents, marketable securities and					
restricted cash	\$136,884	\$44,100	\$ 99,700	\$52,150	\$26,330
Working capital		45,473	103,246	52,690	23,651
Total assets	174,279	86,645	140,484	76,046	39,881
Total long-term obligations	3,562	5,226	4,779	5,744	3,525
Total stockholders' equity	150,732	63,658	116,213	54,265	25,450

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

## Overview

We are a molecular diagnostics and genetics analysis company committed to providing products, services, applications and genetic analysis products that translate the results of genomic science into solutions for biomedical research, translational research, molecular medicine applications, and agricultural, livestock, and other areas of research.

Our proprietary MassARRAY system, comprised of hardware, software applications, consumable chips and reagents, is a high performance (in speed, accuracy and cost efficiency) nucleic acid analysis system that quantitatively and precisely measures genetic target material and variations. Our system is widely accepted as a leading high-performance DNA analysis system for the fine mapping genotyping market and continues to gain traction for newer applications, such as agricultural-biotechnology and clinical research. Our customérs include premier clinical research laboratories, bio-agriculture, bio-technology and pharmaceutical companies, academic institutions, and various government agencies worldwide. To provide customer support for our expanding user base and in an effort to maximize market penetration, we have established direct sales and support personnel serving North America, Europe and Asia, in addition to distribution partners in several major countries throughout the world.

We are researching, developing and pursuing the commercialization of various noninvasive molecular diagnostic tests for prenatal genetic disorders and diseases, women's health-related disorders and diseases, ophthalmology, oncology, infectious diseases, and other medical conditions, disorders and diseases. We have branded our patented technology for prenatal diagnostics under the trademark SEQureDx. Our efforts in molecular diagnostics are focused on noninvasive diagnostics currently using our proprietary MassARRAY system; however, we may also employ other instrumentation platforms, such MPSS with our diagnostic applications as may be more suitable on a case-by-case basis considering optimum test performance and commercialization factors.

Currently, we are primarily focused on developing and commercializing prenatal screening and diagnostic tests using our foundational, patent protected, noninvasive, circulating cell-free fetal (ccff) nucleic acid based assay technology, which we in-license from Isis Innovation Limited (Isis). This technology uses a simple maternal blood draw (meaning the test does not involve tools that break the skin or physically enter the body, as compared to invasive procedures such as amniocentesis, chorionic villus sampling, or surgery) for a prenatal diagnosis or risk assessment in order to provide reliable information about the status of the fetus early in pregnancy. In early 2010, Sequenom CMM, our wholly-owned CLIA-certified, CAP accredited molecular diagnostics laboratory in Grand Rapids, Michigan, launched a noninvasive fetal Rhesus D genotyping and Fetal<sup>xy</sup> sex determination as a testing service to physicians using this patented ccff technology. In September 2009, Sequenom CMM launched a noninvasive molecular based cystic fibrosis carrier screening as a testing service to physicians. In August 2010, we announced that we would no longer offer the Fetal<sup>xy</sup> sex determination test after September 15, 2010.

We have made substantial investments in our information technology infrastructure to enhance the capabilities of Sequenom CMM to track samples and provide electronic ordering and reporting, and have put in place sample collection and transportation logistics that can be readily scaled. Sequenom CMM is entering into contracts with third party payors to establish pricing for our tests and provide reimbursement. We also plan to conduct the development, validation, and other activities necessary to file submissions with the FDA seeking clearance or approval for selected diagnostic tests.

Our research use only MassARRAY system provides reliable results for a wide range of DNA/RNA analysis applications including single nucleotide polymorphism (SNP) genotyping detection of mutations, analysis of copy number variants and other structural genome variations. In addition, the system provides quantitative gene expression analysis, quantitative DNA methylation analysis, comparative sequence analysis of

haploid organisms, SNP discovery, and oligonucleotide quality control. These applications are provided through proprietary research use only application software that operates on the MassARRAY system and through the purchase of consumable chips and reagent sets. While the MassARRAY system is versatile across many applications, it is a robust and cost-effective genotyping solution for fine mapping projects enabled through our iPLEX multiplexing assay, which permits multiplexed SNP analysis using approximately the same amount of reagents and chip surface area as is used for a single locus/SNP analysis.

We have targeted customers conducting quality genotyping and performing fine mapping studies, candidate gene studies, comparative sequencing, gene expression analysis, and epigenetic analysis in the molecular medicine market. Epigenetic analysis is an important part of cancer and other research areas. DNA methylation analysis is the most frequently studied epigenetic change, and examines changes in the presence or absence of methyl groups in specific areas of the DNA.

We are targeting customers for our genetic analysis technology and products across five segments: oncology and translational research, pharmaceutical research, academic biomedical research, agricultural, and clinical research, public health initiatives and biodefense. We believe the market and opportunities for growth for fine mapping genotyping are increasing as more researchers are completing their larger genomic studies such as whole genome scans. Epigenetic analysis is an emerging market that, along with gene expression analysis, is increasingly being utilized by researchers in conjunction with genotyping to attempt to fully understand genetic cause and effect.

As of December 31, 2010, our revenues consisted of sales of MassARRAY hardware, software, consumables, maintenance agreements, contract research services, and Sequenom CMM testing services. The impact of our product offerings, contract research services and Sequenom CMM testing services on future revenues, margins, expenses, and cash flows remains uncertain and depends on many factors as described in Item 1A of this report under the caption "Risk Factors."

Sequenom CMM's testing services for cystic fibrosis carrier screening and fetal Rhesus D genotyping have only recently been launched and demand for and acceptance of these tests by physicians and their patients is uncertain, and the level of reimbursement (applicable to the cystic fibrosis carrier screen and fetal Rhesus D genotyping tests) is also uncertain. As a result, expected revenues from Sequenom CMM's testing services are uncertain and difficult to predict. Such revenues are uncertain and also depend on many factors as described in Item 1A of this report under the caption "Risk Factors."

We have a history of recurring losses from operations and had an accumulated deficit of \$718.1 million as of December 31, 2010, and we expect to incur further losses for the foreseeable future. Our capital requirements to sustain operations, including research and development projects, have been and will continue to be significant. As of December 31, 2010, we had available cash and cash equivalents and current marketable securities totaling \$135.5 million and working capital of \$132.2 million.

### **Critical Accounting Policies**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions in certain circumstances that affect amounts reported in the accompanying consolidated financial statements and related notes. Certain of these accounting policies that we believe are the most critical to our investors' understanding of our financial results and conditions are discussed below. Our significant accounting policies are more fully described in Note 2 to our Consolidated Financial Statements included elsewhere in this report. In preparing these financial statements, management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Management considers many factors in selecting appropriate financial accounting policies and controls and in developing the estimates and assumptions that are used in the preparation of the consolidated financial statements. Management must apply significant judgment in this process. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must

select an assessment that falls within the range of reasonable estimates. The application of these accounting policies involves the exercise of judgment and use of estimates and assumptions as to future uncertainties and, as a result, actual results could differ from these estimates.

### **Revenue Recognition**

We recognize revenue for consumables, MassARRAY system and other product related sales in accordance with current accounting rules, when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable, and collectability is reasonably assured. Additionally, for MassARRAY system sales, the arrangement consideration is allocated among the separate units of accounting based on their relative fair values. The separate units of accounting are typically the system and software itself and maintenance contracts sold at the time of the system sale. Revenue is deferred for fees received before earned. Revenues from sales of consumables are recognized generally upon shipment and transfer of title to the customer. Revenue from sales of MassARRAY systems with general standard payment terms of 60 days or less are recognized upon shipment and transfer of title to the customer or when all revenue recognition criteria are met. Revenues from the sale or licensing of our proprietary software are recognized upon transfer of title to the customer or the duration of the software license. We recognize revenue on maintenance services for ongoing customer support over the maintenance period. Revenues from genetic services are recognized at the completion of key stages in the performance of the service, which is generally delivery of SNP assay information. Grant revenue is recorded as the research expenses relating to the grants are incurred, provided that the amounts received are not refundable if the research is not successful. Amounts received that are refundable if the research is not successful would be recorded as deferred revenue and recognized as revenue upon the grantor's acceptance of the success of the research results.

Diagnostic revenues from Sequenom CMM's cystic fibrosis carrier screening and fetal Rhesus D genotyping LDTs, which were commercially launched as a testing service to physicians in September 2009 and February 2010, respectively, have been recognized on a cash basis due to the limited number of contracts or agreements we have with third-party payors and our limited collections experience. We generally bill third-party payors upon generation and delivery of a report to the physician. As such, we take assignment of benefits and risk of collection with the third-party payor. We usually bill the patient directly for amounts not covered by their insurance carrier in the form of co-pays and deductibles, but only after multiple requests for full payment have been denied or only partially paid by the insurance carrier. Some payors may not cover our tests as ordered by the physician under their reimbursement policies. Consequently, we pursue case-by-case reimbursement where policies are not in place.

### Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make certain 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 from those estimates.

Significant estimates are as follows:

Goodwill and impairment of intangible assets. The purchase price allocation for acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired and liabilities assumed based on their respective fair values. Additionally, we must determine whether an acquired entity is considered to be a business or a set of net assets, because a portion of the purchase price can only be allocated to goodwill in a business combination. Goodwill and intangible assets deemed to have indefinite lives are not amortized, but are subject to annual impairment tests. The amounts and useful lives assigned to other intangible assets impact future amortization. Determining the fair values and useful lives of intangible assets requires the use of estimates and the exercise of judgment. These judgments can significantly affect our net operating results. We periodically re-evaluate the original assumptions and rationale utilized in the establishment of the carrying value and estimated lives of our goodwill and long-lived assets. The criteria used for these evaluations include management's estimate of the asset's continuing ability to generate income from operations and positive cash flows in future periods as well as the strategic significance of any intangible assets in our business objectives. If assets are considered to be impaired, the impairment recognized is the amount by which the carrying value of the assets exceeds the fair value of the assets. No impairment of goodwill and long-lived assets was recorded in 2010, 2009 or 2008.

- Allowance for Doubtful Accounts. We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We evaluate the collectability of our accounts receivable balance based on a combination of factors. We regularly analyze customer accounts, review the length of time receivables are outstanding and review the historical loss rates. If the financial condition of our customers were to deteriorate, additional allowances could be required.
- Reserves for obsolete and slow-moving inventory. We operate in an industry characterized by rapid improvements and changes to technology and products. The introduction of new products by us or our competitors can result in our inventory being rendered obsolete or requiring us to sell items at a discount to cost. We estimate the recoverability of our inventory by reference to our internal estimates of future demands and product life cycles. If we incorrectly forecast demand for our products or inadequately manage the introduction of new product lines, we could materially impact our financial statements by having excess inventory on hand. Our future estimates are subjective and could be incorrect.
- Income taxes. Our provision for income taxes is computed using the asset and liability method, under which deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, and for the expected future tax benefit to be derived from tax loss and credit carryforwards. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction by jurisdiction basis, and includes a review of all available positive and negative evidence. As of December 31, 2010, we maintained a valuation allowance against our U.S. and foreign deferred tax assets that we concluded have not met the "more likely than not" threshold.

We recognize excess tax benefits associated with share-based compensation to stockholders' equity only when realized. When assessing whether excess tax benefits relating to share-based compensation have been realized, we follow the with-and-without approach, excluding any indirect effects of the excess tax deductions. Under this approach, excess tax benefits related to share-based compensation are not deemed to be realized until after the utilization of all other tax benefits available to us.

We recognize the impact of a tax position in our financial statements only if that position is more likely than not of being sustained upon examination by taxing authorities, based on the technical merits of the position. Any interest and penalties related to uncertain tax positions will be reflected in income tax expense.

Stock-based compensation. Stock-based compensation cost is estimated at the grant date based on the award's fair-value as calculated by the Black-Scholes option pricing model (BSM) and the portion that is ultimately expected to vest is recognized as compensation expense over the requisite service period using the straight-line single option method. The BSM model requires various highly judgmental assumptions including volatility, forfeiture rates, and expected option life. If any of these assumptions used in the BSM model change significantly, stock-based compensation expense may differ materially in the future from that recorded in the current period.

#### **Recent Accounting Pronouncements**

In 2010, the Financial Accounting Standards Board (FASB) issued an Accounting Standards Update (ASU) related to Revenue Recognition that applies to arrangements with milestones relating to research or development deliverables. This guidance provides criteria that must be met to recognize consideration that is contingent upon achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The update is effective for revenue arrangements entered into or modified in fiscal years beginning on or after June 15, 2010. The adoption of this update is not expected to have a material impact on our consolidated financial statements.

In 2010, the FASB issued an ASU related to Fair Value Measurements and Disclosures that requires reporting entities to make new disclosures about recurring or nonrecurring fair-value measurements including significant transfers into and out of Level 1 and Level 2 fair-value measurements and information on purchases, sales, issuances, and settlements on a gross basis in the reconciliation of Level 3 fair-value measurements. The FASB also clarified existing fair-value measurement disclosure guidance about the level of disaggregation, inputs, and valuation techniques. The new and revised disclosures are required to be implemented in interim or annual periods beginning after December 15, 2009, except for the gross presentation of the Level 3 rollforward, which is required for annual reporting periods beginning after December 15, 2010. The adoption of this standard did not have any effect on our financial position and results of operations.

In 2009, the FASB issued an ASU related to Revenue Recognition that amends the previous guidance on arrangements with multiple deliverables. This guidance provides principles and application guidance on whether multiple deliverables exist, how the arrangements should be separated, and how the consideration should be allocated. It also clarifies the method to allocate revenue in an arrangement using the estimated selling price. The update is effective for revenue arrangements entered into or modified in fiscal years beginning on or after June 15, 2010 with earlier adoption permitted. The adoption of this update is not expected to have a material impact on our consolidated financial statements.

In 2009, the FASB issued authoritative guidance that amends the evaluation criteria to identify the primary beneficiary of a variable interest entity and requires a quarterly reassessment of the treatment of such entities. The guidance also requires additional disclosures about an enterprise's involvement in a variable interest entity. This guidance was effective for us January 1, 2010 and did not have any effect on our financial position and results of operations.

## Results of Operations Years ended December 31, 2010 and 2009

## Revenues

Total revenues were \$47.5 million and \$37.9 million for the years ended December 31, 2010 and 2009, respectively. Consumables revenue consisted of sales of our SpectroCHIP bioarray chips and reagents used with our iPLEX for genotyping and other assays. MassARRAY and other product related revenues were derived from sales of MassARRAY systems, maintenance agreements, sales and licensing of our proprietary software and the receipt of license fees from end-users. Diagnostic revenues were from the testing services primarily associated with Sequenom CMM's cystic fibrosis carrier screening test that was launched in the third quarter of 2009, as well as the fetal Rhesus D genotyping test, which was launched in the first quarter of 2010, and consisted of cash collected from tests performed through December 31, 2010.

Consumable sales increased to \$22.0 million in 2010 from \$20.5 million in 2009. The increase in 2010 compared to 2009 was attributable to our larger installed base of MassARRAY compact systems in 2010 against 2009, as well as increased consumables orders from our customers in the translational and basic markets against the comparative period.

MassARRAY and other product related revenue increased to \$20.4 million in 2010 from \$15.0 million in 2009. The increase of \$5.4 million was primarily due to an increase in MassARRAY hardware and software revenue to \$15.4 million in 2010 from \$10.7 million in 2009, which was attributable to more system placements as compared to the prior year, in addition to a higher average selling price for the year ended December 31, 2010. Revenue from other product sales, including MassARRAY maintenance contracts, license fees and royalties for the years ended December 31, 2010 and 2009 was \$5.0 million and \$4.3 million, respectively. The increase of \$0.7 million in 2010, as compared to 2009, was primarily due to more service contracts in effect over our larger installed base against the comparative period.

We recognized contract research services revenue of \$2.5 million for the year ended December 31, 2010, compared to \$2.2 million in service revenues for the year ended December 31, 2009. The increase from 2009 was attributable to focusing our genetic analysis service business on larger studies and projects with higher revenue and margins. We expect genetic analysis service revenues to be minimal going forward.

We recognized diagnostic revenue from testing services of \$2.6 million and \$0.1 million for the years ended December 31, 2010 and 2009, respectively. Diagnostic revenue has been recognized upon cash collection as payments are received due to the lack of historical sales trends associated with the commercial launch of these tests.

Research and other revenue was \$0 for the year ended December 31, 2010, compared to \$27,000 for the year ended December 31, 2009. The timing of research revenues depends upon our expenditures on grant research and the receipt of the grant funding from the sponsoring agencies. We expect research revenue to continue to be minimal going forward.

Domestic and non-U.S. revenues were \$22.0 million and \$25.6 million for the year ended December 31, 2010, respectively, and \$18.0 million and \$19.8 million for the year ended December 31, 2009, respectively.

The following table presents revenue for each reportable segment (in thousands).

	Year ended December 31,	
	2010	2009
Revenues:		
Molecular Diagnostics	\$ 2,554	\$94
Genetic Analysis	44,905	37,769
	\$47,459	\$37,863

Our revenues have historically fluctuated from period to period and likely will continue to fluctuate substantially in the future based upon the unpredictable sales cycle for the MassARRAY system, general economic conditions, ability to meet revenue recognition criteria, the overall acceptance and demand for our new and existing commercial products and services, as well as the adoption rates of the cystic fibrosis carrier screening and fetal Rhesus D genotyping LDTs, and future LDTs and diagnostic tests.

### Cost of Consumables and Products, Services and Diagnostic Revenues and Gross Margins

Cost of consumables and products revenues were \$14.4 million and \$12.0 million and gross margins were 66% and 66% for the years ended December 31, 2010 and 2009, respectively. Gross margin maintained for product revenues in 2010 compared to 2009, primarily due to the mix of products sold, which consisted of increased system placements and higher consumables sales in the current period as compared to 2009. MassARRAY systems, which historically sell at lower gross margins, were affected by higher consumables sales, which historically sell at higher average gross margins.

Cost of service revenues were \$0.6 million and \$2.2 million and gross margins were 75% and 1% for the years ended December 31, 2010 and 2009, respectively. The improved margins in 2010 were attributable to our focus on larger studies and projects with higher revenue and margins after our April 2009 cost cutting initiative. Gross margins on contract research service revenues are dependent on the particular contract terms of the work undertaken.

Cost of diagnostic revenues from testing services are recognized at the completion of testing and were \$4.0 million and \$0.4 million and gross margins were negative for the years ended December 31, 2010 and 2009, respectively, as we built test volumes to cover costs associated with running our diagnostic tests and other capacity related expenses. Gross margin on diagnostic tests are affected by test volumes, the timing of collections and overall reimbursement for the amount paid per test.

Our overall gross margins were 60% and 62% for the years ended December 31, 2010 and 2009, respectively. The amount of our gross margins were attributable to the activity described above.

We believe that gross margin in future periods will be affected by, among other things, the selling price for MassARRAY systems and consumables, consumable sales per MassARRAY system sold, the mix of product sales and the type of services sold, competitive conditions, sales volumes, discounts offered, the percentage of sales made to distributors, as well as the cost of goods sold, inventory reserves and obsolescence charges required and royalty payment obligations on in-licensed technologies. Our gross margin will also be affected by the adoption rates of the diagnostic tests we commercialize, the testing services Sequenom CMM commercializes and the payor and other contracts Sequenom CMM may enter into for such tests and the volume of tests sold.

#### **Research and Development Expenses**

Research and development costs were \$43.4 million and \$37.5 million for the years ended December 31, 2010 and 2009, respectively. These expenses consisted primarily of salaries and related personnel expenses, product development costs, and clinical expense related costs.

The increase in research and development expenses of \$5.9 million for 2010 compared to 2009 primarily resulted from increased headcount and related costs of \$1.2 million associated with increased investment in our diagnostic development and corporate bonus plan and temporary labor, higher clinical costs of \$4.1 million associated with our development programs, an increase of \$1.6 million in collaboration costs associated primarily with a February 2010 licensing payment to Optherion and a collaboration milestone payment made during the third quarter of 2010, higher share-based compensation expense of \$0.1 million, a \$0.2 million increase in restricted stock compensation expense as a result of a performance based grant to all employees in December 2009 and a \$0.5 million increase in depreciation associated primarily with a larger capital base associated with Sequenom CMM. These increases were offset by a decrease of \$1.8 million in operating supplies and equipment costs due to the commercialization of Sequenom CMM's cystic fibrosis carrier screening that was launched as a testing service in September 2009, as well as the fetal Rhesus D genotyping test, which was launched as a testing service in the first quarter of 2010.

The following table presents a reconciliation of research and development expenses for each reportable segment for the year ended December 31, 2010 (in thousands).

Molecular Diagnostics	\$26,000
Genetic Analysis	3,622
Total segments	
Stock-based compensation	4,186
Indirect overhead (1)	5,879
Allocated and absorbed costs (2)	3,744
Total research and development expenses	\$43,431

- (1) Indirect overhead consists of expenses related to the following departments, which are unallocated to our operating segments for performance assessment by our chief operating decision maker: quality, regulatory, chief science officer and research and development collaborations (licensing costs).
- (2) Allocated costs consist of costs from the following departments, which are unallocated to our operating segments for performance assessment by our chief operating decision maker: human resources, information technology and facilities. Absorbed costs relate to costs incurred that are absorbed into cost of sales.

We expect our research and development expenses to increase in 2011 compared to 2010, as we continue to expand our investment in the development of noninvasive prenatal diagnostic tests, as well as validation of Sequenom CMM's trisomy 21 and AMD LDTs. We also continue to invest in new products and applications for our MassARRAY system.

## Sales and Marketing Expenses

Sales and marketing costs were \$28.4 million and \$26.8 million for the years ended December 31, 2010 and 2009, respectively. These expenses consisted primarily of salaries and related expenses for sales and marketing, customer support, and business development personnel and their related department expenses.

The increase in selling and marketing expenses of \$1.6 million for 2010 compared to 2009 primarily was related to increased headcount and related costs of \$1.2 million due to our corporate bonus plan for 2010 and the expansion of our contract sales force infrastructure in our molecular diagnostics segment, higher commission payouts of \$0.9 million related to increased revenues in our genetic analysis segment and increased diagnostic commissions, an increase in bad debt expense of \$1.0 million associated with a reserve taken on two MassARRAY system sales from prior years, an increase of \$0.6 million associated with higher logistics expenses associated primarily with postage and freight on sample transportation and a \$0.1 million increase in restricted stock compensation expense as a result of a performance-based grant to all employees in December 2009. These increases were offset by higher absorption of diagnostic field operational expenses of \$1.5 million, lower facilities and operating supplies costs of \$0.2 million that were both associated with our workforce reduction in April 2009 and lower share-based compensation charges of \$0.5 million.

The following table presents a reconciliation of sales and marketing expenses for each reportable segment for the year ended December 31, 2010 (in thousands).

Molecular Diagnostics	
Total segments	23,184
Stock-based compensation	
Indirect overhead (1)	1,327
Allocated and absorbed costs (2)	671
Total research and development expenses	

 Indirect overhead consists of expenses related to the following departments, which are unallocated to our operating segments for performance assessment by our chief operating decision maker: business development and European sales administration.

(2) Allocated costs consist of costs from the following departments, which are unallocated to our operating segments for performance assessment by our chief operating decision maker: human resources, information technology and facilities. Absorbed costs relate to costs incurred that are absorbed into cost of sales.

We expect our sales and marketing expenses to remain higher in 2011 compared to 2010, due to our increased headcount and related expenditures as we strengthen our sales force and build our marketing and commercial development teams for our molecular diagnostic tests.

## General and Administrative Expenses

General and administrative costs were \$22.3 million and \$28.1 million for the years ended December 31, 2010 and 2009, respectively. These expenses consisted primarily of salaries and related expenses for legal, finance, and human resource personnel, and their related department expenses. General and administrative costs are not allocated to our business segments for performance assessment by our chief operating decision maker.

The decrease in general and administrative expenses of \$5.8 million for 2010 compared to 2009 was related primarily to a \$4.0 million decrease in legal fees, lower share-based compensation expense of \$0.7 million, a \$0.1 million decrease in travel expenses, a reduction in investor relations and consulting fees of \$0.1 million, lower corporate expenses of \$0.1 million, a \$0.2 million decrease in accounting and tax expenses, lower facilities and related costs of \$0.5 million and an increase in the allocation of IT and other general and administrative expenses to other functional departments of \$0.5 million. These decreases were offset by increased headcount and related costs of \$0.1 million and an increase in restricted stock compensation expense of \$0.3 million as a result of a performance based grant to all employees in December 2009.

We expect general and administrative costs to increase in 2011 compared to 2010, as we build our infrastructure in order to support our anticipated growth, the expansion of diagnostic billing costs and continued legal costs related to ongoing investigations and litigation.

### Litigation settlement expense, net

Litigation settlement expense, net was \$55.4 million for the year ended December 31, 2010, compared to none for the year ended December 31, 2009.

In connection with the court approved settlement of *In re Sequenom, Inc. Securities Litigation* in May 2010, we recorded a litigation settlement charge of \$42.8 million related to the common stock issuable to the members of the plaintiffs' class. This settlement consisted of approximately 6.8 million shares at an initial fair value of \$6.28 per share. In addition, further adjustments to the equity based portion of the settlement were required to be recognized as a gain or loss depending upon fluctuations in the fair market value of our common stock from the initial settlement fair value until all common stock issuable to the members of the plaintiffs' class had been released. Subsequent to the initial accrual, we recognized an additional net aggregate loss of approximately \$11.1 million due to the revaluation to fair value for the portion of the approved share settlement issued to plaintiffs' class on December 31, 2010.

Additionally, in connection with the entry of a stipulation of settlement in connection with *In re Sequenom*, *Inc. Derivative Litigation* in May 2010, we recorded a litigation settlement charge of \$1.5 million during the second quarter of 2010. This charge represented the portion of the settlement not covered by insurance proceeds. In connection with the final approval of the settlement we remitted a cash payment of \$338,000 and issued 200,000 shares of our common stock at a fair value of \$5.81 per share in August 2010.

### Restructuring and long-lived asset impairment charge

Restructuring and long-lived asset impairment charges were none and \$1.6 million for the years ended December 31, 2010 and 2009, respectively. The charges in 2009 were associated with our April 2009 reduction in workforce, which included the closure of our leased facility in Boston, Massachusetts, the closure of our office located in New Delhi, India, as well as a decrease in our genetic analysis workforce primarily associated with our genetic analysis services business. These charges consisted of one-time terminations benefits, office closure expenses and other related costs.

### Interest Income

Interest income was \$0.2 million and \$0.4 million for the years ended December 31, 2010 and 2009, respectively. The decrease was attributable to the overall reduction in the rates of return in our investment portfolios and varying levels of cash, cash equivalents and marketable securities balances during 2010, as compared to the same period in 2009.

### Gain (Loss) on Marketable Securities

Gain on marketable securities was \$0.1 million for the year ended December 31, 2010, as compared to a loss on marketable securities of \$1.9 million for the comparable period in 2009. The gain for 2010 was primarily associated with the sale of an auction rate security, or ARS, during the first quarter of 2010 that was previously written down to zero. The loss on marketable securities for 2009 was due to the sale of five ARS investments, which resulted in a realized loss of \$0.8 million, as well as an other-than-temporary impairment on our ARS investments of \$1.1 million for the year ended December 31, 2009.

#### Interest Expense

Interest expense was \$190,000 and \$261,000 for the years ended December 31, 2010 and 2009, respectively. Interest expense in 2010, as compared to 2009, was due to ongoing payments on our capital lease and debt obligations, offset by reduced payments on our asset-backed loans due to two funding agreements maturing during 2010.

#### Other Income, net

Other income, net, was \$0.1 million for the year ended December 31, 2010, as compared to \$1.6 million for the comparable period in 2009. The decrease for 2010, as compared to the same periods in 2009, was primarily due to the receipt in 2010 of \$0.3 million related to the U.S. Government's Therapeutic Discovery Project Program that was offset by losses on fixed asset disposals, as compared to one-time items received in 2009 for a \$1.0 million payment related to the settlement of our patent infringement lawsuit against Ibis Biosciences, Inc., and the receipt of a research and development tax credit from the U.S. Government of \$0.3 million, as well as more favorable realized foreign currency translations.

#### Income Tax Expense

We had an income tax benefit of \$10,000 and an income tax expense of \$117,000 for the year ended December 31, 2010 and 2009, respectively. Income tax benefit and expense in both periods was primarily due to statutory tax liabilities resulting from our foreign operations.

## Years ended December 31, 2009 and 2008

### Revenues

Total revenues were \$37.9 million and \$47.1 million for the years ended December 31, 2009 and 2008, respectively. MassARRAY and other product related revenues were derived from the sale of MassARRAY systems, consumables, sales and licensing of our proprietary software, maintenance contracts, and license fees from end-users. Diagnostic revenues were from testing services for cystic fibrosis carrier screening and consisted of cash collected from tests performed through December 31, 2009.

Consumable sales increased to \$20.5 million in 2009 from \$19.5 million in 2008. The increase in 2009 compared to 2008 was primarily due to increased consumables orders from our customers in the biomedical research and agricultural biology markets.

MassARRAY and other product related revenue decreased to \$15.0 million in 2009 from \$22.7 million in 2008. The decrease of \$7.7 million was primarily due to a decrease in MassARRAY hardware and software revenue to \$10.7 million in 2009 from \$19.5 million in 2008, which was attributable to fewer system placements during the year ended December 31, 2009. Revenue from other product sales, including MassARRAY maintenance contracts, license fees and royalties for the years ended December 31, 2009 and 2008 was \$4.3 million and \$3.2 million, respectively. Maintenance revenue increased by approximately \$1.1 million in 2009, as compared to 2008 due to higher service contracts in effect over our installed base.

We recorded genetic analysis service revenues of \$2.2 million for the year ended December 31, 2009, compared to \$4.8 million in service revenues for the year ended December 31, 2008. The decrease from 2008 was attributable to our cost cutting initiative that commenced in April 2009, which refocused our genetic analysis service business on fewer, higher margin studies and projects. We recognized diagnostic revenue of \$94,000 and \$0 for the years ended December 31, 2009 and 2008, respectively. Diagnostic revenue from testing services was generated from Sequenom CMM's cystic fibrosis carrier screening, which we commercialized in September 2009. Diagnostic revenue is recognized upon cash collection as payments are received. Research and other revenue was \$27,000 for the year ended December 31, 2009, compared to \$73,000 for the year ended December 31, 2009, respectively, and \$23.8 million and \$19.8 million for the year ended December 31, 2008, respectively.

The following table presents revenue for each reportable segment for the year ended December 31, 2009. Prior to 2009, all revenue was derived from our Genetic Analysis operations (in thousands).

#### Revenues:

Molecular Diagnostics	\$	94
Genetic Analysis	_3′	7,769
	\$3′	7,863

### Cost of Consumables and Products, Services and Diagnostic Revenues and Gross Margins

Cost of consumables products revenues were \$12.0 million and \$15.1 million and gross margins were 66% and 64% for the years ended December 31, 2009 and 2008, respectively. The increase in gross margin for product revenues in 2009 compared to 2008 was attributable to increased consumable sales that generally have higher average gross margins compared to systems sales and was also due to fewer system placements, which historically sell at lower gross margins.

Cost of service revenues were \$2.2 million and \$4.5 million and gross margins were 1% and 7% for the years ended December 31, 2009 and 2008, respectively. Gross margins decreased compared to the prior year due to the completion of remaining unfavorable, low volume contracts. Gross margins on contract research services have been dependent on particular contract terms of the work undertaken, as well as the particular market in which the services are being performed, the size of the projects and the pricing terms.

Cost of diagnostic revenues from testing services are recognized at the completion of testing and were \$0.4 million and \$0 and gross margins were (338%) and 0% for the years ended December 31, 2009 and 2008, respectively. Gross margin on diagnostic tests are primarily affected by test volumes and overall reimbursement for the amount paid per test.

Our overall gross margins were 62% and 58% for the years ended December 31, 2009 and 2008, respectively. The increase in overall gross margin in 2009 was attributable to lower system and contract research revenues, which are sold at a lower margin than consumables. The increase in consumables revenue during 2009, as compared to 2008, also contributed to the improved margin.

## **Research and Development Expenses**

Research and development costs were \$37.5 million and \$27.5 million for the years ended December 31, 2009 and 2008, respectively. These expenses consisted primarily of salaries and related personnel expenses, improvements to our existing products, clinical sample and related operations, validation of products under development and expenses relating to work performed under research contracts.

The increase in research and development expenses of \$10.0 million for 2009 compared to 2008 primarily resulted from increased headcount and related costs of \$3.0 million associated with increased investment in our diagnostic development, an increase of \$3.8 million for clinical study costs associated with our prenatal diagnostic, molecular diagnostic and genetic analysis programs, headcount based overhead allocation expense related to our information technology and facilities departments of \$1.8 million, share-based compensation expense of \$2.2 million, as well as higher depreciation of \$1.0 million associated with capital expenditures and our acquisition of SensiGen, LLC in February 2009, higher facilities operations expenses of \$0.3 million and office expenses of \$0.2 million related to higher freight and postage associated with sample collection activity with our clinical programs. These increases were offset by a decrease of \$2.3 million in collaboration costs associated with various research and development projects and related licensing activities.

The following table presents a reconciliation of research and development expenses for each reportable segment for the year ended December 31, 2009 (in thousands).

Molecular Diagnostics	\$20,935 5,587
Total segments	26,522
Stock-based compensation	4,222
Indirect overhead (1)	3,511
Allocated and absorbed costs (2)	3,199
Total research and development expenses	\$37,454

- (1) Indirect overhead consists of expenses related to the following departments, which are unallocated to our operating segments for performance assessment by our chief operating decision maker: quality, regulatory, chief science officer and research and development collaborations (licensing costs).
- (2) Allocated costs consist of costs from the following departments, which are unallocated to our operating segments for performance assessment by our chief operating decision maker: human resources, information technology and facilities. Absorbed costs relate to costs incurred that are absorbed into cost of sales.

## Sales and Marketing Expenses

Sales and marketing costs were \$26.8 million and \$24.3 million for the years ended December 31, 2009 and 2008, respectively. These expenses consisted primarily of salaries and related expenses for sales and marketing, customer support, and business development personnel and their related department expenses.

The increase in selling and marketing expenses of \$2.5 million for 2009 compared to 2008 primarily resulted from increased headcount and related costs of \$1.1 million associated with building our marketing and contract sales force infrastructure for our noninvasive diagnostics business, \$1.4 million for higher share-based compensation expense and \$0.2 million related to increased travel, postage and freight charges and other general operating expenses as compared to 2008. These increases were offset by a decrease of \$0.2 million in marketing expenses associated with our genetic analysis and diagnostic operations by reducing external consultant costs.

The following table presents a reconciliation of sales and marketing expenses for each reportable segment for the year ended December 31, 2009 (in thousands).

Molecular Diagnostics	
Total segments	
Indirect overhead (1)	
Allocated and absorbed costs (2)	2,012
Total research and development expenses	\$26,845

- Indirect overhead consists of expenses related to the following departments, which are unallocated to our operating segments for performance assessment by our chief operating decision maker: business development and European sales administration.
- (2) Allocated costs consist of costs from the following departments, which are unallocated to our operating segments for performance assessment by our chief operating decision maker: human resources, information technology and facilities. Absorbed costs relate to costs incurred that are absorbed into cost of sales.

### General and Administrative Expenses

General and administrative costs were \$28.1 million and \$18.4 million for the years ended December 31, 2009 and 2008, respectively. These expenses consisted primarily of salaries and related expenses for legal, finance, and human resource personnel, and their related department expenses. General and administrative costs are not allocated to our business segments for performance assessment by our chief operating decision maker.

The increase in general and administrative expenses of \$9.7 million for 2009 compared to 2008 primarily resulted from increased legal expense of \$6.4 million associated with litigation, the independent investigation conducted by the Special Committee of our Board of Directors and the share-based payment related to the settlement of SensiGen, LLC's claim against us, share-based compensation of \$1.0 million, \$0.9 million for increased headcount and related expenses, \$1.0 million of higher rent, taxes and communications expenses associated with our San Diego facilities and \$0.4 million in increased investor relations consulting, audit and tax related expenses.

### Restructuring and long-lived asset impairment charge

Restructuring and long-lived asset impairment charges were \$1.6 million for the year ended December 31, 2009. These charges were associated with our April 2009 reduction in workforce, which included the closure of our leased facility in Boston, Massachusetts, the closure of our office located in New Delhi, India, as well as a decrease in our genetic analysis workforce primarily associated with our genetic analysis services business. These charges consist of one-time terminations benefits, office closure expenses and other related costs. There were no comparative charges for the year ended December 31, 2008.

## Interest Income

Interest income was \$0.4 million and \$1.6 million for the years ended December 31, 2009 and 2008, respectively. The decrease in 2009 compared to 2008 was attributable to a reduction of our cash, cash equivalents and marketable securities balances in 2009, as well as changes in our investment policy in the prior year that resulted in the overall reduction in the rates of return in our investment portfolio.

### Loss on Marketable Securities

Loss on marketable securities was \$1.9 million and \$2.6 million for the years ended December 31, 2009 and 2008, respectively. The loss for the year ended December 31, 2009, was due to the sale of five ARS investments,

which resulted in a realized loss of \$0.8 million, as well as an other-than-temporary impairment in our remaining investments in ARS of \$1.1 million. Two of our four remaining investments in ARS were subsequently sold in January 2010, with the realized loss of \$0.7 million having been included within the \$1.1 million recognized for the year ended December 31, 2009.

#### Interest Expense

Interest expense was \$0.3 million and \$0.1 million for the years ended December 31, 2009 and 2008, respectively. The increase in 2009 compared to 2008 was due to payments on our capital lease and debt obligations obtained in 2009, as well as continued payments on our asset-backed loans.

## Other Income (Expense), net

Other income (expense), net was \$1.6 million and (\$181,000) for the years ended December 31, 2009 and 2008, respectively. The increase in 2009 primarily' related to a \$1.0 million payment we received related to the settlement of our patent infringement lawsuit against Ibis Biosciences, Inc., favorable realized foreign currency translations and the receipt of a research and development tax credit from the U.S. Government of \$0.3 million.

### Income Tax Expense

Income tax expense was \$117,000 and \$211,000 for the year ended December 31, 2009 and 2008, respectively. Income tax expense in both periods was primarily due to statutory tax liabilities resulting from our foreign operations.

## **Liquidity and Capital Resources**

As of December 31, 2010, cash, cash equivalents and current marketable securities totaled \$135.5 million, compared to \$42.7 million at December 31, 2009. Our cash equivalents and current marketable securities are held in a variety of securities that are represented by issuance from the U.S. Government, repurchase agreements collateralized by U.S. Government securities that have ratings of AAA, or are fully guaranteed by the U.S. Government.

As of December 31, 2010 and 2009, we had ARS with an estimated fair value of \$0 million and \$0.5 million, respectively. These estimated fair values reflect a \$2.0 million and \$3.8 million adjustment to the principal value of \$2.0 million and \$4.3 million as of December 31, 2010 and 2009, respectively. Additional discussion with respect to the risks and uncertainties associated with our ARS is included in "Quantitative and Qualitative Disclosures about Market Risk" in Item 7A of this report and in the notes to our consolidated financial statements included elsewhere in this report.

We have a history of recurring losses from operations and had an accumulated deficit of \$718.1 million as of December 31, 2010. Our capital requirements to sustain operations, including research and development projects, have been and will continue to be significant. As of December 31, 2010 and 2009, we had working capital of \$132.2 million and \$45.5 million, respectively.

We consider the material drivers of our cash flow to be sales volumes, working capital, inventory management and operating expenses. Our principal sources of liquidity are our cash, cash equivalents and marketable securities. Cash used in operations for the year ended December 31, 2010 was \$42.6 million, compared to \$48.7 million and \$34.6 million for the years ended December 31, 2009 and 2008, respectively. Our use of cash was primarily a result of the net loss of \$120.8 million for the year ended December 31, 2010, adjusted for non-cash items of \$55.0 million related to the equity portion of our litigation settlement, net of revaluation adjustments, depreciation and amortization of \$5.6 million, stock-based compensation of \$11.5 million, an increase to our bad debt reserve primarily related to two system sales in prior years of \$0.9 million, losses on the disposal of fixed assets of \$0.2 million and other non-cash items of \$0.2 million, which were offset by the non-cash item related to deferred rent of \$0.7 million. The changes in our operating assets and liabilities

consisted of lower prepaid expenses and other assets, as well as lower other liabilities that resulted in a cash provision of \$0.2 million and a cash usage of \$0.6 million, respectively. These changes in operating assets and liabilities were offset by our continuing efforts to maximize working capital, which resulted in lower accounts receivable and inventory balances compared to prior year that provided cash of \$0.6 million and \$2.0 million, respectively, as well as increased accounts payable and accrued expense balances that provided cash of \$2.2 million. Additionally, an increase in our deferred revenue balance primarily associated with an increase in the sale of maintenance contracts as compared to the same period in 2009, resulted in a cash provision of \$1.0 million. At our current and anticipated level of operating loss, we expect to continue to incur an operating cash outflow for the next several years.

Investing activities, other than the net changes in our current marketable securities and restricted cash that used \$3.0 million, consisted of purchases for capital equipment, leasehold improvements and intangible assets that used \$4.9 million in cash during the year ended December 31, 2010, compared to \$8.7 million and \$4.3 million for the same periods in 2009 and 2008, respectively. Additionally, we received proceeds of \$0.1 million from the sale of equipment during 2010.

Net cash provided by financing activities was \$140.3 million during the year ended December 31, 2010, compared to \$0.2 million in 2009. Financing activities during the year ended December 31, 2010, included proceeds from the issuance of common stock, net of issuance costs of \$138.3 million, \$3.3 million from the exercise of stock options and employee contributions under our employee stock purchase plan, offset by \$1.3 million in payments on our long-term debt and capital lease obligation.

The following table summarized our contractual obligations as of December 31, 2010 (in thousands):

Contractual obligations	Total	Less Than 1 Year	1-3 Years	3-5 Years	After 5 Years
Open purchase orders	\$ 2,402	\$ 2,402	\$ —	\$ —	\$ —
Long-term debt obligations	1,840	857	693	61	229
Collaborations	22,489	5,034	3,265	3,150	11,040
Operating leases	24,074	6,294	9,896	7,884	
Total contractual obligations	\$50,805	\$14,587	\$13,854	\$11,095	\$11,269

Open purchase orders are primarily for inventory items and research and development supplies. Collaborations primarily consist of agreements with institutions to conduct sponsored research and clinical study agreements.

In September 2005, we entered into an amendment to our lease for our corporate headquarters in San Diego. The lease amendment provides for the deferral of approximately \$3.2 million of the monthly rent payments by reducing the monthly payments through September 30, 2007 and increasing the aggregate monthly payments by the deferred amount for the remaining term of the lease, from October 1, 2007 to September 30, 2015. The total obligation under the lease remains unchanged. The contractual obligation table above reflects the deferral of these rent payments.

Long-term debt obligations include the associated interest payable on these borrowings. Other commitments and contingencies that may result in contractual obligations to pay are described in the notes to our consolidated financial statements included elsewhere in this report.

Based on our current plans, we believe our cash, cash equivalents and current marketable securities will be sufficient to fund our operating expenses and capital requirements into early 2013. However, the actual amount of funds that we will need will be determined by many factors, some of which are beyond our control, and we may need funds sooner than currently anticipated. These factors include but are not limited to:

- the size of our future operating losses;
- our success and our distributors' success in selling our MassARRAY system, ancillary reagents, software and services;

- Sequenom CMM's success in making available its testing service for cystic fibrosis carrier screening and fetal Rhesus D genotyping and the level of reimbursement it receives and its collections for those tests;
- the terms and conditions of sales contracts, including extended payment terms;
- our ability to introduce and sell new MassARRAY system, ancillary reagents, software and services, including the MassARRAY Analyzer 4;
- the level of our selling, general and administrative expenses;
- our success and the extent of our investment in the research, development and commercialization of diagnostic technology, including genetic analysis technology, molecular diagnostics and noninvasive prenatal diagnostic technology;
- our success in obtaining sufficient quantities and quality of patient samples;
- our success in obtaining regulatory clearance or approval to market our diagnostic products in various countries, including the United States;
- our success in validating our diagnostic tests and the levels of clinical performance achieved;
- our success either alone or in collaboration with our partners in launching and selling additional diagnostic products or services;
- our success and the extent of our investment in the research and development in our genetic analysis business;
- the extent to which we enter into, maintain, and derive revenues from licensing agreements, including agreements to out-license our noninvasive prenatal analysis technology, research and other collaborations, joint ventures and other business arrangements;
- the amount of our legal expenses and any fines or damages arising out of the matters that were the subject of an investigation by a special committee of our board of directors in 2009, including such amounts associated with the investigations by the SEC, the Office of the U.S. Attorney for the Southern District of California and the FBI, and the claims asserted by TrovaGene (formerly Xenomics), none of which are currently covered by insurance;
- the level of our legal expenses and any damages or settlement payments arising from the lawsuit filed by our former chief financial officer to the extent our insurance coverage is insufficient;
- the amount of any legal expenses, settlement payments, fines or damages arising from any future investigation or litigation and the extent to which any of the foregoing is covered by insurance;
- the dilution from any issuance of securities, whether in connection with future capital-raising or acquisition transactions, the settlement of litigation, or otherwise;
- the extent to which we acquire, and our success in integrating, technologies or companies;
- the level of our expenses associated with the audit of our consolidated financial statements as well as compliance with other corporate governance and regulatory developments or initiatives;
- · regulatory changes by the FDA and other worldwide regulatory authorities; and
- technological developments in our markets.

At December 31, 2010, we had outstanding stand-by letters of credit with financial institutions totaling \$1.4 million related to a building and customer guarantees. The letter of credit related to our Newton, Massachusetts building lease agreement totaling \$1.3 million expired on December 31, 2010 and subsequent to year end was released from its restriction.

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

## **Marketable Securities**

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the fair value of the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and interest rates later rise, the fair value of the principal amount of our investment will probably decline. To minimize this risk our current investment policy requires us to maintain our portfolio of cash equivalents and marketable securities in a variety of securities that are represented by issuances from the U.S. Government, repurchase agreements collateralized by U.S. Government securities that have ratings of AAA or are fully guaranteed by the U.S. Government. Our investment policy also includes a minimum quality rating for all new investments and the overall amount that may be invested in a single security. If an investment we hold falls below the minimum quality rating, we research the reasons for the fall and determine if we should continue to hold the investment in order to minimize our exposure to the market risk of the investment.

The appropriate classification of marketable securities is determined at the time of purchase and reevaluated as of each balance sheet date. Based on this determination, as of December 31, 2010 and 2009, all of our investments in marketable securities were classified as available for sale and were reported at fair value. We measure fair value based on the prices that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value is determined based on observable market quotes or valuation models using assessments of counterparty credit worthiness, credit default risk or underlying security and overall capital market liquidity. Declines in fair value that are considered other-than-temporary are charged to operations and those that are considered temporary are reported as a component of accumulated other comprehensive income in stockholders' equity. We use the specific identification method of determining the cost basis in computing realized and unrealized gains and losses on the sale of our available for sale securities.

At December 31, 2010 and 2009, we had \$2.0 million and \$4.3 million, respectively, of principal invested in ARS and had an estimated fair value of \$0 and \$0.5 million, respectively. Consistent with our investment policy guidelines in effect when originally purchased, these ARS investments had AAA/AA credit ratings at the time of purchase. During the first quarter of 2010, we sold two ARS investments with an aggregate principal value of \$2.3 million, but an estimated fair value of \$0.5 million. These sales resulted in a gain on the sale of approximately \$0.1 million. For the year ended December 31, 2010, no other-than-temporary impairment losses were charged to operations and there are no accumulated unrealized losses in other comprehensive income related to our investment in ARS.

Our remaining ARS as of December 31, 2010, was a private placement security with a long-term nominal maturity in 2028 and with an interest rate that resets through a Dutch auction each month and represents an interest in collateralized debt obligations supported by insurance securitizations. With the liquidity issues experienced in global credit and capital markets our remaining ARS had experienced multiple failed auctions as the amount of securities submitted for sale has exceeded the amount of purchase orders and we have been unable to liquidate this security. Since there is a lack of observable market quotes on our remaining marketable security investment in ARS, as necessary we utilize valuation models including those that are based on expected cash flow streams and collateral values, including assessments of counterparty credit quality, default risk underlying the security, discount rates, overall capital market liquidity and our overall intent and ability to liquidate our ARS. The valuation include changes to credit ratings of the securities as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity. Based on the factors outlined above, our remaining ARS continues to have an estimated fair value of \$0 since December 31, 2009.

#### Foreign currency rate fluctuations

We have foreign subsidiaries whose functional currencies are the Great British Pound (GBP), the Japanese Yen (Yen), the Indian Rupee (INR) and the Euro (EUR). The subsidiaries' accounts are translated from the relevant functional currency to the U.S. dollar using the current exchange rate in effect at the balance sheet date, for balance sheet accounts, and using the average exchange rate during the period for revenues and expense accounts. The effects of translation are recorded as a separate component of stockholders' equity. Our subsidiaries conduct their business with customers in local currencies. Additionally, we occasionally invoice Australian customers in their local currency. Exchange gains and losses arising from these transactions are recorded using the actual exchange differences on the date of the transaction. We have not taken any action to reduce our exposure to changes in foreign currency exchange rates, such as options or futures contracts, with respect to transactions with our subsidiaries or transactions with our customers where the invoicing currency is not the U.S. dollar.

The table below sets forth our currency exposure (i.e., those transactional exposures that give rise to the net currency gains and losses recognized in the income and expenditure account) on our net monetary assets and liabilities. These exposures consist of our monetary assets and liabilities that are not denominated in the functional currency used by us or our subsidiary having the asset or liability.

	As of December 31, 2010 Net foreign monetary assets/(liabilities)		
Functional currency of operations	AUS dollars	Euro	
	(\$ in millions)		
USD	\$0.5	\$1.1	

A movement of 10% in the U.S. dollar to Australian dollar exchange rate would create an unrealized gain or loss of approximately \$52,000. A movement of 10% in the U.S. dollar to EUR exchange rate would create an unrealized gain or loss of approximately \$107,000. We had no off balance sheet, or unrecognized, gains and losses in respect of financial instruments used as hedges at the beginning or end of the year ended December 31, 2010. We had no deferred gains or losses during the years ended December 31, 2010, 2009 or 2008.

#### Inflation

We do not believe that inflation has had a material adverse impact on our business or operating results during the periods presented.

## Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and the reports of Ernst & Young LLP, our independent registered public accounting firm, are included in this report on Pages F-1 through F-38.

## Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

#### Item 9A. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the year covered by this report. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2010 to ensure that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our management does not expect that even our recently enhanced disclosure controls or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived, implemented and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## Management's Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our 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:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(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 our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk. Management is responsible for establishing and maintaining adequate internal control over financial reporting for the company, as defined in Exchange Act Rule 13a-15(f).

Management has used the framework set forth in the report entitled Internal Control-Integrated Framework published by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, to evaluate the effectiveness of our internal control over financial reporting as of December 31, 2010. Based on our assessment, management, including our Chief Executive Officer and Chief Financial Officer has concluded that our internal control over financial reporting were effective as of December 31, 2010. The effectiveness of our internal control over financial reporting as of December 31, 2010 has been audited by Ernst & Young LLP, an independent registered public accounting firm, which has issued an attestation report on our internal control over financial reporting were financial reporting as a stepstation report on our internal control over financial reporting firm, which has issued an attestation report on our internal control over financial reporting included herein.

## Changes in Internal Control Over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of Sequenom, Inc.

We have audited Sequenom, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Sequenom, 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's 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, Sequenom, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, 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 Sequenom, Inc. as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010 of Sequenom, Inc. and our report dated March 8, 2011 expressed an unqualified opinion thereon.

#### /s/ ERNST & YOUNG LLP

San Diego, California March 8, 2011

## Item 9B. OTHER INFORMATION

None

#### PART III

Certain information required by Part III is omitted from this report because we will file with the Securities and Exchange Commission a definitive proxy statement within 120 days after the end of our fiscal year for our annual meeting of stockholder (Proxy Statement), and the information included in the Proxy Statement is incorporated herein by reference.

#### Item 10. DIRECTORS, AND EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Proxy Statement under the heading "Election of Directors." Information regarding executive officers is set forth in Item 1 of Part I of this report and is incorporated herein by reference.

We have adopted a code of business conduct and ethics for directors, officers (including our principal executive, financial and accounting officers) and all employees, which we refer to as our Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at http:// www.sequenom.com. Stockholders may request a free copy of our Code of Business Conduct and Ethics from:

Sequenom, Inc. Attention: Investor Relations 3595 John Hopkins Court San Diego, CA 92121-1331 (858) 202-9000

If we make any substantive amendments to the code of business conduct and ethics or grant any waiver from a provision of the code to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver.

#### Section 16(a) Beneficial Ownership Reporting Compliance

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by Section 16 of the Exchange Act. This disclosure is incorporated by reference from the information in the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement.

#### Item 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated herein by reference from the information in the sections entitled "Executive Compensation" and "Election of Directors" in the Proxy Statement.

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

The information required by this item is incorporated herein by reference from the information in the sections entitled "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans" in the Proxy Statement.

## Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated herein by reference from the information in the sections entitled "Certain Transactions" and "Independence of the Board of Directors" in the Proxy Statement.

## Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated herein by reference from the information in the section entitled "Principal Accountant Fees and Services" and "Pre-Approval Policies and Procedures" in the Proxy Statement.

#### PART IV

## Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

#### (a)(1) Financial Statements

The financial statements of Sequenom, Inc. are included herein as required under Item 8 of this report. See Index to Consolidated Financial Statements on page F-l.

(a)(2) Financial Statement Schedules

Schedule II—Valuation and Qualifying Accounts. The other financial statement schedules have been omitted because they are either not required, not applicable, or the information is otherwise included.

(a)(3) Exhibits

The exhibits listed below are required by Item 601 of Regulation S-K. Each management contract or compensatory plan or arrangement required to be filed as an exhibit to this report has been identified.

Exhibit Number	Description of Document
3.1(1)	Restated Certificate of Incorporation of the Registrant.
3.2(2)	Restated bylaws of Registrant, as amended.
3.3(3)	Registrant's Certificate of Designation of Series A Junior Participating Preferred Stock.
4.1(1)	Specimen common stock certificate.
4.2(3)	Rights Agreement dated as of March 3, 2009, between the Registrant and American Stock Transfer and Trust Company, LLC.
4.3(3)	Form of Right Certificate.
10.1(4)	Form of Warrant Agreement between the Registrant and holders of the Series C Preferred Stock warrants.
10.2(1)	Form of Indemnification Agreement between the Registrant and each of its officers and directors.
10.3(4)#	1994 Stock Plan.
10.4(4)#	1994 Stock Plan Form of Non-Qualified Stock Option Grant.
$10.5^{(4)}$ #	1994 Stock Plan Form of Incentive Stock Option Grant.
$10.6^{(4)}$ #	1994 Stock Plan Form of Stock Restriction Agreement.
10.7(4)#	1998 Stock Option/Stock Issuance Plan.
$10.8^{(4)}$ #	1998 Stock Option/Stock Issuance Plan Form of Notice of Grant of Stock Option.
10.9(4)#	1998 Stock Option/Stock Issuance Plan Form of Stock Option Agreement.
10.10(4)#	1998 Stock Option/Stock Issuance Plan Form of Stock Purchase Agreement.
10.11(4)#	1998 Stock Option/Stock Issuance Plan Form of Stock Issuance Agreement.
10.12(5)#	1999 Stock Incentive Plan, as amended.
10.13(4)#	1999 Stock Incentive Plan Form of Notice of Grant of Stock Option.
10.14(4)#	1999 Stock Incentive Plan Form of Stock Option Agreement.
10.15(6)#	1999 Employee Stock Purchase Plan, as amended.
10.16 <sup>(7)</sup> #	2006 Equity Incentive Plan, as amended.
10.17(1)#	2006 Equity Incentive Plan Form of Stock Option Grant Notice.

Exhibit Number	Description of Document
10.18(1)#	2006 Equity Incentive Plan Form of Stock Option Agreement.
10.19(8)#	
10.20(9)#	
10.21 <sup>(9)</sup> #	
10.22(10)	Business Loan Agreement, dated March 3, 2000, between the Registrant and Union Bank of California.
10.23(11)	Building Lease Agreement, dated March 29, 2000, between the Registrant and TPSC IV LLC.
10.24(12)#	
10.25(13)#	Form of Medical Expense Reimbursement Exec-U-Care Plan.
10.26(14)#	Employment Agreement, dated July 19, 2004, by and between the Registrant and Clarke Neumann.
10.27(15)*	
10.28(15)#	Form of Stock Issuance Agreement under 1999 Stock Incentive Plan.
10.29(16)	Amendment Number One to Lease dated March 29, 2000, by and between the Registrant and TPSC IV LLC dated September 9, 2005.
10.30(16)	Common Stock Warrant, dated September 9, 2005, issued to Kwacker, Ltd.
10.31(16)#	Employment Agreement Amendment, dated September 12, 2005, by and between the Registrant and Dr. Charles R. Cantor.
10.32(17)*	Exclusive License of Technology Agreement, dated October 14, 2005, by and between the Registrant and ISIS Innovation Limited.
10.33(18)	Amended and Restated Securities Purchase Agreement, dated March 30, 2006, by and among the Registrant, ComVest Investment Partners II LLC, LB I Group Inc., Pequot Private Equity Fund IV, L.P. and Siemens Venture Capital GmbH.
10.34(18)	Form of Warrant issued pursuant to the Amended and Restated Securities Purchase Agreement dated March 30, 2006.
10.35(19)#	Letter agreement dated April 6, 2006, by and between the Registrant and John E. Lucas.
10.36(1)	Registration Rights Agreement dated June 6, 2006 by and between the Registrant, ComVest Investment Partners II LLC, LB I Group Inc., Pequot Private Equity Fund IV, L.P. and Siemens Venture Capital GmbH.
10.37(20)*	Amendment to Exclusive License of Technology Agreement dated October 19, 2006, by and between the Registrant and ISIS Innovation Limited.
10.38(20)*	Supply Agreement dated November 3, 2006, by and between the Registrant and Bruker Daltonics Inc.
10.39(21)#	Form of Restricted Stock Bonus Grant Notice under 2006 Equity Incentive Plan.
	Form of Restricted Stock Bonus Agreement under 2006 Equity Incentive Plan.
10.41(22)*	Collaboration and License Agreement dated January 24, 2007, between the Registrant and Lenetix Medical Screening Laboratory, Inc.
10.42(23)	Placement Agency Agreement dated April 25, 2007, between the Registrant and Lehman Brothers Inc.
10.43(24)	Letter agreement dated June 25, 2007, by and between the Registrant and Kathleen Wiltsey.
	Letter agreement dated July 2, 2007, by and between the Registrant and Richard Alan Lerner, M.D.

Exhibit Number	Description of Document
10.45(25)	Form of Purchase Agreement, dated October 25, 2007, by and between the Registrant and the variou purchasers of shares of the Registrant's common stock.
10.46 <sup>(26)</sup> *	Amendment to Exclusive License of Technology Agreement dated November 5, 2007, by and between the Registrant and ISIS Innovation, Limited.
10.47(27)#	Non-Employee Director Compensation Policy.
10.48(27)#	Amended and Restated Change in Control Severance Benefit Plan.
10.49(27)#	Deferred Compensation Plan, as amended.
10.50(28)#	New-Hire Equity Incentive Plan.
10.51(28)*	Amendment to Exclusive License of Technology Agreement dated November 3, 2009, by and between the Registrant and ISIS Innovation Limited.
10.52(28)*	License Agreement, dated February 4, 2010, by and between the Registrant and Optherion, Inc.
10.53 <sup>(28)</sup> #	Agreement dated March 13, 2010 by and between the Registrant and Harry F. Hixson, Jr., Ph.D.
10.54(28)#	Letter agreement dated October 21, 2010 by and between the Registrant and Paul V. Maier.
10.55(29)	Stipulation of Settlement in In re Sequenom, Inc. Derivative Litigation.
10.56(30)	Securities Purchase Agreement, dated May 12, 2010, by and among the Registrant and the other parties named therein.
10.57(30)	Registration Rights Agreement, dated May 12, 2010, by and among the Registrant and the other parties named therein.
10.58*	License Agreement, dated September 16, 2008, by and between the Registrant and The Chinese University of Hong Kong.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of Principal Executive Officer pursuant to Rule13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
* Cert trea	- agement contract or compensatory plan. ain confidential portions of this Exhibit have been omitted pursuant to a request for confidential ment. Omitted portions have been filed separately with the Securities and Exchange Commission. apporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed June 6,
2) Inco	proproved by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed urry 15, 2010.
<ol> <li>Inco 200</li> </ol>	proproted by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed March 4, 9.
ame	reported by reference to the Registrant's Registration Statement on Form S-1 (No. 333-91665), as nded.
5) Inco	proprieted by reference to the Registrant's Annual Report on Form 10-K (No. 000-29101) for the year

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- (6) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed February 1, 2010.
- (7) Incorporated by reference to the Registrant's Definitive Proxy Statement on Schedule 14A filed April 29, 2010.
- (8) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed June 6, 2006.
- (9) Incorporated by reference to the Registrant's Registration Statement on Form S-8 (No. 333-152230) filed July 10, 2008.
- (10) Incorporated by reference to the Registrant's Annual Report on Form 10-K (No. 000-29101) for the year ended December 31, 1999.
- (11) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended March 31, 2000.
- (12) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (No. 333-91665), as amended, which exhibit is hereby supplemented with an additional Schedule A filed with the Registrant's Annual Report on Form 10-K (No. 000-29101) for the year ended December 31, 2000.
- (13) Incorporated by reference to the Registrant's Annual Report on Form 10-K (No. 000-29101) for the year ended December 31, 2003.
- (14) Incorporated by reference to the Registrant's Annual Report on Form 10-K (No. 000-29101) for the year ended December 31, 2005.
- (15) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended September 30, 2004.
- (16) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed September 14, 2005.
- (17) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended September 30, 2005.
- (18) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed April 3, 2006.
- (19) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed April 10, 2006.
- (20) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended September 30, 2006.
- (21) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed January 24, 2007.
- (22) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended March 31, 2007.
- (23) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed April 25, 2007.
- (24) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended June 30, 2007.
- (25) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed October 26, 2007.
- (26) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended September 30, 2007.
- (27) Incorporated by reference to the Registrant's Annual Report on Form 10-K (No. 000-29101) for the year ended December 31, 2008.
- (28) Incorporated by reference to the Registrant's Annual Report on Form 10-K (No. 000-29101) for the year ended December 31, 2009.
- (29) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (No. 000-29101) for the quarter ended March 31, 2010.
- (30) Incorporated by reference to the Registrant's Current Report on Form 8-K (No. 000-29101) filed May 13, 2010.

#### 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.

Date: March 8, 2011

#### SEQUENOM, INC.

By: /s/ HARRY F. HIXSON, JR., PH.D. Harry F. Hixson, Jr., Ph.D. Chief Executive Officer

#### **POWER OF ATTORNEY**

Know all men by these presents, that each person whose signature appears below constitutes and appoints Harry F. Hixson and Paul V. Maier, and each of them, as his attorneys-in-fact and agents, each with power of substitution in any and all capacities, to sign any amendments to this annual report on Form 10-K, and to file the same with exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that the attorney-in-fact or his substitute or substitutes may do or cause to be done by virtue hereof.

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 in the capacities and on the dates indicated.

Signature	Title	Date
/s/ HARRY F. HIXSON, JR., PH.D. Harry F. Hixson, Jr., Ph.D.	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 8, 2011
/s/ PAUL V. MAIER Paul V. Maier	Chief Financial Officer (Principal Financial and Accounting Officer)	March 8, 2011
/s/ ERNST-GUNTER AFTING, PH.D., M.D. Ernst-Gunter Afting, Ph.D., M.D.	Director	March 8, 2011
/s/ KENNETH F. BUECHLER, PH.D. Kenneth F. Buechler, Ph.D.	Director	March 8, 2011
/s/ JOHN A. FAZIO John A. Fazio	Director	March 8, 2011
/s/ RICHARD A. LERNER, M.D. Richard A. Lerner, M.D.	Director	March 8, 2011
/s/ RONALD M. LINDSAY, PH.D. Ronald M. Lindsay, Ph.D.	Executive Vice President and Director	March 8, 2011
/s/ DAVID PENDARVIS David Pendarvis	Director	March 8, 2011

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#### INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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All other schedules have been omitted for the reason that the required information is presented in the financial statements or notes thereto, the amounts involved are not significant or the schedules are not applicable.

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

The Board of Directors and Stockholders of Sequenom, Inc.

We have audited the accompanying consolidated balance sheets of Sequenom, Inc. as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010. Our audits also included the financial statement schedule listed in the Index at Item 15(a)(2). These financial statements and the financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule 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 Sequenom, Inc. at December 31, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Sequenom, Inc.'s internal control over financial reporting as of December 31, 2010, 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 8, 2011 expressed an unqualified opinion thereon.

#### /s/ ERNST & YOUNG LLP

San Diego, California March 8, 2011

## CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share information)

	Decen	ıber 31,
;	2010	2009
Assets		
Current assets:		
Cash and cash equivalents	\$ 116,647	\$ 26,919
Marketable securities	18,833	15,762
Restricted cash	1,404	1,419
Accounts receivable, net	6,911	8,510
Inventories, net	5,605	7,722
Other current assets and prepaid expenses	2,387	2,598
Total current assets	151,787	62,930
Equipment and leasehold improvements, net	11,038	11,811
Intangible assets, net	773	1.172
Goodwill	10,007	10,007
Other assets	674	725
Total assets	\$ 174,279	\$ 86,645
	<u> </u>	\$ <u>80,04</u> 5
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,958	\$ 6,064
Accrued expenses	9,947	8,202
Deferred revenue	2,624	1,871
Current portion of debt and obligations	938	1,320
Total current liabilities	19,467	17,457
Deferred revenue, less current portion	518	304
Other long-term liabilities	2,660	3,389
Long-term portion of debt and obligations	902	1,837
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock, par value \$0.001; authorized shares-5,000,000, no		
shares issued or outstanding at December 31, 2010 or 2009, respectively	—	
Common stock, par value \$0.001; authorized shares—185,000,000, issued and		
outstanding shares 98,849,381 and 61,988,473 at December 31, 2010 and 2009,		
respectively	99	62
Additional paid-in capital	867,977	659,798
Accumulated other comprehensive income	786	1,084
Accumulated deficit	(718,130)	(597,286
Total stockholders' equity	150,732	63,658
Total liabilities and stockholders' equity	\$ 174,279	\$ 86,645
		÷ 00,045

See accompanying notes.

## CONSOLIDATED STATEMENTS OF OPERATIONS (In thousands, except per share information)

	Year ended December 31,		
	2010	2009	2008
Revenues:			
Consumables	\$ 22,019	\$ 20,534	\$ 19,535
MassARRAY and other product related	20,403	14,999	22,724
Contract research services	2,483	2,209	4,817
Diagnostic	2,554	94	
Research and other		- 27	73
Total revenues	47,459	37,863	47,149
Costs and expenses:			
Cost of consumables and products revenue	14,415	11,980	15,109
Cost of services revenue	616	2,178	4,481
Cost of diagnostic revenue	3,965	412	
Research and development	43,431	37,454	27,455
Selling and marketing	28,387	26,845	24,299
General and administrative	22,280	28,127	18,436
Litigation settlement, net	55,384	· —	·
Restructuring		1,589	
Total operating costs and expenses	168,478	108,585	89,780
Loss from operations	(121,019)	(70,722)	(42,631)
Interest income	162	442	1,592
Gain (loss) on marketable securities	111	(1,914)	(2,584)
Interest expense	(190)	(261)	(139)
Other income (expense), net	82	1,560	(181)
Loss before income taxes	(120,854)	(70,895)	(43,943)
Income tax benefit (expense)	10	(117)	(211)
Net loss	\$(120,844)	\$(71,012)	\$(44,154)
Net loss per share, basic and diluted	\$ (1.69)	\$ (1.16)	\$ (0.83)
Weighted average shares outstanding, basic and diluted	71,697	61,171	53,129

See accompanying notes.

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## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (In thousands, except share information)

	Common Stock		Additional Other Paid-In Comprehensive		Accumulated	Total Stockholders'	
	Shares	Amount	Capital	Income	Deficit	Equity	
Balance at December 31, 2007	44,888,656	\$ 44	\$536,022	\$ 319	\$(482,120)	\$ 54,265	
Net loss		_	_		• (44,154)	(44,154)	
Unrealized gain on							
available-for-sale securities				898		898	
Translation adjustment	_	—	—	111	—	111	
Comprehensive loss		—	_			(43,145)	
Stock-based compensation	—	<del>,</del>	7,276	,		7,276	
Exercise of stock options	283,810	1	1,295	—	—	1,296	
Vesting of restricted stock	57,126	—	423	-		423	
Exercise of warrants	9,093,302	9	139	_		148	
Purchases under Employee Stock							
Purchase Plan	107,781		568		. —	568	
Issuance of common stock, net of		_					
issuance costs	6,512,794	7	95,375			95,382	
Balance at December 31, 2008	60,943,469	\$ 61	\$641,098	\$1,328	\$(526,274)	\$ 116,213	
Net loss	_	—	—		(71,012)	(71,012)	
Unrealized gain on							
available-for-sale securities				2		2	
Translation adjustment		—	—	(246)		(246)	
Comprehensive loss	—	_	_		_	(71,256)	
Stock-based compensation		_	11,814		—	11,814	
Exercise of stock options	480,153	1	1,145		—	1,146	
Vesting of restricted stock	23,224		1,519		—	1,519	
Purchases under Employee Stock							
Purchase Plan	81,401		760	—	—	760	
Issuance of common stock, net of							
issuance costs	460,226		3,462			3,462	
Balance at December 31, 2009	61,988,473	\$ 62	\$659,798	\$1,084	\$(597,286)	\$ 63,658	
Net loss	·				(120,844)	(120,844)	
Unrealized loss on available-for-sale							
securities				(34)	<i>i</i> —	(34)	
Translation adjustment	_			(264)		(264)	
Comprehensive loss			_	_	_	(121,142)	
Stock-based compensation	_		10,865		_	10,865	
Exercise of stock options	1,036,165	1	2,608	_		2,609	
Vesting of restricted stock	70,911	—	648	_	_	648	
Purchases under Employee Stock							
Purchase Plan	202,089		704	—	<u> </u>	704	
Issuance of common stock,							
litigation settlement	7,016,743	7	55,039		·	55,046	
Issuance of common stock, net of							
issuance costs	28,535,000	29	138,315		·	138,344	
Balance at December 31, 2010	98,849,381	<u>\$ 99</u>	\$867,977	\$ 786	\$(718,130)	\$ 150,732	

See accompanying notes.

# CONSOLIDATED STATEMENTS OF CASH FLOWS (In thousands)

	Year en	ded Decem	ber 31,
	2010	2009	2008
Operating activities			
Net loss	\$(120,844)	\$(71,012)	\$(44,154)
Litigation settlement, net	55,046		
Stock-based compensation	10,865	11,814	7,276
Depreciation and amortization	5,592	5,201	2,893
Loss on marketable securities		1,914	2,893
Loss on disposal of fixed assets	235	193	232
Settlement of SensiGen, LLC claim		1,522	
Contingent consideration fair value adjustment	32	514	
Bad debt expense	873	(139)	400
Restricted stock	648	455	161
Deferred rent	(700)	(569)	(442)
Other non-cash items	179	7	41
Changes in operating assets and liabilities:			
Accounts receivable	581	1,892	(115)
Inventories, net	2,045	2,923	(6,492)
Other current assets and prepaid expenses	213	(1,280)	(212)
Other assets	18	14	(56)
Accounts payable and accrued expenses	2,179	(1,733)	2,471
Deferred revenue	1,016	267	686
Other liabilities	(559)	(691)	111
Net cash used in operating activities	(42,581)	(48,708)	(34,616)
Investing activities			
Purchase of equipment, leasehold improvements, and intangible assets	(4,927)	(8,699)	(4,268)
Restricted cash	43	(49)	(41)
Proceeds from the sale of equipment	86		
Acquisition of CMM, LLC	_	_	(400)
Acquisition of SensiGen, LLC, net of cash acquired	_	(2,017)	
Purchases of marketable securities	(25,782)	(30,297)	(44,483)
Sales of marketable securities	497	3,363	24,012
Maturities of marketable securities	22,180	45,000	21,683
Net cash (used in) provided by investing activities	(7,903)	7,301	(3,497)
<b>Financing activities</b>			
Payments on long-term debt	(1,202)	(1,576)	(637)
Payments on capital lease obligations	(1,202)	(1,570) (80)	(057)
Proceeds from issuance of common stock, net of issuance costs	138,344	(00)	91,782
Proceeds from exercise of warrants, stock options and ESPP purchases	3,313	1,905	2,011
	·		
Net cash provided by financing activities	140,340	249	93,156
Net increase (decrease) in cash and cash equivalents	89,856	(41,158)	55,043
Effect of exchange rate changes on cash and cash equivalents	(128)	(261)	179
Cash and cash equivalents at beginning of year	26,919	68,338	13,116
Cash and cash equivalents at end of year	\$ 116,647	\$ 26,919	\$ 68,338
Supplemental disclosure of cash flow information:			
Interest paid	\$ 203	\$ 247	\$ 134
Supplemental non-cash items:			
Investing activities:			
Equipment purchased under capital lease obligation	<u>\$                                    </u>	\$ 366	<u>\$                                    </u>
Equipment purchased under asset-backed loan	\$	\$	\$ 610
Financing activities:			
Issuance of common stock related to litigation settlement	¢ EE OAC	¢	¢
	\$ 55,046		<u>а —                                   </u>
Issuance of common stock related to acquisition	\$	\$	\$ 3,600
·			

See accompanying notes.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### December 31, 2010

#### 1. Nature of the Business

We are a molecular diagnostic testing and genetics analysis company committed to providing products, services, applications and genetic analysis products that translate the results of genomic science into solutions for biomedical research, translational research, molecular medicine applications, and agricultural, livestock, and other areas of research. Our development and commercialization efforts in various diagnostic areas include noninvasive women's health-related and prenatal diagnostics, ophthalmology, oncology, infectious diseases, and other medical conditions, disorders and diseases.

#### 2. Summary of Significant Accounting Policies and Significant Accounts

#### **Basis of Presentation and Consolidation**

The accompanying consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles (GAAP) and include the accounts of Sequenom, Inc. and our wholly-owned subsidiaries located in the United States, Germany, the United Kingdom, Japan, India and Hong Kong. All significant intercompany accounts and transactions are eliminated in consolidation.

#### Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires us to make certain 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.

#### Goodwill and Purchased Intangible Assets

Goodwill is recorded when the consideration paid for an acquisition exceeds the fair value of the identified net tangible and intangible assets of acquired businesses. The allocation of purchase price for acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired and liabilities assumed based on their respective fair values. Additionally, we must determine whether an acquired entity is considered to be a business or a set of net assets, because a portion of the purchase price can only be allocated to goodwill in a business combination. Goodwill and intangible assets deemed to have indefinite lives are not amortized, but are subject to annual impairment tests. The amounts and useful lives assigned to other intangible assets, such as lab accreditations, patent rights and licenses, requires the use of estimates and the exercise of judgment. These judgments can significantly affect our net operating results. As of December 31, 2010 and 2009, we had goodwill recorded of \$10.0 million, respectively.

We annually evaluate our goodwill and purchased intangibles at the reporting unit level during the fourth quarter each fiscal year or more frequently if we believe indicators of impairment are present. Goodwill and certain intangible assets are assessed for impairment using fair value measurement techniques.

We periodically re-evaluate the original assumptions and rationale utilized in the establishment of the carrying value and estimated lives of our long-lived assets. The criteria used for these evaluations include management's estimate of the asset's continuing ability to generate income from operations and positive cash flows in future periods as well as the strategic significance of any intangible assets in our business objectives. If assets are considered to be impaired, the impairment recognized is the amount by which the carrying value of the assets exceeds the fair value of the assets.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

#### December 31, 2010

#### Collaboration, Development and Licensing Agreements

We enter into license agreements and collaborative research and development arrangements with pharmaceutical and biotechnology partners that may involve multiple deliverables. Our arrangements may contain one or more of the following elements: upfront fees, milestone payments, royalties and license fees. Each deliverable in the arrangement is evaluated to determine whether it meets the criteria to be accounted for as a separate unit of accounting or whether it should be combined with other deliverables. Revenue is recognized for each element when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collection is reasonably assured.

Upfront fees received for license and collaborative agreements are recognized ratably over our expected performance period under the arrangement. Management makes its best estimate of the period over which we expect to fulfill our performance obligations. Given the uncertainties of research and development collaborations, significant judgment is required to determine the duration of the performance period.

Milestone payments received are deferred and recognized as revenue ratably over the period of time from the achievement of the milestone and our estimated date on which the next milestone will be achieved. Management makes its best estimate of the period of time until the next milestone is reached. Final milestone payments are recorded and recognized upon achieving the respective milestone, provided that collection is reasonably assured. The original estimated amortization periods for upfront fees and milestone payments are periodically evaluated to determine if circumstances have caused the estimate to change and if so, amortization of revenue is adjusted prospectively.

#### **Reserves for Obsolete and Slow-moving Inventory**

We operate in an industry characterized by rapid improvements and changes to our technology and products. The introduction of new products by us or our competitors can result in our inventory being rendered obsolete or requiring us to sell items at a discount. We estimate the recoverability of our inventory by reference to our internal estimates of future demands and product life cycles. If we incorrectly forecast demand for our products or inadequately manage the introduction of new product lines, we could materially impact our consolidated financial statements by having excess inventory on hand. Our future estimates are subjective and could be incorrect. During 2010, slow-moving and obsolete inventory reserves of \$0.5 million, net, were credited against cost of goods sold and the reserve was \$1.0 million and \$1.5 million at December 31, 2010 and 2009, respectively.

#### Shipping and Handling Costs

Shipping and handling costs are included within cost of product revenue on the statement of operations.

#### Cash and Cash-Equivalents

Cash equivalents consist of short-term, highly liquid investments with original maturities of three months or less when purchased.

#### Marketable Securities

The classification of marketable securities is determined by management at the time of purchase and reevaluated as of each balance sheet date. As of December 31, 2010 and 2009, all of our investments in

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

marketable securities were classified as available for sale and were reported at fair value. We measure fair value based on the prices that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value is determined based on observable market quotes or valuation models using assessments of counterparty credit worthiness, credit default risk or underlying security and overall capital market liquidity. Declines in fair value that are considered other-than-temporary are charged to operations and those that are considered temporary are reported as a component of accumulated other comprehensive income (loss) in stockholders' equity. We use the specific identification method of determining the cost basis in computing realized and unrealized gains and losses on the sale of our available for sale securities. Gross realized gains on sales of available-for sale securities for the year ended December 31, 2010 were \$0.1 million and gross realized losses were immaterial. Gross realized gains for the years ended December 31, 2009 and 2008 were immaterial and gross realized losses on sales of available-for-sale securities were \$1.9 million and \$2.6 million, respectively.

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the fair value of the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and interest rates later rise, the fair value of the principal amount of our investment will probably decline. To minimize this risk our current investment policy requires us to maintain our portfolio of cash equivalents and marketable securities in a variety of securities that are represented by issuances from the U.S. Government, repurchase agreements collateralized by U.S. Government securities that have ratings of AAA or are fully guaranteed by the U.S. Government. Our investment policy also includes a minimum quality rating for all new investments and the overall amount that may be invested with a single security. If an investment we hold falls below the minimum quality rating, we research the reasons for the fall and determine if we should continue to hold the investment in order to minimize our exposure to the market risk of the investment.

At December 31, 2010 and 2009, we had \$2.0 million and \$4.3 million, respectively, of principal invested in auction rate securities (ARS) with an estimated fair value of \$0 and \$0.5 million, respectively. Consistent with our investment policy guidelines in effect when originally purchased, these ARS investments had AAA/AA credit ratings at the time of purchase. Our remaining ARS as of December 31, 2010, was a private placement security with a long-term nominal maturity in 2028 and with an interest rate that resets/through a Dutch auction each month and represents an interest in collateralized debt obligations supported by insurance securitizations. With the liquidity issues experienced in global credit and capital markets our remaining ARS had experienced multiple failed auctions as the amount of securities submitted for sale has exceeded the amount of purchase orders and we have been unable to liquidate this security. Since there is a lack of observable market quotes on our remaining marketable security investment in ARS, as necessary we utilize valuation models including those that are based on expected term, expected cash flow streams and collateral values, including assessments of counterparty credit quality, default risk underlying the security, discount rates, overall capital market liquidity and our overall intent and ability to liquidate our ARS. The valuation of our investment portfolio is subject to uncertainties that are difficult to predict. Factors that may impact our valuation include changes to credit ratings of the securities as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity. Based on the factors outlined above, our remaining ARS continues to have an estimated fair value of \$0 since December 31, 2009

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

#### December 31, 2010

#### **Restricted Cash**

Restricted cash and investments of \$1.4 million and \$1.4 million as of December 31, 2010 and 2009, respectively, are held in interest bearing cash accounts with restrictions on withdrawal, in support of certain customer guarantees and a stand-by letter of credit. The restricted cash related to our letter of credit associated with our Newton, Massachusetts building lease agreement totaling \$1.3 million expired on December 31, 2010 and subsequent to year end was released from its restriction.

#### **Concentration of Risks**

Financial instruments that we are potentially subject to credit risk consist of trade receivables. We grant credit generally on an unsecured basis to customers throughout North America, Europe, and Asia. We establish an allowance for doubtful accounts based upon factors surrounding the credit risk of specific customers, historical trends, and other information. To reduce credit risk, certain sales are secured by letters of credit from commercial banks. The regional concentration of accounts receivables were as follows:

Region	December 31, 2010	Percent of receivable balance	December 31, 2009	Percent of receivable balance
	(In th	ousands, exce	pt for percentag	es)
Europe	\$1,903	28%	\$2,921	34%
Asia	1,285	18%	1,906	23%
North America	3,723	_54%	3,683	43%
Total	\$6,911	100%	\$8,510	100%

Our Asia-based major distributors represented \$12.4 million and \$8.7 million, or 26% and 23%, of our total product revenues during the year ended December 31, 2010 and 2009, respectively. At December 31, 2010, one customer had an accounts receivable balance greater than 10% of the total balance outstanding and no single customer represented more than 10% of total world-wide revenue for the year ended December 31, 2010.

Our products incorporate components that are available from only one or a limited number of suppliers. Many of these components are manufactured with lead times, which can be significant. Shortages of various essential materials could occur due to interruption of supply. If we were unable to procure certain such components from suppliers or sub-contractors, it could affect our ability to meet demand for our products, which would have an adverse effect upon our results.

#### Inventories

Inventories are valued at the lower of cost (first-in, first-out) or market value (net realizable value). The components of inventories were as follows (in thousands):

	Decem	ber 31,
	2010	2009
Raw materials		
Work in process	45	11
Finished goods	1,822	3,054
Total	\$5,605	\$7,722

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#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

Inventories are shown net of reserves totaling \$1.3 million and \$1.9 million at December 31, 2010 and 2009, respectively.

#### **Equipment and Leasehold Improvements**

Equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally 3 to 5 years). Leasehold improvements are amortized using the straight-line method over the estimated useful life of the improvement or the remaining term of the lease, whichever is shorter. The maximum estimated useful life of any leasehold improvement is 15 years from the completion of the improvement. Maintenance and repairs are charged to operations as incurred. When assets are sold, or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and any gain or loss is included in operating expense.

Equipment and leasehold improvements and related accumulated depreciation and amortization were as follows (in thousands):

	December 31,	
	2010	2009
Laboratory equipment	\$ 23,562	\$ 21,610
Leasehold improvements	5,319	5,092
Office furniture and equipment	11,900	10,980
Less accumulated depreciation and amortization	40,781 (29,743)	37,682 (25,871)
	\$ 11,038	<u>\$ 11,811</u>

Depreciation expense for the years ended December 31, 2010, 2009 and 2008 was \$5.2 million, \$5.1 million and \$2.8 million, respectively, and included \$122,000 and \$92,000 of depreciation on equipment under capital lease for the years ended December 31, 2010 and 2009, respectively. There was no depreciation on equipment under capital lease for the year ended December 31, 2008.

#### Intangible Assets

Intangible assets consisted of the following (in thousands):

		December 31, 2010		ber 31, 2010 December 31, 2009	
	Weighted Average Life	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Clinical data collections Purchased patent rights and	5	\$13,552	\$(13,552)	\$13,552	\$(13,552)
licenses	3	5,608	(4,902)	5,621	(4,539)
Lab accreditation	5	117	(50)	117	. (27)
Total		\$19,277	\$(18,504)	\$19,290	\$(18,118)

Intangible assets are amortized using the straight-line method over their estimated useful lives. Amortization of intangible assets for the years ended December 31, 2010, 2009 and 2008 was \$0.4 million, \$0.1 million and \$0.1 million, respectively.

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#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

#### December 31, 2010

The following table is a schedule of future estimated amortization expense at December 31, 2010 (in thousands):

2011	+-++
2012 2013	
Total	

#### Warranty Cost and Reserves

We provide a warranty provision related to the sales of our MassARRAY equipment based on our historical experience of returns and repairs required under the warranty period.

We generally provide a one-year warranty on our MassARRAY system and related equipment. We establish an accrual for estimated warranty expenses associated with system sales based on historical amounts. This expense is recorded as a component of cost of product revenue.

Changes in our warranty liability during the three years ended December 31, 2010 were as follows (in thousands):

Balance as of December 31, 2007	\$ 526
Additions charged to cost of revenues	385
Repairs and replacements	(305)
Balance as of December 31, 2008	606
Additions charged to cost of revenues	199
Repairs, replacements and reduction in liability requirements	(630)
Balance as of December 31, 2009	175
Additions charged to cost of revenues	195
Repairs, replacements and reduction in liability requirements	(218)
Balance as of December 31, 2010	\$ 152

#### Fair Value of Financial Instruments

Financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, are carried at cost, which management believes approximates fair value because of the short-term maturity of these instruments. The fair value of our asset-backed loan approximated carrying value because the terms are equivalent to borrowing rates currently available to us for debt with similar terms and maturities.

#### Accounts Receivable

Trade accounts receivable are recorded at net invoice values. We consider receivables past due based on the contractual payment terms. We review our exposure to amounts receivable and reserve specific amounts if collectability is no longer reasonably assured. We also reserve a percentage of our trade receivable balance based on collection history. We re-evaluate such reserves on a regular basis and adjust our reserves as needed. Amounts determined to be uncollectible are charged or written off against the reserve.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

#### December 31, 2010

#### **Revenue Recognition**

Revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable and collectability is reasonably assured. In regard to MassARRAY system sales, the arrangement consideration is allocated among the separate units of accounting based on their relative fair values. The separate units of accounting are typically the system and software itself and maintenance contracts sold at the time of the system sale. Revenue is deferred for fees received before earned. Revenues from sales of consumables are recognized generally upon shipment and transfer of title to the customer. Revenue from sales of MassARRAY systems with standard payment terms of net 90 days or less are recognized upon shipment and transfer of title to the customer and when all revenue recognition criteria are met. Our contracts do not contain refund or cancellation clauses. Revenues from the sale or licensing of our proprietary software are recognized upon transfer of title to the customer. We recognize revenue on maintenance services for ongoing customer support over the maintenance period. Revenues from genetic services are recognized at the completion of key stages in the performance of the service, which is generally delivery of single nucleotide polymorphism (SNP) assay information. Grant revenue is recorded as the research expenses relating to the grants are incurred, provided that the amounts received are not refundable if the research is not successful. Amounts received that are refundable if the research is not successful would be recorded as deferred revenue and recognized as revenue upon the grantor's acceptance of the success of the research results.

Diagnostic revenues from Sequenom CMM's cystic fibrosis carrier screening and fetal Rhesus D genotyping laboratory developed tests, which were commercially launched in September 2009 and February 2010, respectively, have been recognized on a cash basis due to the limited number of contract or agreements with third-party payors and limited collections experience. We generally bill third-party payors upon generation and delivery of a report to the physician. As such, we take assignment of benefits and risk of collection with the third-party payor. We usually bill the patient directly for amounts not covered by their insurance carrier in the form of co-pays and deductibles, but only after multiple requests for full payment have been denied or only partially paid by the insurance carrier. Some payors may not cover our test as ordered by the physician under their reimbursement policies. Consequently, we pursue case-by-case reimbursement where policies are not in place.

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

Research and development costs are expensed as incurred. These costs include personnel expenses, fees paid to collaborators, laboratory supplies, facilities, miscellaneous expenses and allocation of corporate costs. These expenses are incurred during proprietary research and development activities, as well as providing services under collaborative research agreements.

#### Foreign Currency Translation and Transactions

The financial statements of our German, United Kingdom, India, and Japanese subsidiaries are measured using, respectively, the Euro (EUR), Great British pound (GBP), the Indian Rupee (INR), and the Japanese Yen (JPY), as the functional currency. Assets and liabilities of these subsidiaries are translated at the rates of exchange in effect at the balance sheet date. Income and expense items are translated at the average daily rate of exchange during the reporting period. Resulting remeasurement gains or losses are recognized as a component of other comprehensive income (loss). Transactions denominated in currencies other than the local currency are recorded based on exchange rates at the time such transactions arise. Subsequent changes in exchange rates result in transaction gains and losses, which are reflected in income as unrealized (based on period-end translations) or realized upon settlement of the transaction. Transaction gains or losses were not material for the years ended December 31, 2010, 2009 and 2008.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

#### Income Taxes

Our provision for income taxes is computed using the asset and liability method, under which deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, and for the expected future tax benefit to be derived from tax loss and credit carryforwards. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction by jurisdiction basis, and includes a review of all available positive and negative evidence. As of December 31, 2010 and 2009, we maintained a valuation allowance against U.S. and foreign deferred tax assets that we concluded had not met the "more likely than not" threshold. Changes in the valuation allowance when they are recognized in the provision for income taxes are included as a component of the estimated annual effective tax rate.

We recognize excess tax benefits associated with stock-based compensation to stockholders' equity only when realized. When assessing whether excess tax benefits relating to stock-based compensation have been realized, we follow the with-and-without approach, excluding any indirect effects of the excess tax deductions. Under this approach, excess tax benefits related to stock-based compensation are not deemed to be realized until after the utilization of all other tax benefits available to us.

We recognize the impact of a tax position in our financial statements only if that position is more likely than not of being sustained upon examination by taxing authorities, based on the technical merits of the position. Any interest and penalties related to uncertain tax positions will be reflected in income tax expense.

#### Stock-based Compensation

Stock-based compensation cost is measured at grant date based on the estimated fair value of the award using the Black-Scholes option pricing model and the portion that is ultimately expected to vest and is recognized as expense over the requisite service period for all stock-based awards granted, modified or cancelled. Our net loss for the years ended December 31, 2010, 2009 and 2008, included the following compensation expense related to our stock-based compensation awards (in thousands):

	2010 '	2009	2008
Research and development expense		\$ 4,222	\$1,723
Selling and marketing expense	3,205	4,009	2,235
General and administrative expense	4,122	5,102	3,742
	\$11,513	\$13,333	\$7,699

Cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) are classified as cash inflows from financing activities and cash outflows from operating activities. Due to our net loss position, no tax benefits have been recognized in the consolidated statements of cash flows.

We have not recognized, and do not expect to recognize in the near future, any tax benefit related to stockbased compensation cost as a result of the full valuation allowance of our net deferred tax assets and our net operating loss carryforwards.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

The fair value of options granted to non-employees is estimated at the measurement date using the Black-Scholes option pricing model and remeasured at each reporting date to fair value, with changes recorded in the statement of operations in the current period. Total stock-based compensation for options granted to non-employees for the years ended December 31, 2010, 2009, and 2008, was \$229,000, \$273,000 and \$731,000, respectively. Stock-based compensation for options granted to non-employees was included in general and administrative, research and development, and selling and marketing expenses in the statement of operations for the years ended December 31, 2010, 2009 and 2008 totaling \$42,000, \$1,000 and \$0; \$47,000, \$59,000 and \$181,000; and \$140,000, \$213,000 and \$550,000, respectively.

#### Comprehensive Income (Loss)

Comprehensive income (loss) and its components encompasses all changes in equity other than those with stockholders and includes net loss, unrealized gains and losses on our available for sale marketable securities and foreign currency translation gains and losses, and are disclosed as a separate component of stockholders' equity.

#### Net Loss Per Share

Basic net loss per share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of common and common equivalent shares outstanding during the period. Common stock equivalents consisting of exercisable stock options of 3,875,636, warrants of 59,035 and restricted stock of 1,091,825 were not included in the computation of diluted net loss per share as their effect was anti-dilutive for all periods presented.

#### **Recent Accounting Pronouncements**

In 2010, the Financial Accounting Standards Board (FASB) issued an Accounting Standards Update (ASU) related to Revenue Recognition that applies to arrangements with milestones relating to research or development deliverables. This guidance provides criteria that must be met to recognize consideration that is contingent upon achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The update is effective for revenue arrangements entered into or modified in fiscal years beginning on or after June 15, 2010. The adoption of this update is not expected to have a material impact on our consolidated financial statements.

In 2010, the FASB issued an ASU related to Fair Value Measurements and Disclosures that requires reporting entities to make new disclosures about recurring or nonrecurring fair-value measurements including significant transfers into and out of Level 1 and Level 2 fair-value measurements and information on purchases, sales, issuances, and settlements on a gross basis in the reconciliation of Level 3 fair-value measurements. The FASB also clarified existing fair-value measurement disclosure guidance about the level of disaggregation, inputs, and valuation techniques. The new and revised disclosures are required to be implemented in interim or annual periods beginning after December 15, 2009, except for the gross presentation of the Level 3 rollforward, which is required for annual reporting periods beginning after December 15, 2010. The adoption of this standard did not have any effect on our financial position and results of operations.

In 2009, the FASB issued an ASU related to Revenue Recognition that amends the previous guidance on arrangements with multiple deliverables. This guidance provides principles and application guidance on whether multiple deliverables exist, how the arrangements should be separated, and how the consideration should be

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

allocated. It also clarifies the method to allocate revenue in an arrangement using the estimated selling price. The update is effective for revenue arrangements entered into or modified in fiscal years beginning on or after June 15, 2010 with earlier adoption permitted. The adoption of this update is not expected to have a material impact on our consolidated financial statements.

In 2009, the FASB issued authoritative guidance that amends the evaluation criteria to identify the primary beneficiary of a variable interest entity and requires a quarterly reassessment of the treatment of such entities. The guidance also requires additional disclosures about an enterprise's involvement in a variable interest entity. This guidance was effective for us January 1, 2010 and did not have any effect on our financial position and results of operations.

#### 3. Acquisitions

#### SensiGen, LLC

On February 27, 2009, we completed a taxable acquisition of certain assets and assumption of certain liabilities of SensiGen, LLC (SensiGen). The assets are now part of our wholly-owned subsidiary, Sequenom CMM. Under the terms of the asset purchase agreement (the Agreement), we acquired certain assets related to SensiGen's business in gene-based molecular diagnostic tests relating to cervical cancer, head and neck cancer, chronic kidney disease and lupus. We paid SensiGen cash consideration of approximately \$1.9 million, which included a loan advance of \$340,000, and issued common stock valued at \$1.9 million (utilizing the minimum floor price of \$20.94 per share in accordance with the Agreement). An additional \$1.3 million is contingently payable to SensiGen upon the completion of certain triggering events with either cash or shares of our common stock (priced at the average closing price of our common stock over the ten trading day period ending on the third trading day prior to the applicable triggering event for such payment). During 2009, we satisfied one of the triggering events related to the Agreement with a cash payment of \$130,000. This triggering event had previously been recorded at a fair value of \$130,000 during our initial fair value measurement of contingent consideration associated with the allocation of purchase price. After the payment of this triggering event, our remaining fair value of contingent consideration in the allocation of purchase price at the date of closing was \$27,000. For the year ended December 31, 2009, we increased our contingent consideration liability for two triggering events by \$514,000, which was recognized as a component of research and development (\$260,000) and general and administrative expenses (\$254,000). During the first quarter of 2010, we satisfied our obligations associated with these two triggering events with an aggregate cash payment of \$520,000. As of December 31, 2010, we have \$53,000 recorded as our fair value estimate for the remaining contingent consideration associated with the SensiGen acquisition, which is further discussed below.

In December 2009, we entered into stipulations with certain stockholders of SensiGen for their release of claims against us related to the acquisition in exchange for the issuance of an aggregate 367,547 shares of our common stock. The issuance of these additional shares was charged to operations for the year ended December 31, 2009, and was valued at approximately \$1.5 million as of the date of share delivery.

The acquisition of the SensiGen assets provides us with intellectual property related to certain molecular diagnostics for women's health and cancer and have contributed to the purchase price for the acquisition of SensiGen, which resulted in the recognition of goodwill of approximately \$7.0 million.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

The total purchase consideration, excluding potential contingent consideration fair values, consisted of (in thousands, except share and per share data):

Cash paid to SensiGen	\$1,887
Sequenom common stock issued on the closing date (92,679 shares at \$20.94 per share)	1,941
Assumed liabilities	3,242
Write-off of preexisting receivables	403
Total purchase price	\$7,473

In connection with this acquisition we completed a valuation study of the intangible assets acquired in order to allocate the purchase price. We have allocated the excess purchase price over the fair value of net tangible assets and liabilities assumed to goodwill, as well as provided an estimate of the fair value of the contingent consideration as of the closing date of the acquisition. We believe the fair values assigned to SensiGen's assets acquired and contingent consideration were based on reasonable assumptions, as determined by management. The purchase price has been allocated as follows (in thousands):

Net tangible assets	\$ 613
Goodwill	6,860
	7,473
Fair value of contingent consideration	157
Total consideration	\$7,630

At each reporting date, we re-measure the contingent consideration liability at fair value, until the contingency is resolved with the changes in fair value recognized as a charge to operations in the current period. This analysis, which includes a probability assessment regarding the likelihood of payment and a discounted present value factor, concluded that the fair value of the remaining contingently payable triggering events based on currently available information was \$53,000. The increase in our contingent consideration liability of \$32,000 was recognized as a component of general and administrative expenses.

#### 4. Litigation Settlement

In May 2010, the U.S. District Court for the Southern District of California entered an order approving the stipulation of settlement reached in the class action securities lawsuits consolidated under the caption *In re Sequenom, Inc. Securities Litigation*, Master File No. 3:09-cv-00921 LAB-WMC. Pursuant to the stipulation, we have paid \$14 million in cash, which was funded by insurance proceeds, and as of December 31, 2010 issued in aggregate approximately 6.8 million shares of our common stock to the plaintiffs' class.

In connection with the court approved settlement of *In re Sequenom, Inc. Securities Litigation* in May 2010, we initially recorded a litigation settlement charge of approximately \$42.8 million related to the common stock issuable to the members of the plaintiffs' class. This settlement consisted of approximately 6.8 million shares at an initial fair value of \$6.28 per share. In addition, further adjustments to the equity based portion of the settlement were required to be recognized as a gain or loss depending upon fluctuations in the fair market value of our common stock from the initial settlement fair value until all common stock issuable to the members of the plaintiffs' class had been released. Subsequent to the initial accrual, we recognized an additional net aggregate loss of approximately \$11.1 million due to the revaluation to fair value for the portion of the remaining shares that were issued to the members of the plaintiffs' class on December 31, 2010.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

Additionally, in May 2010 we entered into a stipulation of settlement to resolve the various derivative actions filed in federal and state court. Pursuant to the financial terms of the stipulation we agreed to pay the plaintiffs' attorneys a total of \$2.5 million in fees, of which \$1.0 million was funded by insurance proceeds. In connection with the entry of a stipulation of settlement in connection with *In re Sequenom, Inc. Derivative Litigation* in May 2010, we recorded a litigation settlement charge of \$1.5 million during the second quarter of 2010. This charge represented the portion of the settlement not covered by insurance proceeds. In connection with the final approval of settlement in July 2010, we remitted a cash payment of \$338,000 and as permitted by the stipulation of settlement issued 200,000 shares of our common stock at a fair value of \$5.81 per share in payment of the portion of the plaintiffs' attorneys' fees not covered by insurance.

#### 5. Marketable Securities and Fair Value Measurements

#### Marketable securities

The estimated fair market value of our ARS holdings at December 31, 2010 and 2009 was \$0 and \$0.5 million and reflects a \$2.0 million and \$3.8 million adjustment to the principal value of \$2.0 million and \$4.3 million, respectively. There was no adjustment to our remaining ARS during 2010 and the \$3.8 million adjustment included a \$1.1 million other-than-temporary impairment loss charged to operations for the year ended December 31, 2009. The other-than-temporary impairment recognized for the year ended December 31, 2009, resulted from management's determination that it was no longer our intent to hold our remaining ARS to maturity and to actively pursue liquidation of our remaining ARS in the secondary market. As a result of this decision, during the fourth quarter of 2009 we sold ARS with an estimated fair value of \$4.1 million, which resulted in a net realized loss of approximately \$0.8 million for a total loss on our ARS of \$1.9 million for the year ended December 31, 2009.

During the first quarter of 2010, we sold two ARS investments with an aggregate principal value of \$2.3 million, but an estimated fair value of \$0.5 million. These sales resulted in a gain on the sale of approximately \$0.1 million. For the year ended December 31, 2010, no other-than-temporary impairment losses were charged to operations and there are no accumulated unrealized losses in other comprehensive income related to our remaining investment in ARS.

#### Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants on the measurement date. Accounting guidance also establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1—Quoted prices in active markets for identical assets or liabilities. We have determined that our investments in money market accounts, certificates of deposit and U.S. Government securities or guaranteed by the U.S. Government meet the criteria for definition within the Level 1 hierarchy.

Level 2—Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. These inputs include quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. We have determined that no investments as of December 31, 2010, met the criteria for definition within Level 2 hierarchy. As of December 31, 2009, our investments in ARS with an estimated fair value of \$0.5 million, which were sold

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

in the first quarter of 2010, had sufficient moderate secondary market activity and met the criteria for definition within the Level 2 hierarchy.

*Level 3*—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. We have determined that our remaining investment in ARS with an estimated fair value of \$0 at December 31, 2010, meets the criteria for definition within Level 3 hierarchy.

The fair values of our investment in ARS instruments of \$0 are estimated utilizing a discounted cash flow analysis valuation model as of December 31, 2010. This analysis considers, among other items, the collateral underlying the security investments, the credit quality of the counterparty, the timing of expected future cash flows, the default risk underlying the security, discount rates, the expected time until a successful auction and the overall capital market liquidity. These securities were also compared, when possible, to other observable market data with similar characteristics to the securities. Management has also reviewed the valuation input criteria, which generally consists of the price of credit protection, information available on the trading of senior and subordinated securities and other debt in the market place for comparable types of maturities, the current credit rating of the trust sponsor and/or bond insurer, as well as the ultimate maturity and the underlying collateral of the securities that are difficult to predict. Factors that may impact our valuation include changes to credit ratings of the securities, as well as to the underlying assets supporting those securities, rates of credit default of the underlying assets, underlying collateral value, discount rates, counterparty risk and the ongoing strength and quality of market credit and liquidity.

We endeavor to utilize the best available information in measuring fair value. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. All of the available for sale securities have a contractual maturity at December 31, 2010 of one year or less. The following table sets forth our financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2010 (in thousands):

Description	Total	Level 1	Level 2	Level 3
Cash equivalents	\$107,126	\$107,126	\$	\$—
Restricted cash	1,404	1,404		
Marketable securities, current <sup>1</sup>		18,833	—	
Total	\$127,363	\$127,363	\$	<u>\$—</u>

<sup>1</sup> Gains or losses considered to be temporary are recorded to other comprehensive income (loss) at each measurement date. Other than temporary losses are recorded to operations at each measurement date.

The following table sets forth our financial assets and liabilities, net of cash, that were accounted for at fair value on a recurring basis as of December 31, 2009 (in thousands):

Description	Total	Level 1	Level 2	Level 3
Cash equivalents	\$14,941	\$14,941	\$—	\$—
Marketable securities, current <sup>1</sup>	15,762	15,291	471	
Restricted cash (current and long-term)		1,419		
Total	\$32,122	\$31,651	\$471	\$—

<sup>1</sup> Gains or losses considered to be temporary are recorded to other comprehensive income (loss) at each measurement date. Other than temporary losses are recorded to operations at each measurement date.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

For our Level 3 ARS investment with an estimated fair value of \$0 as of December 31, 2010, there were no transfers, gains or losses, or purchases and settlements during 2010.

#### 6. Segment Reporting

In connection with changes to our management structure, internal performance reporting and incentive compensation plans that became effective during 2009, we began reporting results for two segments, Molecular Diagnostics and Genetic Analysis for the year ended December 31, 2009. Prior to 2009, our business had been reported as a single segment with operating performance measured as a single unit and management incentive plans that were based on total life sciences segment performance.

#### Description of the types of products and services from which each reportable segment derives its revenues

We operate two primary business segments, Molecular Diagnostics and Genetic Analysis. Molecular Diagnostics researches, develops and commercializes noninvasive molecular diagnostic tests for noninvasive womens' health-related and prenatal diagnostics, ophthalmology, oncology, infectious diseases, and other medical conditions disorders and diseases. Genetic Analysis designs, markets and provides maintenance services for our proprietary MassARRAY system, comprised of hardware, software applications, consumable chips and reagents which are marketed to premier clinical research laboratories, bio-agriculture, bio-technology and pharmaceutical companies.

Revenue for Molecular Diagnostics is generated from customers located within the United States. Revenue for Genetic Analysis is generated from customers and/or distributors located in North America, Europe and Asia.

#### Measurement of segment profit or loss and segment assets

We evaluate performance and allocate resources based on total segment revenue, operating expenses and operating profit or loss exclusive of general and administrative expenses, other indirect overhead costs and restructuring charges, which are not allocated to our segments for performance assessment by our chief operating decision maker. No evaluation of segment performance or allocation of resources is done in consideration of segment assets. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies. Intersegment revenues and transfers are immaterial.

Unallocated expenses for research and development and sales and marketing expenses consist of stockbased compensation, indirect overhead expenses and allocated and absorbed costs. Unallocated operating loss consists of general and administrative expenses, stock-based compensation, indirect overhead expenses and unabsorbed costs.

#### Factors management used to identify our reportable segments

Our reportable segments are business units that offer different products and services and are each managed separately. Operating results for each segment are reported separately to senior management to make decisions as to the allocation of resources and to assess performance.

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#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

Operating segment financial data is as follows (in thousands):

	2010	2009
Revenues:		
Molecular Diagnostics	\$ 2,554	\$ 94
Genetic Analysis	44,905	
	\$ 47,459	\$ 37,863
Research and development expenses:		
Molecular Diagnostics	\$ 26,000	\$ 20,935
Genetic Analysis	3,622	5,587
Stock-based compensation	4,186	4,222
Indirect overhead (1)	5,879	3,511
Allocated and absorbed costs (2)	3,744	3,199
Total	\$ 43,431	\$ 37,454
Sales and marketing expenses:		
Molecular Diagnostics	\$ 8,805	\$ 5,780
Genetic Analysis	14,379	13,644
Stock-based compensation	3,205	4,009
Indirect overhead (3)	1,327	1,400
Allocated and absorbed costs (4)	671	2,012
Total	\$ 28,387	\$ 26,845
Operating (loss) income:		
Molecular Diagnostics	\$ (36,216)	\$(27,034)
Genetic Analysis	11,873	4,379
Unallocated (5)	(96,676)	(48,067)
·	\$(121,019)	\$(70,722)

(1) Indirect overhead consists of expenses related to the following departments, which are unallocated to our operating segments for performance assessment by our chief operating decision maker: quality, regulatory, chief science officer and research and development collaborations (licensing costs).

(2) Allocated costs consist of costs from the following departments, which are unallocated to our operating segments for performance assessment by our chief operating decision maker: human resources, information technology and facilities. Absorbed costs relate to costs incurred that are absorbed into cost of sales.

(3) Indirect overhead consists of expenses related to the following departments, which are unallocated to our operating segments for performance assessment by our chief operating decision maker: business development and European sales administration.

(4) Allocated costs consist of costs from the following departments, which are unallocated to our operating segments for performance assessment by our chief operating decision maker: human resources, information technology and facilities. Absorbed costs relate to costs incurred that are absorbed into cost of sales.

(5) Unallocated costs consist of those reconciling items for research and development and sales and marketing expenses, as well as general and administrative expenses and litigation settlement, net, which are unallocated to our operating segment for performance assessment by our chief operating decision maker.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

#### 7. Debt and Obligations

#### Asset-backed Loan

As of December 31, 2010, we had an aggregate of \$0.1 million outstanding on our asset-backed loan line, which had an aggregate limit of \$3.0 million and our rights to borrow funds expired in December 2008. The remaining balance outstanding relates to two funding agreements with interest rates of 10.3% and 10.6%. All borrowings are secured by the underlying financed equipment. The borrowings are to be repaid in 36 monthly installments with final payment dates in February 2011 and May 2011.

#### Debt

In connection with our acquisition of SensiGen in February 2009, we assumed two loans with the Michigan Economic Development Corporation with an aggregate balance at the closing date of approximately \$3.2 million. The first loan of approximately \$0.3 million has a stated interest rate of 1% with all payments deferred until March 2013. Commencing March 2013, principal payments of approximately \$3,000 are due monthly through March 2018, at which time a final balloon payment of approximately \$161,000 is due. The second loan of approximately \$2.9 million has a stated interest rate of 7% with monthly principal payments of approximately \$68,000 through September 2012. As of December 31, 2010 and 2009, we had an aggregate of \$1.6 million and \$2.3 million outstanding on these loans, respectively. Both loans are collateralized by all of Sequenom CMM's tangible and intangible property and rights in which a security interest or lien may be taken.

The following is a schedule of future maturities on our asset-back loans and debt at December 31, 2010 (in thousands):

Year Ending December 31,	Payments
2011	\$ 744
2012	625
2013	25
2014	30
Thereafter	
-	229
	\$1,684

#### Capital Lease

In the second quarter of 2009, we entered into a 36 month capital lease arrangement for new phone equipment, which was capitalized with office furniture and equipment at an aggregate balance of approximately \$366,000.

The following is a schedule of minimum future rental payments on non-cancelable capital leases at December 31, 2010 (in thousands):

Year Ending December 31,	Payments
2011	. \$131
2012	44
Total minimum payments required	. 175
Less, amount representing interest	. (8)
Present value of net minimum lease payments	. \$167

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

#### 8. Commitments and Contingencies

#### **Building Leases**

We lease facilities in the United States, Germany, China, United Kingdom and Japan. During 2010, we leased space in 10 buildings under leases that expire at various dates through September 2015. Two of these leased building facilities expired at December 31, 2010. Certain of our remaining leases contain extension, return, or renewal provisions for two years at existing lease rates and/or purchase options. Total rent expense under these leases was approximately \$5.3 million, \$5.4 million and \$5.0 million in 2010, 2009 and 2008, respectively.

In September 2005, we entered into an amendment to our lease for our corporate headquarters in San Diego. The lease amendment provides for the deferral of approximately \$3.2 million of the monthly rent payments by reducing the monthly payments during the period commencing October 1, 2005 and ending September 30, 2007 and increasing the aggregate monthly payments by the deferred amount for the remaining term of the lease, from October 1, 2007 to September 30, 2015. The total obligation under the lease remains unchanged. Rent expense is calculated on a straight-line basis. In connection with the lease amendment, we issued our landlord a warrant to purchase 50,000 shares of our common stock with an exercise price of \$2.64 per share. The warrants are exercisable and have a ten year term. The fair value of the warrants, calculated using the Black-Scholes option pricing model, was recorded as prepaid rent and is being amortized as rent expense over the remaining life of the lease.

The following is a schedule of future minimum lease payments under non-cancelable operating lease commitments at December 31, 2010 (in thousands):

Year Ending December 31,	Operating Leases
2011	\$ 6,294
2012	5,559
2013	4,337
2014	4,455
2015	3,429
Thereafter	
	\$24,074

#### Letters of Credit

At December 31, 2010, we had outstanding stand-by letters of credit with financial institutions totaling \$1.4 million related to a building and customer guarantees. The letter of credit related to our Newton, Massachusetts building lease agreement totaling \$1.3 million expired on December 31, 2010 and subsequent to year end was released from its restriction.

#### Collaboration, Development and Licensing Agreements

In October 2005 we acquired exclusive rights in certain countries, including the United States, United Kingdom and other countries in Europe and elsewhere, to noninvasive prenatal diagnostic intellectual property from Isis Innovation Ltd. (ISIS), the technology transfer company of the University of Oxford. The intellectual property covers noninvasive prenatal genetic diagnostic testing on fetal nucleic acids derived from

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

plasma or serum on any platform including mass spectrometry and real time polymerase chain reaction amplification platforms. In October 2006 and November 2007 we entered into additional related agreements with other entities, as well as amendments to the ISIS agreement that expanded the licensed applications and territory. Under the terms of this agreement and its amendments, we have paid up-front fees totaling \$0.8 million and are required to pay up to approximately \$0.5 million in aggregate milestone payments upon the achievement of initial sales or tests performed of various products or the issuance of a patent, as well as royalties on product sales. No such milestones were achieved as of December 31, 2010.

In November 2009, we entered into a third amendment to the Isis Agreement pursuant to which Isis agreed to a modification of certain time-based commercial launch milestones relating to aneuploidy and other products. In exchange for this modification, we agreed to make an immediate one-time payment of \$1,000,000, increase royalty payments under the agreement during the final 12 months of the patent term and increase the specified minimum royalty amounts.

We have entered into various license agreements since 1996 allowing us to utilize certain patents rights. If these patents are used in connection with a commercial product sale, we will pay royalties based on a percentage of the related product revenues. During the years ended December 31, 2010, 2009 and 2008, the amount of royalties incurred in connection primarily with product sales was \$0.1 million, \$0.1 million, and \$0.1 million, respectively.

#### Litigation

#### IPO Litigation

In November 2001, we and certain of our current or former officers and directors were named as defendants in a class action shareholder complaint filed by Collegeware USA in the U.S. District Court for the Southern District of New York (now captioned In re Sequenom, Inc. IPO Securities Litigation) Case No. 01-CV-10831. In the complaint, the plaintiffs allege that our underwriters, certain of our officers and directors and we violated the federal securities laws because our registration statement and prospectus contained untrue statements of material fact or omitted material facts regarding the compensation to be received by and the stock allocation practices of the underwriters. The plaintiffs seek unspecified monetary damages and other relief. Similar complaints were filed in the same District Court against hundreds of other public companies that conducted initial public offerings of their common stock in the late 1990s and 2000 (the IPO Cases).

In October 2002, our officers and directors were dismissed without prejudice pursuant to a stipulated dismissal and tolling agreement with the plaintiffs. In February 2003, the District Court dismissed the claim against us brought under Section 10(b) of the Exchange Act, without giving the plaintiffs leave to amend the complaint with respect to that claim. The District Court declined to dismiss the claim against us brought under Section 11 of the Securities Act of 1933, as amended (the Securities Act).

In September 2003, pursuant to the authorization of a special litigation committee of our board of directors, we approved in principle a settlement offer by the plaintiffs. In September 2004, we entered into a settlement agreement with the plaintiffs. In February 2005, the District Court issued a decision certifying a class action for settlement purposes and granting preliminary approval of the settlement subject to modification of certain bar orders contemplated by the settlement. In August 2005, the District Court reaffirmed class certification and preliminary approval of the modified settlement. In December 2006, the U.S. Court of Appeals for the Second Circuit vacated the District Court's decision certifying as class actions the six lawsuits designated as "focus cases." Thereafter the District Court ordered a stay of all proceedings in all of the lawsuits pending the outcome of plaintiffs' petition to the Second Circuit for rehearing en banc. In April 2007, the Second Circuit denied

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

plaintiffs' rehearing petition, but clarified that the plaintiffs may seek to certify a more limited class in the District Court. Accordingly, the settlement as originally negotiated was terminated pursuant to stipulation and will not receive final approval.

In February 2009, liaison counsel for plaintiffs informed the District Court that a new settlement of all IPO Cases had been agreed to in principle, subject to formal approval by the parties and preliminary and final approval by the District Court. In April 2009, the parties submitted a tentative settlement agreement to the District Court and moved for preliminary approval thereof. In June 2009, the District Court granted preliminary approval thereof. In June 2009, the District Court granted preliminary approval of the tentative settlement and ordered that notice of the settlement be published and mailed to class members. In September 2009, the District Court held a final fairness hearing. In October 2009, the District Court certified the settlement class in each IPO Case and granted final approval to the settlement. Thereafter, three shareholders filed a Petition for Permission to Appeal Class Certification Order, asserting that the District Court's certification of the settlement classes violates the Second Circuit's earlier class certification decisions in the IPO Cases and a number of shareholders also filed direct appeals, objecting to final approval of the settlement is affirmed on appeal, the settlement will result in the dismissal of all claims against us and our officers and directors with prejudice, and our pro rata share of the settlement fund will be fully funded by insurance.

#### Securities and Shareholder Derivative Litigation

In April 2009, we announced that the expected launch of our a test for trisomy 21 then under development by Sequenom CMM had been delayed and that they were no longer relying on the previously announced test data and results for that test, as a result of inadequately substantiated claims, inconsistencies and errors and inadequate protocols and controls, which included: the mischaracterization of tests as having been conducted in a blinded manner (i.e., that the tests had been performed by scientists who did not know the true outcomes for the samples tested before the test results had been determined); the improper unblinding of true outcomes for samples being tested; the use of the unblinded true outcomes to alter and improve reported test results; the unsubstantiated reporting of test results for low-risk samples (i.e., samples from expectant mothers who were less likely to be carrying a fetus with trisomy 21) without knowing the true outcomes for such samples; the failure to perform testing on those low-risk samples; the inadequate storage of serum samples resulting in breakdown of nucleic acids; and other improper practices. Following the April 2009 announcement, several complaints were filed in the U.S. District Court for the Southern District of California against us and certain of our current and former officers and directors on behalf of certain purchasers of our common stock. The complaints included claims asserted under Sections 10 and 20(a) of the Exchange Act and Sections 11 and 12(a)(2) of the Securities Act and were brought as shareholder class actions. In general, the complaints alleged that we and certain of our officers and directors violated federal securities laws by making materially false and misleading statements regarding our test, thereby artificially inflating the price of our common stock. In September 2009 the complaints were consolidated under the caption In re Sequenom, Inc. Securities Litigation, Master File No. 3:09-cv-00921 LAB-WMC and a lead plaintiff was appointed. In December 2009 we entered into a stipulation of settlement with the lead plaintiff on behalf of the plaintiffs' class. Pursuant to the terms of the stipulation, we paid \$14 million, which was funded by insurance proceeds. We also agreed to issue to the plaintiffs' class approximately 6.8 million shares of our common stock, and to adopt or continue our implementation of changes and additions to certain corporate governance policies, protocols and practices. The court held a final settlement approval hearing in May 2010, following which the court approved the final settlement. The time for appeals lapsed without any appeal. Of the 6.8 million shares of common stock to be issued in the settlement, 409,005 shares were issued in June 2010 to counsel for the plaintiffs' class in accordance with the stipulation of settlement. Following completion of the class action claim procedures, we issued the balance of 6,407,738 shares as of December 31, 2010.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

In May 2009, a shareholder derivative complaint was filed in the Superior Court of California for the County of San Diego against certain of our current and former directors and officers. Thereafter, a number of similar actions, also styled as shareholder derivative suits, were filed in state court and were consolidated in a single court. In July 2009 the first of three shareholder derivative suits were filed in the U.S. District Court for the Southern District of California. The federal shareholder derivative actions were consolidated before a single court under the caption In re Sequenom, Inc. Derivative Litigation, S.D. Cal. Case No. 09-CV-1341 LAB (WMc) and plaintiffs filed a single consolidated complaint. A separate federal derivative compliant, Ries, et al. v. Stylli, et al, case no. 09-CV-2517 LAB (WMc), was filed thereafter and it was coordinated with the consolidated federal derivative action. The state and federal shareholder derivative actions are hereinafter collectively referred to as the "Derivative Actions." The complaints in the Derivative Actions allege breaches of fiduciary duties by the defendants and other violations of law. In general, the complaints allege that our directors and certain of our officers caused or allowed for the dissemination of materially false and misleading statements regarding the trisomy 21 test then under development, thereby artificially inflating the price of our common stock. In May 2010, we entered into a stipulation of settlement to resolve the Derivative Actions. The current and former directors and officers named as individual defendants in the Derivative Actions also entered into the stipulation of settlement. In exchange for a release of all claims by the plaintiffs and a dismissal of the Derivative Actions, we agreed (i) to adopt or continue certain corporate governance measures and (ii) to pay the plaintiffs' attorneys a total of \$2.5 million, of which \$1.0 million has been funded by insurance proceeds. The U.S. District Court issued its final approval of the settlement in accordance with the terms of the stipulation of settlement in July 2010, and entered an order dismissing the federal shareholder derivative actions in July 2010. In accordance with the terms of the stipulation of settlement, the parties in the state shareholder derivative actions filed a joint stipulation to dismiss the actions with prejudice in San Diego Superior Court in July 2010. In connection with the final approval of settlement, we remitted a cash payment of \$338,000 and issued 200,000 shares of our common stock at a fair value of \$5.81 per share in payment of the portion of the plaintiffs' attorneys' fees not funded by insurance proceeds.

#### SEC Investigation

In June 2009, we received written notification that the Enforcement staff of the SEC has initiated an investigation following our April 2009 announcement regarding the trisomy 21 test then under development. As part of this investigation, the SEC staff has also required us to produce information with respect to our announcement relating to our offer to acquire EXACT Sciences, Inc. in January 2009. On March 7, 2011, the staff of the SEC advised us that it is considering recommending that the SEC bring a civil injunctive action against us alleging that we violated Sections 10(b) and 13(a) of the Exchange Act of 1934 and Rules 10b-5, 12b-20, 13a-1 and 13a-11 thereunder. We have cooperated fully with the SEC in its investigation and will endeavor to negotiate an acceptable injunctive resolution with the staff, but any resolution that we may negotiate with the staff will be subject to the approval of the SEC. There can be no assurance that such resolution will be limited to injunctive relief or that such resolution will not have a material adverse effect on our business, results of operation or financial condition.

In June 2010, the SEC filed a complaint against Elizabeth Dragon, who was formerly our Senior Vice President, Research and Development. The complaint alleged that between June 2008 and January 2009 Dr. Dragon made or allowed for the dissemination of materially false and misleading statements regarding the trisomy 21 test then under development, thereby inflating the price of our stock. The SEC sought a permanent injunction against any future violations of the federal securities laws by Dr. Dragon, civil penalties, and imposition of an officer and director bar against her. On the same day, Dr. Dragon filed a consent to judgment of permanent injunction and other relief. In the consent to judgment, Dr. Dragon, without admitting or denying the

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

allegations in the SEC's complaint, agreed to the permanent injunction against future violations of federal securities laws, the director and officer bar, and civil penalties to be determined by the court.

#### DOJ and FBI Investigation

Following our September 2009 announcement regarding the work and recommendations of a special committee of independent directors after it had completed its independent investigation of activity related to the trisomy 21 test, representatives of the Office of the U.S. Attorney for the Southern District of California contacted us to inquire about the announcement. We intend to continue to cooperate fully with the U.S. Attorney and the Federal Bureau of Investigation (FBI) in this matter.

In June 2010, the U.S. Attorney filed a criminal information against Dr. Dragon. The criminal information charged Dr. Dragon with one count of conspiracy to commit securities fraud by conspiring to disseminate materially false and misleading statements regarding the trisomy 21 test then under development. On the same day, Dr. Dragon pled guilty to the criminal information, and the magistrate judge assigned to this matter recommended that the district court judge accept Dr. Dragon's guilty plea. Prior to sentencing, Dr. Dragon passed away in February 2011.

#### **Xenomics** Litigation

In October 2009, plaintiff Xenomics, Inc. (now known as TrovaGene) filed a complaint in the Supreme Court of the State of New York naming us as the defendant. In the complaint, the plaintiff alleged that due to materially false and misleading statements regarding the trisomy 21 test under development, we had breached the license agreement entered into by the parties on October 29, 2008, which provides us with exclusively licensed patent rights for the use of fetal nucleic acids obtained from maternal urine, and that the plaintiff has suffered damages as a result. The plaintiff sought equitable relief and \$300 million in damages. In December 2009, we removed the case to the U.S. District Court for the Southern District of New York. In May 2010, the district court granted our motion to dismiss the action because the license agreement specifically provides that if TrovaGene seeks to resolve a dispute arising under the agreement, it must do so by commencing an arbitration in San Diego. As of the date of this report, TrovaGene has not commenced arbitration proceedings in San Diego.

#### Paul Hawran Litigation

In August 2010, Paul Hawran, our former chief financial officer, sued the three directors who comprised the special committee that conducted the investigation of activity related to the trisomy 21 test, alleging that they had defamed him, invaded his privacy, negligently and intentionally interfered with his prospective economic advantage, and committed unfair business practices under California Business and Professions Code Section 17200. Mr. Hawran alleged in his complaint that he was asked to resign because he had raised concerns about the conduct of certain of our directors. The lawsuit, Hawran v. Hixson et al, case no. 37-2010-00058632-CU-DF-NC, was filed in the Superior Court of California for the North County of San Diego. In September 2010, we were served with an amended complaint in this lawsuit, in which Mr. Hawran named us as a defendant in addition to the three individuals previously named and added claims of breach of contract and intentional and negligent misrepresentation. In October 2010, the defendants filed a motion to strike the complaint under California Code of Civil Procedure Section 425.16 on the grounds that Mr. Hawran's claims arise from acts in furtherance of the defendants' right of petition or free speech under the United States or California Constitution in connection with a public issue and filed a demurrer to each and every cause of action in the complaint. On January 3, 2011, the court issued a minute order dismissing some, but not all, of the claims

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

#### December 31, 2010

alleged in the amended complaint. The defendants filed a notice of appeal regarding the minute order on January 11, 2011 and Mr. Hawran filed a cross-appeal regarding the same on January 31, 2011. The individual defendants and we intend to vigorously defend ourselves against the claims advanced.

In addition, from time to time, we may be involved in litigation that is not material relating to claims arising out of our operations in the normal course of business. These other matters are, in the opinion of management, immaterial with respect to our consolidated financial position, liquidity, or results of operations.

Claim estimates that are probable and can be reasonably estimated are reflected as liabilities of the Company. Because of the uncertainties related to the incurrence, amount and range of loss on any pending litigation, investigation, inquiry or claim, management is currently unable to predict the ultimate outcome of any litigation, investigation, inquiry or claim, determine whether a liability has been incurred or make an estimate of the reasonably possible liability that could result from an unfavorable outcome. It is reasonably possible that some of the matters, which are pending or may be asserted, could be decided unfavorably to the Company. An adverse ruling or outcome in any lawsuit involving us could materially affect our business, liquidity, consolidated financial position or results of operations ability to sell one or more of our products or could result in additional competition. In view of the unpredictable nature of such matters, we cannot provide any assurances regarding the outcome of any litigation, investigation, inquiry or claim to which we are a party or the impact on us of an adverse ruling of such matters.

#### 9. Related Party Transactions

We recorded the following transactions with parties related to certain of our officers and Board members:

- Boston University. Dr. Charles Cantor is our Chief Scientific Officer and was a board member until November 2010 and was previously the chair and professor of the department of biomedical engineering and biophysics, and Director of the Center for Advanced Biotechnology at Boston University. We recorded product revenue for MassARRAY hardware and consumables, totaling \$17,000, \$141,000 and \$71,000, in the years ended December 31, 2010, 2009 and 2008, respectively. We have agreements with Boston University in which Dr. Cantor participates that we paid \$0.2 million, \$0.4 million and \$0.9 million in the years ended December 31, 2010, 2009 and 2008 respectively.
- University of California, San Diego (UCSD). Dr. Cantor is adjunct professor in the department of bioengineering at UCSD. We recorded product revenue for MassARRAY hardware and consumables, totaling \$187,000, \$3,300 and \$24,000 in the years ended December 31, 2010, 2009 and 2008, respectively. We have agreements with UCSD that we paid zero, \$56,600, and \$9,800 in the years ended December 31, 2010, 2009, and 2008, respectively.
- The Scripps Research Institute (Scripps). Dr. Richard Lerner is a member of our Board of Directors and is President of Scripps. Dr. Cantor is adjunct professor in the department of molecular biology at Scripps. For the years ended December 31, 2010, 2009, and 2008, we have recorded product revenue for MassARRAY hardware and consumables totaling approximately \$86,000, \$35,200 and \$30,000, respectively. We have agreements with Scripps that we paid \$1,500, \$61,300 and \$14,700 in the years ended December 31, 2010, 2009, respectively.
- Albert Einstein College of Medicine. Dr. Allan Bombard is our Chief Medical Officer and is clinical professor, obstetrics and gynecology, Albert Einstein College of Medicine. For the years ended December 31, 2010, 2009, and 2008, we have recorded product revenue for MassARRAY hardware and consumables totaling approximately \$89,000, \$0 and \$0, respectively.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

#### December 31, 2010

At December 31, 2010, we had the following receivable and payable balances with the following related parties (in thousands):

Related party	Receivables	Payables
Boston University	· \$6	\$ 51
Scripps	20	
UCSD	5	—
Albert Einstein College of Medicine	8	
Total	\$39	\$ 51

At December 31, 2009, we had the following receivable and payable balances with the following related parties (in thousands):

Related party	Receivables	Payables
Boston University	\$ 47	\$42
Scripps	2	2
UCSD		26
Total	\$ 49	\$70

#### **10. Stockholders' Equity**

On December 31, 2010, we issued 6,407,738 shares of our common stock at a fair value of \$8.03 per share, which represented the remaining portion of the court approved share settlement to the plaintiffs' class in the class action securities lawsuits consolidated under the caption *In re Sequenom, Inc. Securities Litigation*.

On December 2, 2010, we closed an underwritten public offering of our common stock totaling 16,100,000 shares of our common stock at \$6.00 per share. The offering resulted in aggregate net proceeds of approximately \$90.6 million after deducting underwriting commissions and transaction expenses.

In July 2010 we issued 200,000 shares of our common stock at a fair value of \$5.81 per share, which represented the portion of the plaintiffs' attorneys' fees not covered by insurance to resolve the various derivative actions filed in federal and state court. The shares were issued in accordance with the court's stipulation of settlement.

In June 2010 we issued 409,005 shares of our common stock at a fair value of \$5.94 per share, which represented a portion of the court approved share settlement in the class action securities lawsuits consolidated under the caption *In re Sequenom, Inc. Securities Litigation.* The shares were issued to counsel for the plaintiffs' class in accordance with the court's order awarding attorneys' fees.

In May 2010 we issued 12,435,000 shares of our common stock at \$4.15 per share to certain investors in a private placement. The private placement resulted in aggregate net proceeds of \$47.8 million after deducting commissions and transaction expenses.

#### Stock Compensation Plans

On May 31, 2006, our stockholders approved our 2006 equity incentive plan (the 2006 plan), as the successor to our 1999 stock option plan (the 1999 plan). In connection with the adoption of the 2006 plan, we

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

terminated the automatic annual increase feature under the 1999 plan and resolved to cease to grant additional stock awards under the 1999 plan following the effectiveness of the 2006 plan. The aggregate number of shares of common stock that may be issued under the 2006 plan is 9,711,271, plus the number of shares subject to any stock awards under the 1999 plan that terminate or are forfeited or repurchased and would otherwise have been returned to the share reserve under the 1999 plan.

#### Stock Options

The estimated fair value of each stock option award granted was determined on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for stock option grants during the years ended December 31, 2010, 2009 and 2008:

	2010	2009	2008
Risk free interest rate	2.62%	2.81%	3.17%
Volatility	99.7%	100%	87%
Dividend yield	0%	0%	0%
Expected option life (years)	7.3	7.0	6.6
Weighted average fair value of stock option grants to employees	\$4.99	\$11.17	\$8.81

Our determination of fair value is affected by our stock price as well as a number of assumptions that require judgment. The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of our employee stock options. The expected volatility is based on the historical volatility of our stock. We have not paid any dividends on common stock since our inception and do not anticipate paying dividends on common stock in the foreseeable future. The computation of the expected option life assumption is based on a weighted-average calculation combining the average historical exercise activity with the estimated life of all unexercised, outstanding stock options.

We recognize stock-based compensation cost over the vesting period using the straight-line single option method. Stock-based compensation expense is recognized only for those awards that are ultimately expected to vest. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures were estimated to be 11.5% based on historical experience. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

A summary of the status of our stock option plans as of December 31, 2010 and of changes in stock options outstanding under the plans during the years ended December 31, 2010, 2009 and 2008 is as follows:

-	Shares Subject to Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2007	5,080,236	\$ 6.16		
Granted	1,705,652	11.63		
Canceled	(265,892)	6.73		
Exercised	(281,925)	4.55		
Outstanding at December 31, 2008	6,238,071	\$ 7.70		
Granted	2,263,091	14.09		
Canceled	(1,848,852)	10.73		
Exercised	(479,503)	2.38		
Outstanding at December 31, 2009	6,172,807	\$ 9.55		
Granted	1,590,916	5.93		
Canceled	(574,136)	25.27		
Exercised	(1,036,165)	2.52		
Outstanding at December 31, 2010	6,153,422	\$ 8.33	7.17	\$14,405,442
Options vested and exercisable at				
December 31, 2010	3,875,636	<u>\$ 7.90</u>	6.39	\$10,161,422

The aggregate intrinsic value of stock options exercised in 2010, 2009 and 2008 was \$4.3 million, \$1.6 million and \$3.6 million, respectively. As of December 31, 2010, there was \$16.7 million of unamortized compensation cost related to unvested stock option awards, which is expected to be recognized over a remaining weighted-average vesting period of 2.3 years. Cash received from stock option exercises for the years ended December 31, 2010 and 2009 was \$2.6 million and \$1.1 million, respectively. At December 31, 2010, there were 2,414,298 shares available for future option grants.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

#### **Restricted Stock**

The following table summarizes our restricted stock activity for the year ended December 31, 2010:

Outstanding	Number of Shares	Weighted Average Grant Date Fair Value
Restricted Stock - December 31, 2007	50,000	\$11.04
Granted	95,157	\$13.01
Cancelled	(1,781)	\$ 8.16
Restricted Stock - December 31, 2008	143,376	\$12.21
Granted	1,287,813	\$ 8.33
Vested	(82,978)	\$10.67
Cancelled	(78,661)	\$16.55
Restricted stock - December 31, 2009	1,269,550	· \$ 5.15
Granted	32,962	\$ 5.21
Vested	(64,126)	\$ 6.75
Cancelled	(146,561)	\$ 3.84
Restricted stock - December 31, 2010	1,091,825	\$ 3.88

The fair value of restricted stock that vested was \$0.4 million, \$1.0 million, and \$0 in 2010, 2009, and 2008, respectively.

#### **Employee Stock Purchase Plan**

In 1999, we adopted the 1999 Employee Stock Purchase Plan (the 1999 ESPP). As of December 31, 2010, we had reserved 901,520 shares of common stock for issuance under the 1999 ESPP. Beginning in 2001, the amount of authorized shares available under the 1999 ESPP automatically increased each January 1st by an amount equal to 1% of the outstanding common stock on the last trading day of the prior year, subject to an annual increase limitation of 166,666 shares. In 2010 the 1999 ESPP was amended to remove the automatic annual increase provision.

Offerings under the 1999 ESPP are for a duration of six months and consist of one purchase interval. The 1999 ESPP limits stock purchases to (i) no more than 10,000 shares per individual per offering and (ii) no more than \$25,000 per individual per calendar year. Shares are purchased at 85% of the lower of the beginning or end of the period price. As of December 31, 2010, employees have contributed approximately \$0.3 million to the current offering of the 1999 ESPP since the beginning of the offering period that commenced August 1, 2010. For the years ended December 31, 2010, 2009 and 2008, we have recognized approximately \$352,000, \$243,000 and \$360,000, respectively, as share-based compensation expense related to the 1999 ESPP Plan.

#### New-Hire Equity Incentive Plan

In February 2010, our Board of Directors approved a New-Hire Equity Incentive Plan (New-Hire Plan) with a total share reserve of 150,000 shares of common stock. Equity awards under the New-Hire Plan are eligible to be issued only to persons entering into employment with us and are not available to current or former employees or directors unless there has been a bona fide period of non-employment. As of December 31, 2010, no equity awards had been issued under the New-Hire Plan. Subsequent to year-end, the total share reserve was granted to a new executive. Also, subsequent to year-end, our Board of Directors amended the New-Hire Plan to make an additional 400,000 shares available for issuance.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

#### Warrants

In connection with the acquisition of Axiom Biotechnologies in 2002, we assumed an outstanding warrant to purchase 7,333 Axiom ordinary shares at an exercise price of \$10.50, which was adjusted to become a warrant to purchase 1,535 shares of our common stock at an exercise price of \$50.19 per share. As of December 31, 2010, this warrant had not been exercised and expires in December 2011.

In connection with an amendment to our lease for our corporate headquarters in San Diego, California in September 2005, we issued to the landlord a warrant to purchase 50,000 shares of our common stock with an exercise price of \$2.64 per share. As of December 31, 2010, the warrant had not been exercised and expires in October 2015.

In connection with our June 2006 private placement financing, we issued to our placement agent a warrant to purchase 866,666 shares of our common stock at an exercise price of \$2.52 per share. This warrant contains anti-dilution provisions that adjust the exercise price and number of shares subject to the warrants upon reorganization, mergers, stock splits and combinations, reclassifications of our common stock, or stock dividends, but not for other issuances of our common stock. During 2007 the placement agent transferred portions of the warrant to certain of its employees. During 2008, the placement agent and its transferees exercised warrants in both cash and cashless exercises to purchase an aggregate of 110,781 shares of our common stock. As of December 31, 2010, warrants to purchase an aggregate of 7,500 shares remained outstanding and exercisable and expire in June 2011.

#### 11. Income Taxes

The Company recognizes the impact of an uncertain income tax position on our income tax return at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

Upon the adoption of new accounting principles relating to uncertain tax positions as of January 1, 2007 and through the year ended December 31, 2009, we did not record any reserves for uncertain tax positions. During the year ended December 31, 2010, we determined that we have an uncertain tax position related to 2009 for \$548,000. Following is a tabular reconciliation of the Unrecognized Tax Benefit ("UTB") activity during the year ended December 31, 2010 (excluding interest and penalties):

	12/31/2010
	(In thousands)
Beginning balance, January 1, 2010	\$ —
Additions based on tax positions related to the prior year	548
Additions based on tax positions related to the current year	1,112
Reductions for tax positions of prior year	—
Settlements	—
Reductions due to lapse of applicable statue of limitations	
Ending balance, December 31, 2010	\$1,660

Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense. We had no accrual for interest and penalties on our balance sheets at December 31, 2010 and 2009 and have recognized no interest and/or penalties in the statement of operations for the year ended December 31, 2010.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

We are subject to taxation in the U.S., foreign and various state jurisdictions. Our tax years for 1995 and forward are subject to examination by the Federal and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

We completed a Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards in April 2008. We are currently in the process of updating the Section 382/383 analysis and we are removing our federal and state net operating losses and research and development credits from the deferred table until this analysis is complete. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

The reconciliation of income tax computed at the Federal statutory tax rate to the expense for income taxes is as follows (in thousands):

	December 31,			
	2010	2009	2008	
Tax at statutory rate	\$(42,299)	\$(24,805)	\$(15,380)	
State taxes, net of federal benefit	(5,365)	(2,910)	(2,525)	
Change in valuation allowance	125	(30,458)	29,532	
Federal and state NOL limitations	45,556	49,045	(14,625)	
Change in state rate	(134)	3,724		
Credits and other	2,107	5,521	3,209	
	<u>\$ (10)</u>	<u>\$ 117</u>	\$ 211	

The 2010 and 2009 income tax benefit of \$10,000 and expense of \$117,000 are comprised of foreign current and deferred taxes.

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities are shown below. A full valuation allowance has been recorded, as realization of such assets is uncertain (in thousands).

	December 31,			31,
	20	)10		2009
Deferred tax assets:				
Foreign net operating loss carryforwards	\$ 2	2,679	\$	3.161
Capitalized research expenses	e	5,888		8,260
Depreciation	1	,107		1,605
Stock options		5,012		3,243
Accruals and reserves	e	5,623		5,655
Other, net		216		490
Total deferred tax assets	22	2.525		22.414
Valuation allowance	(22	2,525)	(2	22,414)
Net deferred tax assets	\$		\$	

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#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

At December 31, 2010, we had federal and state tax net operating loss carryforwards of approximately \$246.4 million and \$226.0 million, respectively. The federal and state net operating losses have been reduced by the Section 382 limitation. The federal tax loss carryforwards will begin to expire in 2026, unless previously utilized. The state tax loss carryforwards began to expire in 2010.

We also have federal and California research and development tax credit carryforwards of approximately \$3.6 million and \$11.0 million, respectively. The federal research and development credits have been reduced by the Section 383 limitation. The federal research and development tax credit carryforwards will begin to expire in 2026 unless previously utilized. The California research and development credit carryforward indefinitely.

#### **12. Savings and Pension Plans**

We have a 401(k) savings plan covering most United States employees. In the United Kingdom we make contributions to defined contribution pension plans. Under these plans, individual employees may make contributions to the plan, which can be matched by us in an amount determined by our Board of Directors or as determined by local statutes. We made no matching contributions in 2010, 2009 and 2008.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2010

#### 13. Geographic Information

We have wholly-owned subsidiaries located in Germany, the United Kingdom, India, Hong Kong and Japan and have customer and vendor relationships worldwide. The following table presents information about us by geographic area. There were no material amounts of transfers between geographic areas. Included in the consolidated balance sheets and consolidated statements of operations are the following domestic and foreign components at December 31, 2010, 2009 and 2008 (in thousands):

	December 31,		
, , ,	2010	2009	2008
Current assets:			
United States	\$ 143,178	\$ 54,153	\$111,717
Europe	6,390	5,182	6,911
Asia	2,219	3,595	3,656
	\$ 151,787	\$ 62,930	\$122,284
Equipment and leasehold improvements, net:			
United States	\$ 10,596	\$ 11,306	\$ 8,331
Europe	288	262	433
Asia	154	243	431
	\$ 11,038	\$ 11,811	\$ 9,195
Long-term assets:	<u> </u>	<u> </u>	
United States	\$ 11,244	\$ 11,632	\$ 8,928
Europe	157	<sup>©</sup> 11,052 204	Ψ 0,920
Asia	53	68	78
	\$ 11,454	\$ 11,904	\$ 9,006
	↓ 11,4J4 	\$ 11,904 	ş 9,000
Total assets:			
United States	\$ 165,019	\$ 77,091	\$128,975
Europe	6,834	5,648	7,344
Asia	2,426	3,906	4,165
	<u>\$ 174,279</u>	\$ 86,645	\$140,484
Revenues:			
United States	\$ 21,891	\$ 18,017	\$ 23,805
Europe	13,121	11,153	13,273
Asia	12,447	8,693	10,071
	\$ 47,459	\$ 37,863	\$ 47,149
Net loss:			
United States	\$(129,903)	\$(76,958)	\$ (50,263)
Europe	φ(129,903) 5,647	3,673	4,386
Asia	3,412	2,273	1,723
	\$(120,844)	\$(71,012)	$\frac{1,725}{$(44,154)}$
	=	=	φ(44,134) 

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

# December 31, 2010

# 14. Selected Quarterly Financial Data (unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
	(In tho	usands, excep	t share and p	er share infor	mation)
2010			;		
Net sales	\$ 10,610	\$ 11,412	\$ 11,684	\$ 13,753	\$ 47,459
Gross profit	5,353	6,952	7,581	8,579	28,463
Net loss	(16,948)	(59,138)	(22,736)	(22,022)	(120,844)
Net loss per share, basic and fully diluted	\$ (0.27)	\$ (0.86)	\$ (0.30)	\$ (0.27)	\$ (1.69)
Shares used in calculated per share amounts, historical,					
basic and fully diluted	62,085	68,421	75,260	80,777	71,697
2009					
Net sales	\$ 8,688	\$ 9,168	\$ 9,220	\$ 10,787	\$ 37,863
Gross profit	5,264	6,042	6,542	5,445	23,293
Net loss	(17,489)	(20,246)	(14,875)	(18,402)	(71,012)
Net loss per share, basic and fully diluted	\$ (0.29)	\$ (0.33)	\$ (0.24)	\$ (0.30)	\$ (1.16)
Shares used in calculated per share amounts, historical, basic and fully diluted	61,014	61,138	61,211	61,313	61,171

# Schedule II—SEQUENOM, INC.

# Valuation and Qualifying Accounts (In thousands)

Description	Balance at Beginning of Period	Charged to Costs and Expenses	Deductions	Balance at End of Period
Year ended December 31, 2010:			<u> </u>	
Allowance for doubtful accounts	\$ 241	923	12	\$1,152
Reserve for obsolete or excess inventory Year ended December 31, 2009:	\$1,504	141	642(1)	\$1,003
Allowance for doubtful accounts	\$ 405	(145)	19	\$ 241
Reserve for obsolete or excess inventory Year ended December 31, 2008:	\$1,473	2,488	2,457(1)	\$1,504
Allowance for doubtful accounts Reserve for obsolete or excess inventory	\$ 186 \$ 996	281 2,458	62 1,981 <sup>(1)</sup>	\$   405 \$1,473

 $\overline{(1)}$  Write off of obsolete or excess inventory

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#### **Corporate Officers**

Harry F. Hixson, Jr. Ph.D. Chairman of the Board & Chief Executive Officer

Allan Bombard, M.D. Chief Medical Officer

Charles Cantor, Ph.D. Chief Scientific Officer

Ronald Lindsay, Ph.D. Executive Vice President, Research & Development

Paul V. Maier Chief Financial Officer

Michael Monko Senior Vice President, Sales & Marketing

Dirk van den Boom, Ph.D. Senior Vice President, Research & Development

Wiliam Welch Senior Vice President, Diagnostics

Robin Weiner Senior Vice President, Regulatory Affairs & Quality

Alisa Judge Vice President, Human Resources

Larry Myers Vice President, Operations

Clarke Neumann Vice President & General Counsel

#### **Board of Directors**

Harry F. Hixson, Jr. Ph.D. Chairman of the Board

Ernst-Günter Afting, Ph.D., M.D.

Kenneth Buechler, Ph.D.

John Fazio

Richard Lerner, M.D.

Ronald Lindsay, Ph.D.

#### David Pendarvis

#### Corporate Headquarters

Sequenom, Inc. 3595 John Hopkins Court San Diego, CA 92121 Telephone: +1 (858) 202-9000 Fax: +1 (858) 202-9001

#### Investor Information

Marcy Graham Senior Director, Investor Relations & Corporate Communications Telephone: +1 (858) 202-9028 Email: ir@sequenom.com

#### Corporate Counsel

Cooley LLP San Diego, CA

#### Auditors

Ernst & Young, LLP San Diego, CA

#### Transfer Agent

American Stock Transfer and Trust Company 59 Maiden Lane Plaza Level New York, NY 10038 Telephone: +1 (718) 921-8282 http://www.amstock.com

**Common Stock Listing** 

Ticker Symbol: SQNM

The NASDAQ Global Stock Market

#### Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this Annual Report contain forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements regarding Sequenom's expected business growth and expansion, focus, and positioning, anticipated products in development including the anticipated launch and transformative potential of two laboratory test offerings, developing and commercializing a portfolio of meaningful proprietary genetic tests driven by unmet clinical needs in ophthalmology, the expected launch and timing of launch of the age-related macular degeneration (AMD) laboratory developed test and bringing such testing service to market nationwide, the viability of massively parallel shotgun sequencing as a technology for trisomy 2l detection, Sequenom's expectations, plans, and timing for completion of the ongoing, larger blinded clinical validation study for the trisomy 21 laboratory developed test and the expectations for and timing of a publication reporting the results of the study and bringing the trisomy 21 laboratory developed test to market, a premarket approval (PMA) application for an in vitro diagnostic device for trisomy 2l and anticipated constructive dialogue with the FDA to define PMA requirements, expectations regarding sufficiency of Sequenom's cash, cash equivalents and marketable securities to finance operations, Sequenom's plan to continue investing in new products and its facilities and infrastructure, and Sequenom's commitment to improving healthcare through revolutionary genetic analysis solutions. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including the risks and uncertainties associated with Sequenom's ability to develop and commercialize new technologies and products, particularly new technologies such as genetic analysis platforms, prenatal and other diagnostics and laboratory developed tests, reliance upon the collaborative efforts of other parties, Sequenom's ability to manage its existing cash resources or raise additional cash resources, competition, intellectual property protection and intellectual property rights of others, government regulation particularly with respect to diagnostic products and laboratory developed tests, obtaining or maintaining regulatory approvals, ongoing litigation and investigations and other risks detailed from time to time in Sequenom's most recent Annual Report on Form 10-K and other documents subsequently filed with or furnished to the Securities and Exchange Commission. These forward-looking statements are based on current information that may change and the reader is cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. All forward-looking statements are qualified in their entirety by this cautionary statement, and Sequenom undertakes no obligation to revise or update any forwardlooking statement to reflect events or circumstances after the issuance of this report.

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